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Title 3—

The President

Proclamation 10862 of November 19, 2024

National Child's Day, 2024

By the President of the United States of America

A Proclamation

This generation's young people are some of the most gifted, educated, and talented our Nation has ever known. They are the kite strings that keep our national ambitions aloft. On National Child's Day, we recommit to building a future worthy of their highest aspirations.

So many of our Nation's children begin building their futures at our public schools—that is why I am proud that my Administration secured a historic $130 billion in funding for our Nation's K–12 schools through my American Rescue Plan. That law put more teachers in classrooms and more counselors, social workers, and other support staff in our schools. It also invested in high-quality tutoring and made historic expansions in summer and after-school programs. My Bipartisan Infrastructure Law is expanding access to high-speed internet so students can access it regardless of their zip code. And my Administration has worked to advance a pathway to provide free, healthy school meals for all children as a part of our national strategy to end hunger and reduce diet-related diseases in America by 2030.

My Administration has also worked hard to give families some well-deserved breathing room so that they can care for their children without worrying about how they are going to pay the bills. My American Rescue Plan expanded the Child Tax Credit, which helped reduce child poverty by nearly half across the Nation. That law also made our Nation's biggest investment in child care ever, helping hundreds of thousands of child care providers keep their doors open and continue providing care. I signed the Inflation Reduction Act, saving millions of families $800 per year on their health insurance premiums. My Administration also raised pay for early childhood educators across the country participating in the Head Start program. And my Administration modernized the Thrifty Food Plan for the first time in nearly five decades so that millions more families receiving Supplemental Nutrition Assistance Program benefits can afford nutritious foods.

Securing the health and safety of children has always been a priority for my Administration. I signed the most significant gun safety law in nearly 30 years, working towards a future where no student or child has to live in fear of gun violence. That law also made the largest investment in youth mental health ever to help schools across the country train and hire new mental health counselors. At the same time, we made it easier for schools to leverage Medicaid to deliver health care. And we are working to support LGBTQI+ children and families by protecting their access to health care and preventing harmful practices, including the use of so-called conversion therapy.

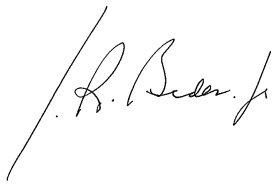
My Administration has also been dedicated to addressing the existential threat of climate change—a critical task to secure our children's futures. My Inflation Reduction Act made the most significant investment in climate ever, which includes funding to get communities cleaner air and drinking water, and protect them from the harmful effects of pollution. My Bipartisan Infrastructure Law is working to replace every lead pipe in America, so that every family can turn on the faucet and drink clean, safe water. And my Administration has conserved more than 45 million acres of our Nation's

lands and waters in an effort to ensure they can be enjoyed for generations to come.

On National Child's Day, we recommit to ensuring that every child in America has the opportunity to pursue the limits of their talents and ambitions, and we uplift them as the leaders and doers of the future.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim November 20, 2024, as National Child's Day. I call upon all government officials, educators, volunteers, and all the people of the United States of America to observe this day with appropriate programs, ceremonies, and activities.

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



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Rules and Regulations

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

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DEPARTMENT OF AGRICULTURE

Federal Crop Insurance Corporation

7 CFR Parts 407 and 457

RIN 0563–AC86

[Docket ID FCIC–24–0005]

Flax Revenue and Expanded Unit Options for Crop Insurance

AGENCY: Federal Crop Insurance Corporation, USDA.

ACTION: Final rule with request for comments.

SUMMARY: The Federal Crop Insurance Corporation (FCIC) is amending its regulations to allow revenue coverage for flax under the Small Grain Crop Insurance Provisions, to combine written agreement deadlines in the Dry Bean Crop Insurance Provisions to match other insurance policies, to expand the availability of enterprise and optional units for some specialty and perennial crops, and to make clarifications and corrections to the Area Risk Protection Insurance, Basic Provisions; Common Crop Insurance Policy, Basic Provisions; and several Crop Provisions. The changes will be effective for the 2025 and succeeding crop years for crops with a contract change date on or after November 30, 2024. For all other crops, the changes to the policies made in this rule are applicable for the 2026 and succeeding crop years.

DATES: *Effective date:* This final rule is effective November 30, 2024.

Comment Date: We will consider comments that we receive by the close of business January 27, 2025. FCIC may consider the comments received and may conduct additional rulemaking based on the comments.

ADDRESSES: We invite you to submit comments on this rule. You may submit comments by going through the Federal eRulemaking Portal as follows:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov* and search for Docket ID FCIC–24–0005. Follow the instructions for submitting comments.

All comments will be posted without change and will be publicly available on *www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Chandra Place; telephone (816) 926–3875; or email *chandra.place@usda.gov*. Persons with disabilities who require alternative means for communication should contact the USDA Target Center at (202) 720–2600 or (844) 433–2774 (toll-free nationwide).

SUPPLEMENTARY INFORMATION:

Background

FCIC serves America's agricultural producers through effective, market-based risk management tools to strengthen the economic stability of agricultural producers and rural communities. FCIC is committed to increasing the availability and effectiveness of Federal crop insurance as a risk management tool. Approved Insurance Providers (AIPs) sell and service Federal crop insurance policies in every state through a public-private partnership. FCIC reinsures the AIPs who share the risks associated with catastrophic losses due to major weather events. FCIC's vision is to secure the future of agriculture by providing world class risk management tools to rural America.

Federal crop insurance policies typically consist of the Basic Provisions, the Crop Provisions, the Special Provisions, the Commodity Exchange Price Provisions, if applicable, other applicable endorsements or options, the actuarial documents for the insured agricultural commodity, the Catastrophic Risk Protection Endorsement, if applicable, and the applicable regulations published in 7 CFR chapter IV. Throughout this rule, the terms ''Crop Provisions,'' ''Special Provisions,'' and ''policy'' are used as defined in the Common Crop Insurance Policy (CCIP) Basic Provisions in 7 CFR 457.8. Additional information and definitions related to Federal crop insurance policies are in 7 CFR 457.8.

FCIC is amending the following regulations:

- Area Risk Protection Insurance Basic Provisions (7 CFR part 407);
- Common Crop Insurance Policy Basic Provisions (7 CFR 457.8);
- Small grain crop insurance provisions (7 CFR 457.101);
- Prune crop insurance provisions (7 CFR 457.133);
- Green pea crop insurance provisions (7 CFR 457.137);
- Northern potato crop insurance provisions (7 CFR 457.142);
- Central and Southern potato crop insurance provisions (7 CFR 457.147);
- Dry bean crop insurance provisions (7 CFR 457.150);
- Processing sweet corn crop insurance provisions (7 CFR 457.154); and
- Blueberry crop insurance provisions (7 CFR 457.166).

The changes to the crop insurance policies resulting from the amendments in this rule are applicable for the 2025 and succeeding crop years for crops with a contract change date on or after November 30, 2024. For all other crops, the changes to the crop insurance policies resulting from the amendments in this rule are applicable for the 2026 and succeeding crop years.

Flax Revenue Coverage

The Small Grain Crop Provisions previously offered actual production history (APH) coverage to buckwheat and flax; and offered yield protection (YP), revenue protection (RP), and revenue protection with harvest price exclusion (RP–HPE) to barley, oats, rye, and wheat. In this Final Rule, FCIC is expanding revenue protection (RP and RP–HPE) to flax, matching available coverage for barley, oats, rye, and wheat.

The current APH coverage for flax is now converted to YP. For producers who wish to maintain yield coverage, the only difference in coverage is the price guarantee matches the projected price offered for revenue protection (established approximately two weeks prior to the sales closing date), instead of a price election established by the Risk Management Agency (RMA) (established prior to the contract change date).

With the availability of revenue protection for flax, the terms ''price election'' and ''production guarantee'' are no longer applicable. Instead, the terms ''projected price,'' ''yield protection guarantee,'' and ''revenue protection guarantee'' are applicable. These changes appear in the following sections of the Small Grain Crop Provisions: 3(a) and (b), 9(c), and 11(b) and (c).

FCIC is revising section 3(a) to remove the references to flax. This provision previously stated that revenue protection is not available for flax or buckwheat. FCIC is removing flax from the list of crops because revenue coverage is now available for flax. FCIC is also revising section 3(b) to add references to flax. These provisions previously stated that revenue protection is available for barley, oats, rye, and wheat. FCIC is adding flax to the list of crops in the two places where the list occurs.

FCIC is revising section 9(c)(2)(i) to remove the reference to flax and revise section 9(c)(2)(ii) to add a reference to flax. When a crop does not have yield or revenue protection available, the price used for determining coverage and any indemnity payments, including replanting payments, is called the price election. For crops for which yield and revenue protection are available, this price is called the projected price. In section 9(c)(2)(i), the provision previously stated that the replanting payment for flax will be determined by using the price election. Under this rule, revenue and yield protection plans of insurance are now available for flax; therefore, the price used is the projected price. FCIC is revising section 9(c)(2)(i) to remove the reference to flax. Section 9(c)(2)(ii) contains provisions applicable to the projected price. FCIC is revising section 9(c)(2)(ii) to include flax, as the projected price will now be used.

For crops for which yield and revenue protection are available, the applicable terms for insurance coverage are yield protection guarantee and revenue protection guarantee. For crops for which yield and revenue protection are not available, the applicable term is production guarantee. FCIC is revising sections 11(b)(1)(i), (ii), and (iii). These sections refer to ''yield protection guarantee,'' ''production guarantee,'' and ''revenue protection guarantee,'' respectively. The references to flax in section 11(b)(1)(ii), which addresses production guarantee, were removed and added to sections 11(b)(1)(i) and (iii), which address yield protection guarantee and revenue protection guarantee.

FCIC is also revising section 11(b)(3)(i) to add a reference to flax and revising section 11(b)(3)(ii) to remove the reference to flax. This change is consistent with the change in section 9(c)(2). Section 11(b)(3)(i) refers to computations using the projected price; section 11(b)(3)(ii) refers to computations using the price election. Flax was removed from section 11(b)(3)(ii) and added to section 11(b)(3)(i) to align with the proper terms for crops for which revenue protection is available.

Section 11(c)(1)(i) explains what is included in appraised production. Previously, flax was contained in a list of crops with buckwheat. Those two crops had similar coverage and used the same crop insurance terminology under the Small Grain Crop Provisions when revenue coverage was not yet available for flax. Now, flax has been removed from the list of crops containing buckwheat and added to the list of crops containing barley, oats, rye, and wheat in two places because allowing revenue coverage for flax makes coverage and crop insurance terminology for that crop consistent with coverage and terminology for barley, oats, rye, and wheat.

Dry Bean Written Agreement Deadlines

FCIC is combining written agreement deadlines to reduce confusion and administrative complexity when a producer requests a written agreement based on multiple criteria. Previously, the written agreement deadline to add an insurable practice or type was the acreage reporting date for new requests and the sales closing date for renewal requests; however, the deadline to add an insurable dry bean type that is not on the actuarial documents was the sales closing date. This created extra paperwork and confusion in instances where a producer wanted to insure a new dry bean type and under a practice that is not currently available in the county. FCIC is combining the deadline for all written agreements to match all other insurance policies with this type of request, so that for the first year of coverage, the deadline is the acreage reporting date and for subsequent years of coverage, the deadline is the sales closing date.

Enterprise and Optional Units

The CCIP Basic Provisions allow enterprise units (EU) by organic farming practice, beginning with the June 30, 2024, contract change date. Unlike major row crops, optional units (OUs) by organic farming practice were not available for most specialty and perennial crops due to language in the Crop Provisions (CP) that superseded the standard OU definition in the CCIP Basic Provisions. In this rule, FCIC is removing limitations on OUs by organic farming practice and making clarifications and edits for consistency with the EU and OU choices provisions in the CCIP Basic Provisions in the following Crop Provisions:

- Green pea crop insurance provisions (7 CFR 457.137); and
- Processing sweet corn crop insurance provisions (7 CFR 457.154).

These changes are responsive to organic growers and the Climate Smart Initiative.

Clarifications and Corrections

FCIC is making the following corrections and clarifications in the Small Grain Crop Provisions (7 CFR 457.101):

- Updating the effective crop year of the Crop Provisions;
- Removing the hyphen in the phrase ''initially-planted'' in section 2(b) for consistency with the defined phrase in the Crop Provisions;
- Making plain language clarifications in sections 5, 6, and 7;
- Combining the two introductory paragraphs in section 8 into one introductory paragraph;
- Replacing the word ''and'' with ''or'' in sections 11(d)(2)(i)(A) and 11(d)(2)(ii). Section 11(d) contains six subparagraphs for deficiencies in quality for the small grain crop. The list of deficiencies in quality varies by crop. In four of the six subparagraphs, the last item in the list is preceded by ''or,'' while in the other two paragraphs, the last item is preceded by ''and.'' FCIC is changing the word ''and'' to ''or'' for consistency among subparagraphs; and
- Replacing the word ''flaxseed'' with ''flax'' in section 11(d)(2)(E). This is the only instance of ''flaxseed,'' whereas ''flax'' is used elsewhere.

FCIC is making the following clarifications and corrections in the Green pea crop insurance provision (7 CFR 457.137):

- Updating the effective crop year of the Crop Provisions;
- Removing the paragraph immediately preceding section 1, which refers to the order of priority if a conflict exists among the policy provisions. This same provision is contained in the Basic Provisions. Therefore, the appearance here is duplicative and should be removed. FCIC is clarifying which Basic Provisions apply by replacing the aforementioned paragraph with an introductory sentence preceding the Crop Provisions;
- Removing all instances of the phrase ''the provisions of,'' ''the provisions contained in,'' and ''contained'' where a policy reference follows;
- Revising the definition of ''good farming practices'' to clarify that the definition in the Crop Provisions expands upon the definition contained in the Basic Provisions because good farming practices include the cultural practices required by the processor contract;

• Revising the definition of ''practical to replant'' to clarify that the definition in the Crop Provisions does not replace, but rather expands upon the definition in the Basic Provisions, and remove duplicative criteria that are already included in the definition in the Basic Provisions;

• Revising the definition of ''processor contract'' to replace the phrase ''a written agreement'' with the phrase ''a written contract.'' The phrase ''written agreement'' is a specifically defined term in the Basic Provisions and is not applicable to a processor contract for green peas. This change is necessary to minimize confusion between a written contract and a written agreement, which is a document that alters designated terms of a policy as authorized under these Basic Provisions, the Crop Provisions, or the Special Provisions for the insured crop;

• Removing the phrase ''for determining indemnities'' from the section heading for section 3. The section heading will now read ''Insurance Guarantees, Coverage, Levels, and Prices.'' The new section heading is more accurate because insurance guarantees, coverage levels, and prices are not exclusively used for determining indemnities. This change is also for consistency with section headings of the same name in other Crop Provisions;

• Replacing the reference to Special Provisions with actuarial documents in section 3(a), since the price election information referred to in this section is displayed in the actuarial documents;

• Replacing abbreviated months (''Feb'' and ''Mar'') with the full spelling for the months (''February'' and ''March'') in the cancellation and termination date table, in section 5;

• Adding a hyphen to the adjective compound ''15-day'' as it describes a ''15-day period'' in section 11(c); and

• Updating prices in the settlement of claim examples to be more reflective of current crop prices and potential indemnities, in section 12.

FCIC is making the following clarifications and corrections in the Processing sweet corn crop insurance provisions (7 CFR 457.154):

• Updating the effective crop year of the Crop Provisions;

• Clarifying which Basic Provisions apply by adding an introductory sentence preceding the Crop Provisions; and

• Adding a hyphen to the adjective compound ''15-day'' as it describes a ''15-day period'' in section 11(c).

In addition, the Common Crop Insurance Regulations in 7 CFR part 457 were revised by a final rule with request for comments published in the **Federal Register** on June 27, 2024 (89 FR 53822–53847). Changes were made in that rule to the Area Risk Protection Insurance Basic Provisions (7 CFR part 407), Common Crop Insurance Policy (Common Crop Insurance Policy (CCIP) Basic Provisions (7 CFR 457.8), the General Administrative Regulations in subpart J of part 400 (7 CFR 400.98), and 18 Crop Provisions. In reviewing the changes made, FCIC found some incorrect references, missing words, missing parentheses, incorrect paragraph designations, and an extra word. This rule will also make these corrections in the following provisions:

• Area Risk Protection Insurance Basic Provisions (7 CFR part 407);

• Common Crop Insurance Policy Basic Provisions (7 CFR 457.8);

• Prune crop insurance provisions (7 CFR 457.133);

• Northern potato crop insurance provisions (7 CFR 457.142);

• Central and Southern potato crop insurance provisions (7 CFR 457.147); and

• Blueberry crop insurance provisions (7 CFR 457.166).

Effective Date, Notice and Comment, and Exemptions

The Administrative Procedure Act (APA, 5 U.S.C. 553) provides that the notice and comment and 30-day delay in the effective date provisions do not apply when the rule involves specified actions, including matters relating to contracts. This rule governs contracts for crop insurance policies and therefore falls within that exemption.

This rule is exempt from the regulatory analysis requirements of the Regulatory Flexibility Act (5 U.S.C. 601–612), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996.

Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996, (also known as the Congressional Review Act) requires a delay of the effective date of 60 days after publication to allow for Congressional review. The Office of Information and Regulatory Affairs has determined that this rule does not meet the criteria in 5 U.S.C. 804(2). Therefore, this final rule is effective on November 30, 2024. Although not required by APA or any other law, FCIC has chosen to request comments on this rule.

Executive Orders 12866, 13563, and 14094

Executive Order 12866, ''Regulatory Planning and Review,'' was amended by and Executive Order 13563, ''Improving Regulation and Regulatory Review,'' and Executive Order 14094, ''Modernizing Regulatory Review.'' Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasized the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The requirements in Executive Orders 12866 and 13563 for the analysis of costs and benefits apply to rules that are determined to be significant.

The Office of Management and Budget (OMB) has designated this rule as not significant under Executive Order 12866, ''Regulatory Planning and Review,'' and therefore, OMB has not reviewed this rule and analysis of the costs and benefits is not required under either Executive Order 12866 or 13563.

Clarity of the Regulation

Executive Order 12866, as supplemented by Executive Order 13563, requires each agency to write all rules in plain language. Executive Order 14094 requires Federal agencies to increase and improve public participation in the regulatory process. The Executive order's objective is to improve public trust in the regulatory process by reducing the risk or appearance of unequal or unfair influence in regulatory development. Under Executive Order 14904, agencies must, to the extent they can under law, seek out, assist with, and include your input in the regulatory process. We welcome comments from public (State, local, Tribal, and territorial) and private sector regulated entities; members of underserved communities; consumers; workers and labor organizations; businesses; and program beneficiaries, among others. In addition to your substantive comments on this rule, we invite your comments on how to make the rule easier to understand. For example:

• Are the requirements in the rule clearly stated? Are the scope and intent of the rule clear?

• Does the rule contain technical language or jargon that is not clear?

• Is the material logically organized?

• Would changing the grouping or order of sections or adding headings make the rule easier to understand?

• Could we improve clarity by adding tables, lists, or diagrams?

• Would more, but shorter, sections be better? Are there specific sections that are too long or confusing?

• What else could we do to make the rule easier to understand?

Environmental Review

The environmental impacts of this final rule have been considered in a manner consistent with the provisions of the National Environmental Policy Act (NEPA, 42 U.S.C. 4321–4347), the regulations of the Council on Environmental Quality (40 CFR parts 1500–1508), and because USDA will be making the payments to producers, the USDA regulation for compliance with NEPA (7 CFR part 1b). As specified in 7 CFR 1b.4(b)(4), FCIC is categorically excluded from the preparation of an Environmental Analysis or Environmental Impact Statement unless the FCIC Manager (agency head) determines that an action may have a significant environmental effect. The FCIC Manager has determined this rule will not have a significant environmental effect. Therefore, FCIC will not prepare an environmental assessment or environmental impact statement for this action and this rule serves as documentation of the programmatic environmental compliance decision.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, ''Civil Justice Reform.'' This rule will not preempt State or local laws, regulations, or policies unless they represent an irreconcilable conflict with this rule. Before any judicial actions may be brought regarding the provisions of this rule, the administrative appeal provisions of 7 CFR part 11 are to be exhausted. For good farming practice determinations, the administrative appeal provisions under 7 CFR part 11 do not apply.

Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments.'' Executive Order 13175 requires Federal agencies to consult and coordinate with Tribes on a government-to-government basis on policies that have Tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

RMA has assessed the impact of this rule on Indian Tribes and determined that this rule does not, to our knowledge, have Tribal implications that require Tribal consultation under E.O. 13175. The regulation changes do not have Tribal implications that preempt Tribal law and are not expected have a substantial direct effect on one or more Indian Tribes. If a Tribe requests consultation, RMA will work with the USDA Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions and modifications identified in this rule are not expressly mandated by Congress.

The Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA, Pub. L. 104–4) requires Federal agencies to assess the effects of their regulatory actions of State, local, and Tribal governments or the private sector. Agencies generally must prepare a written statement, including cost benefits analysis, for proposed and final rules with Federal mandates that may result in expenditures of $100 million or more in any 1 year for State, local or Tribal governments, in the aggregate, or to the private sector. UMRA generally requires agencies to consider alternatives and adopt the more cost effective or least burdensome alternative that achieves the objectives of the rule. This rule contains no Federal mandates, as defined in Title II of UMRA, for State, local, and Tribal governments or the private sector. Therefore, this rule is not subject to the requirements of sections 202 and 205 of UMRA.

Federal Assistance Program

The title and number of the Assistance Listing, to which this rule applies is No. 10.450—Crop Insurance.

Paperwork Reduction Act of 1995

In accordance with the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35, subchapter I), the rule does not change the information collection approved by OMB under control numbers 0563–0053 and 0563–0083.

USDA Non-Discrimination Policy

In accordance with Federal civil rights law and USDA civil rights regulations and policies, USDA, its Agencies, offices, and employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family or parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Individuals who require alternative means of communication for program information (for example, braille, large print, audiotape, American Sign Language, etc.) should contact the responsible Agency or USDA TARGET Center at (202) 720–2600 (voice and text telephone (TTY)) or dial 711 for Telecommunications Relay Service (both voice and text telephone users can initiate this call from any telephone). Additionally, program information may be made available in languages other than English. To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD–3027, found online at *https://www.usda.gov/oascr/how-to-file-a-program-discrimination-complaint* and at any USDA office or write a letter addressed to USDA and provide in the letter all the information requested in the form. To request a copy of the complaint form, call (866) 632–9992. Submit your completed form or letter to USDA by: (1) mail to: U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250–9410; (2) fax: (202) 690–7442; or (3) email: *program.intake@usda.gov.*

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List of Subjects

7 CFR Part 407

Acreage allotments, Administrative practice and procedure, Barley, Corn, Cotton, Crop insurance, Peanuts, Reporting and recordkeeping requirements, Sorghum, Soybeans, Wheat.

7 CFR Part 457

Acreage allotments, Crop insurance, Reporting and recordkeeping requirements.

Final Rule

For the reasons discussed above, FCIC amends 7 CFR parts 407 and 457, effective for the 2025 and succeeding crop years for crops with a contract change date on or after November 30, 2024, and for the 2026 and succeeding crop years for all other crops, as follows:

PART 407—AREA RISK PROTECTION INSURANCE REGULATIONS

■ 1. The authority citation for part 407 continues to read as follows:

Authority: 7 U.S.C. 1506(l) and 1506(o).

■ 2. Amend § 407.9 as follows:
■ a. In section 5, in paragraph (c)(3), remove the words ''stated in section 5(c)'' and add ''stated in section 5(c)(2)'' in their place; and
■ b. In section 7, in paragraph (d)(2), remove '';'' at the end of the paragraph and add in its place ''; and''.

PART 457—COMMON CROP INSURANCE REGULATIONS

■ 3. The authority citation for 7 CFR part 457 continues to read as follows:

Authority: 7 U.S.C. 1506(l), 1506(o).

■ 4. In § 457.8, in the ''Common Crop Insurance Policy'', section 3, in paragraph (i) introductory text, remove the words ''not applicable'' and add ''(not applicable'' in their place.

■ 5. Amend § 457.101 as follows:
■ a. Revise the introductory text and the undesignated text at the beginning of the ''Small Grain Crop Provisions'';
■ b. In section 2, in paragraph (b) remove the phrase ''initially-planted'' and add the phrase ''initially planted'' in its place;
■ c. In section 3, revise paragraphs (a), (b) introductory text, and (b)(1);
■ d. In section 5, in the table, remove the word ''thereof'' wherever it appears and add the words ''of the named counties'' in its place;
■ e. In section 6 in paragraph (c)(2), remove the phrase ''set forth herein'' and add the phrase ''described in these Crop Provisions'' in its place;
■ f. In section 7 in paragraph (a) introductory text, remove the word ''thereof'' and add the words ''of a unit'' in its place;
■ g. In section 9:
■ i. In paragraph (c)(2)(i), remove the phrase ''flax or''; and
■ ii. In paragraph (c)(2)(ii), add the phrase '', flax'' after the word ''barley'';
■ h. In section 11:
■ i. In paragraph (b)(1)(i), add the phrase '', flax'' after the word ''barley'';
■ ii. In paragraph (b)(1)(ii), remove the phrase ''flax or'';
■ iii. In paragraph (b)(1)(iii), add the phrase '', flax'' after the word ''barley'';
■ iv. In paragraph (b)(3)(i), add the phrase '', flax'' after the word ''barley'';
■ v. In paragraph (b)(3)(ii), remove the phrase ''flax or'';
■ vi. Revise paragraph (c)(1)(i);
■ vii. In paragraph (d)(2)(i)(A), remove the phrase ''smutty, and ergoty'' and add the phrase ''smutty, or ergoty'' in its place;
■ viii. In paragraph (d)(2)(i)(E), remove the word ''Flaxseed'' and add the word ''Flax'' in its place; and
■ ix. In paragraph (d)(2)(ii), remove the phrase ''smutty, and ergoty'' and add the phrase ''smutty, or ergoty'' in its place.

The revisions and additions read as follows:

§ 457.101 Small grain crop insurance provisions.

The Small Grain Crop Insurance Provisions for the 2025 and succeeding crop years for crops with a contract change date on or after November 30, 2024, and for the 2026 and succeeding crop years with a contract change date prior to November 30, 2024, are as follows:

United States Department of Agriculture
Federal Crop Insurance Corporation
Small Grain Crop Provisions

In return for your payment of premium and administrative fee for coverage, these Small Grains Crop Provisions and corresponding Commodity Exchange Price Provisions will be attached to and made part of the Common Crop Insurance Policy, Basic Provisions (Basic Provisions) subject to the terms and conditions in your policy.

* * * * *

3. Insurance Guarantees, Coverage Levels, and Prices

(a) Revenue protection is not available for your buckwheat. Therefore, if you elect to insure such crop by the sales closing date, it will only be protected against a loss in yield.

(b) Revenue protection is available for barley, flax, oats, rye, and wheat. Therefore, if you elect to insure your barley, flax, oats, rye, or wheat:

(1) You must elect to insure your barley, flax, oats, rye, or wheat with either revenue protection or yield protection by the sales closing date; and

* * * * *

11. Settlement of Claim

* * * * *

(c) * * *

(1) * * *

(i) For buckwheat, and for barley, flax, oats, rye, or wheat under yield protection, not less than the production guarantee (per acre), and for barley, flax, oats, rye, or wheat under revenue protection, not less than the amount of production that when multiplied by the harvest price equals the revenue protection guarantee (per acre) for acreage:

* * * * *

■ 6. Amend § 457.133 as follows:
■ a. In the introductory text, remove the year ''2025'' and add the year ''2026'' in its place;
■ b. In section 1, revise the definition of ''Standard prunes''.

The revisions read as follows:

§ 457.133 Prune crop insurance provisions.

* * * * *

Definitions

* * * * *

Standard prunes. Any natural condition prunes:

(1) That grade ''C,'' ''U.S. Standard,'' or better in accordance with the United States Standards for Grades of Dried Prunes; or

(2) That meet or exceed the grade standards in effect for the crop year if a Marketing Order for California Prunes has been established for the area in which the insured crop is grown.

* * * * *

■ 7. Amend § 457.137 as follows:
■ a. Revise the introductory text and the undesignated text at the beginning of the ''Green Pea Crop Provisions'';
■ b. In section 1:
■ i. Revise the definition of ''Good farming practices'';
■ ii. In the definition of ''Planted acreage,'' remove the word ''contained'';
■ iii. Revise the definitions of ''Practical to replant'' and ''Price election''; and
■ iv. In the definition of ''Processor contract,'' remove the phrase ''A written agreement'' and add the phrase ''A written contract'' in its place;
■ c. In section 2:
■ i. In paragraph (a)(1), remove the word ''contained''; and
■ ii. Revise paragraphs (a)(2) and (b);
■ d. In section 3:
■ i. Revise the section heading;
■ ii. In paragraph (a), remove the phrase ''Special Provisions'' and add the phrase ''actuarial documents'' in its place;
■ e. In section 5, in the table, replace the words ''Feb.'' and ''Mar.'' and add the words ''February'' and ''March'', respectively, in their place;
■ f. In section 6, remove the phrase ''the provisions of'';
■ g. In section 8, introductory paragraph, remove the phrase ''the provisions of'';
■ h. In section 9, introductory paragraph, remove the phrase ''the provisions contained in'';
■ i. In section 10:
■ i. In the introductory paragraph, remove the phrase ''the provisions of'';
■ ii. In paragraph (a)(4), remove the word ''contained''; and
■ iii. In paragraph (a)(8), remove the word ''contained'';
■ j. In section 11, in paragraph (c), remove the phrase ''15 day period'' and

add the phrase ''15-day period'' in its place; and

■ k. In section 12, revise paragraph (b)(7).

The revisions and additions read as follows:

§ 7 CFR 457.137 Green pea crop insurance provisions.

The Green Pea Crop Insurance Provisions for the 2025 and succeeding crop years are as follows:

United States Department of Agriculture
Federal Crop Insurance Corporation.
Green Pea Crop Provisions

In return for your payment of premium and administrative fee for the coverage, these Green Pea Crop Provisions will be attached to and made part of the Common Crop Insurance Policy, Basic Provisions (Basic Provisions) subject to the terms and conditions in your policy.

* * * * *

1. Definitions

* * * * *

Good farming practices. In addition to the definition of ''good farming practices'' in the Basic Provisions, the cultural practices required by the processor contract.

* * * * *

Practical to replant. In addition to the definition of ''practical to replant'' in the Basic Provisions, practical to replant is defined as our determination, after loss or damage to the insured crop, based on factors including, but not limited to, moisture availability, and marketing window, that replanting the insured crop will allow the crop to attain maturity prior to the calendar date for the end of the insurance period. It will not be considered practical to replant unless the replanted acreage can produce at least 75 percent of the approved yield, and the processor agrees in writing that it will accept the production from the replanted acreage.

Price election. In lieu of the definition of ''price election'' in the Basic Provisions, price election is defined as the price per pound stated in the processor contract (contracted price) for the tenderometer reading, grade factor, or sieve size contained in the Special Provisions.

* * * * *

Unit Division

(a) * * *

(2) Optional units may be established by:

(i) Organic and non-organic farming practices as provided in Section 34(c)(3) of the Basic Provisions; or

(ii) Shell type and pod type for green peas if the shell type acreage does not continue into the pod type acreage in the same rows or planting pattern.

(b) For any processor contract that stipulates the number of acres to be planted, in addition to or instead of, establishing optional units as provided in Section 34(c) of the Basic Provisions, optional units may be established by the shell type and pod type for green peas if the shell type acreage does not continue into the pod type acreage in the same rows or planting pattern.

Insurance Guarantees, Coverage Levels, and Prices

* * * * *

12. Settlement of Claim

* * * * *

(b) * * *

(7) Multiplying the result of section 12(b)(6) by your share.

For example:

You have a 100 percent share in 100 acres of shell type green peas in the unit, with a guarantee of 4,000 pounds per acre and a price election of $0.15 per pound. You are only able to harvest 200,000 pounds. Your indemnity would be calculated as follows:

(1) 100 acres × 4,000 pounds = 400,000 pounds guarantee;

(2) 400,000 pounds × $0.15 price election = $60,000.00 value of guarantee;

(3) Not applicable;

(4) 200,000 pounds × $0.15 price election = $30,000.00 value of production to count;

(5) Not applicable;

(6) $60,000.00 − $30,000.00 = $30,000.00 loss; and

(7) $30,000.00 × 100 percent = $30,000.00 indemnity payment.

You also have a 100 percent share in 100 acres of pod type green peas in the same unit, with a guarantee of 5,000 pounds per acre and a price election of $0.15 per pound. You are only able to harvest 450,000 pounds. Your total indemnity for both shell type and pod type green peas would be calculated as follows:

(1) 100 acres × 4,000 pounds = 400,000 pounds guarantee for the shell type, and 100 acres × 5,000 pounds = 500,000 pounds guarantee for the pod type;

(2) 400,000 pounds guarantee × $0.15 price election = $60,000.00 value of guarantee for the shell type, and 500,000 pounds guarantee × $0.15 price election = $75,000.00 value of guarantee for the pod type;

(3) $60,000.00 + $75,000.00 = $135,000.00 total value of guarantee;

(4) 200,000 pounds × $0.15 price election = $30,000.00 value of production to count for the shell type; and 450,000 pounds × $0.15 = $67,500.00 value of production to count for the pod type;

(5) $30,000.00 + $67,500.00 = $97,500.00 total value of production to count;

(6) $135,000.00—$97,500.00 = $37,500.00 loss; and

(7) $37,500.00 loss × 100 percent = $37,500.00 indemnity payment.

* * * * *

■ 8. Amend § 457.142 as follows:

■ a. Revise the introductory text and the undesignated text at the beginning of the ''Northern Potato Crop Provisions'';

■ b. In section 11, revise paragraph (e)(2).

The revisions read as follows:

§ 457.142 Northern potato crop insurance provisions.

The Northern Potato Crop Insurance Provisions for the 2025 and succeeding crop years in counties with a contract change date of November 30, and for the 2026 and succeeding crop years in counties with a contract change date of April 30, June 30, and September 30, are as follows:

United States Department of Agriculture
Federal Crop Insurance Corporation
Northern Potato Crop Provisions

In return for your payment of premium and administrative fee for the coverage, these Northern Potato Crop Provisions will be attached to and made part of the Common Crop Insurance Policy, Basic Provisions (Basic Provisions) subject to the terms and conditions in your policy.

These provisions will be applicable in: Alaska; Humboldt, Modoc, and Siskiyou Counties, California; Colorado; Connecticut; Idaho; Indiana; Iowa; Kansas; Maine; Massachusetts; Michigan; Minnesota; Montana; Nebraska; Nevada; San Juan County, New Mexico; New York; North Dakota; Ohio; Oregon; Pennsylvania; Rhode Island; South Dakota; Utah; Washington; Wisconsin; and Wyoming; and any other states or counties if allowed by the Special Provisions.

* * * * *

11. Settlement of Claim

* * * * *

(e) * * *

(2) A grade inspection is completed no later than 21 days after the end of insurance period (if the Northern Potato Storage Coverage Endorsement is applicable, samples must be obtained within 60 days after the end of insurance period and quality (grade) determinations must be completed within 21 days of sampling; and

* * * * *

■ 9. Amend § 457.147 as follows:
■ a. Revise the introductory text and the undesignated text at the beginning of the ''Central and Southern Potato Crop Provisions'';
■ b. In section 12, revise the example after paragraph (b)(7) and before paragraph (c).

The revision reads as follows:

§ 457.147 Central and Southern potato crop insurance provisions.

The Central and Southern Potato Crop Insurance Provisions for the 2025 and succeeding crop years in counties with a contract change date of November 30, and for the 2026 and succeeding crop years in counties with a contract change date of April 30, June 30, and September 30, are as follows:

United States Department of Agriculture
Federal Crop Insurance Corporation
Central and Southern Potato Crop Provisions

In return for your payment of premium and administrative fee for the coverage, these Central and Southern Potato Crop Provisions will be attached to and made part of the Common Crop Insurance Policy, Basic Provisions (Basic Provisions) subject to the terms and conditions in your policy.

These provisions will be applicable in Alabama; Arizona; all California counties except Humboldt, Modoc, and Siskiyou; Delaware; Florida; Georgia; Maryland; Missouri; New Jersey; all New Mexico counties except San Juan; North Carolina; Oklahoma; Texas; and Virginia; and other states or counties if allowed by the Special Provisions.

* * * * *

12. Settlement of Claim

* * * * *

(b) * * *

(7) * * *

For example: You have a 100 percent share in 100 harvested acres of potatoes in the unit, with a guarantee of 150 hundredweight per acre and a price election of $4.00 per hundredweight. You are only able to harvest 10,000 hundredweight. Your indemnity would be calculated as follows:

(1) 100 acres × 150 hundredweight = 15,000 hundredweight guarantee;

(2) 15,000 hundredweight × $4.00 price election = $60,000.00 value of guarantee;

(4) 10,000 hundredweight × $4.00 price election = $40,000.00 value of production to count;

(6) $60,000.00 − $40,000.00 = $20,000.00 loss; and

(7) $20,000.00 × 100 percent = $20,000.00 indemnity payment.

You also have a 100 percent share in 100 unharvested acres of potatoes in the same unit, with a guarantee of 150 hundredweight per acre and a price election of $3.60 per hundredweight. (The price election for unharvested acreage is 90.0 percent of your elected price election ($4.00 × 0.90 = $3.60.)) This unharvested acreage was appraised at 35 hundredweight per acre for a total of 3,500 hundredweight as production to count. Your total indemnity for the harvested and unharvested acreage would be calculated as follows:

(1) 100 acres × 150 hundredweight = 15,000 hundredweight guarantee for the harvested acreage, and 100 acres × 150 hundredweight = 15,000 hundredweight guarantee for the unharvested acreage;

(2) 15,000 hundredweight guarantee × $4.00 price election = $60,000.00 value of guarantee for the harvested acreage, and 15,000 hundredweight guarantee × $3.60 price election = $54,000.00 value of guarantee for the unharvested acreage;

(3) $60,000.00 + $54,000.00 = $114,000.00 total value of guarantee;

(4) 10,000 hundredweight × $4.00 price election = $40,000.00 value of production to count for the harvested acreage, and 3,500 hundredweight × $3.60 = $12,600.00 value of production to count for the unharvested acreage;

(5) $40,000.00 + $12,600.00 = $52,600.00 total value of production to count;

(6) $114,000.00 − $52,600.00 = $61,400.00 loss; and

(7) $61,400.00 loss × 100 percent = $61,400.00 indemnity payment.

* * * * *

■ 10. In § 457.150, in the ''Dry bean crop insurance provisions'', in section 7, revise paragraph (c) to read as follows:

§ 457.150 Dry bean crop insurance provisions.

* * * * *

7. Insured Crop

* * * * *

(c) In addition to the types of dry beans designated in the Special Provisions, we will insure other types by written agreement if:

(1) The type you intend to plant has been demonstrated to be adapted to the area. Evidence of adaptability must include:

(i) Results of test plots for two years and recommendations by a university or seed company; or

(ii) Two years of production reports that indicate your experience producing the type in your production area;

(2) You submit your production reports and prices received, or the test plot results, and evidence of market potential, including the price buyers are willing to pay for the type; and

(3) Both parties (you and us) enter into a written agreement allowing insurance on the type in accordance with section 18 of the Basic Provisions.

* * * * *

■ 11. Amend § 457.154 as follows:
■ a. Revise the introductory text and the undesignated text at the beginning of the ''Processing Sweet Corn Crop Provisions'';
■ b. In section 2, revise paragraphs (a)(2) and (b); and
■ c. In section 11, in paragraph (c), remove the phrase ''15 day period'' and add the phrase ''15-day period'' in its place.

The revisions read as follows:

§ 457.154 Processing sweet corn crop insurance provisions.

The Processing Sweet Corn Crop Insurance Provisions for the 2025 and succeeding crop years are as follows:

United States Department of Agriculture
Federal Crop Insurance Corporation.
Processing Sweet Corn Crop Provisions

In return for your payment of premium and administrative fee for the coverage, these Processing Sweet Corn Crop Provisions will be attached to and made part of the Common Crop Insurance Policy, Basic Provisions (Basic Provisions) subject to the terms and conditions in your policy.

* * * * *

2. Unit Division

(a) * * *

(2) Section 34(c) of the Basic Provisions that allows optional units is not applicable.

(b) For processor contracts that stipulate the number of acres to be planted, optional units as provided in section 34(c) of the Basic Provisions will apply.

* * * * *

■ 12. Amend § 457.166 as follows:
■ a. In the introductory text, remove the year ''2025'' and add the year ''2026'' in its place;
■ b. In section 1, revise the definition of ''prune''.

The revision reads as follows:

§ 457.166 Blueberry crop insurance provisions.

* * * * *

1. Definitions

* * * * *

Prune. A cultural practice performed to increase blueberry production as follows:

(1) For lowbush blueberries, a process by which the acreage is either burned or mowed; and

(2) For all other blueberries, a process by which parts of the bush are cut off or the bush is cut back.

* * * * *

Marcia Bunger,

Manager, Federal Crop Insurance Corporation.

[FR Doc. 2024–27225 Filed 11–26–24; 8:45 am]

BILLING CODE 3410–08–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 317 and 381

[Docket No. FSIS–2022–0016]

RIN 0583–AD77

Uniform Compliance Date for Food Labeling Regulations

AGENCY: Food Safety and Inspection Service (FSIS), U.S. Department of Agriculture (USDA).

ACTION: Final action.

SUMMARY: FSIS is establishing January 1, 2028, as the uniform compliance date for new meat and poultry product labeling regulations that will be issued between January 1, 2025, and December 31, 2026. FSIS periodically announces uniform compliance dates for new meat and poultry product labeling regulations to minimize the economic impact of label changes.

DATES: *Effective date:* This action is effective November 27, 2024.

Compliance date: The uniform compliance date for new meat and poultry product labeling regulations that will be issued between January 1, 2025, and December 31, 2026, is January 1, 2028.

Comments due date: Comments on this final action must be received on or before December 27, 2024.

ADDRESSES: FSIS invites interested persons to submit comments on this rule. Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* This website provides the ability to type short comments directly into the comment field on this web page or attach a file for lengthier comments. Go to *https://www.regulations.gov*. Follow the on-line instructions at that site for submitting comments.
- *Mail:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Washington, DC 20250–3700.
- *Hand- or Courier-Delivered Submittals:* Deliver to 1400 Independence Avenue SW, Jamie L. Whitten Building, Room 350–E, Washington, DC 20250–3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2022–0016. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to *https://www.regulations.gov*.

Docket: For access to background documents or comments received, call 202–720–5046 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Washington, DC 20250–3700.

FOR FURTHER INFORMATION CONTACT: Contact Rosalyn Murphy-Jenkins, Director, Labeling and Program Delivery Staff, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, Telephone: (301) 504–0878.

SUPPLEMENTARY INFORMATION:

Background

On December 14, 2004, FSIS issued a final rule establishing January 1, 2008, as the uniform compliance date for new meat and poultry labeling regulations issued between January 1, 2005, and December 31, 2006 (69 FR 74405). The 2004 final rule also provided that the Agency would set uniform compliance dates for new labeling regulations in 2-year increments and periodically issue final rules announcing and requesting comments on those dates. Consistent with the 2004 final rule, the Agency has since published nine rules establishing the uniform compliance dates of January 1, 2010, January 1, 2012, January 1, 2014, January 1, 2016, January 1, 2018, January 1, 2020, January 1, 2022, January 1, 2024, and January 1, 2026 (72 FR 9651, 73 FR 75564, 75 FR 71344, 77 FR 76824, 79 FR 71007, 81 FR 91670, 83 FR 63052, 85 FR 81339, and 87 FR 77707).

The Final Rule

The new uniform compliance date will apply only to final FSIS regulations that require changes in the labeling of meat and poultry products and that are published after January 1, 2025, and before December 31, 2026. For each final rule that requires changes in labeling, FSIS will specifically identify January 1, 2028, as the compliance date. All meat and poultry food products that are subject to labeling regulations issued between January 1, 2025, and December 31, 2026, will be required to comply with these regulations on products introduced into commerce on or after January 1, 2028. If any food labeling regulation involves special circumstances that justify a compliance date other than January 1, 2028, the Agency will determine an appropriate compliance date and will publish that compliance date in the rulemaking.

Two-year increments increase industry's ability to make orderly adjustments to new labeling requirements without exposing consumers to outdated labels. This approach allows meat and poultry producers to plan for the use of label inventories and to develop new labeling materials that meet the new requirements. It also serves to reduce the economic impact of changing labels on both producers and consumers.

In the March 5, 2007, final rule, FSIS received only four comments on the announced uniform compliance dates, all in support. In the March 5, 2007, final rule, FSIS determined that further rulemaking for uniform compliance dates for labeling requirements is unnecessary (72 FR 9651). The Agency received no comments on the 2007 final rule, the comments FSIS received on the 2012 final rule were outside the scope (77 FR 76824), and FSIS received no comments on the 2014 final rule (79 FR 71007) or the 2016 final rule (81 FR 91670). The Agency received four comments on the 2018 final rule (83 FR 63052), all in support. The Agency received four comments on the 2020 final rule (85 FR 81339); one was outside the scope of the rulemaking and three were in support of the rule. The Agency received two comments on the 2022 final rule (87 FR 77707); one was in support of the rule, and one requested a 90-day extension because of potential supply chain issues for self-adhesive label materials. Because the commenter did not provide any additional information to support their claim about supply shortages and no other members of industry expressed concerns about a shortage, FSIS did not change the uniform compliance date.

Consistent with its statement in 2007, FSIS finds that further rulemaking on this matter is unnecessary. However, FSIS is providing an opportunity for comment on the uniform compliance date established in this final rule.

Executive Orders 12866 and 13563, and the Regulatory Flexibility Act

Executive Orders (E.O.) 12866 (as amended by E.O. 14094) and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic,

environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule has been designated as a ''non-significant'' regulatory action under section 3(f) of E.O. 12866. Accordingly, the final rule has not been reviewed by the Office of Management and Budget (OMB) under E.O. 12866.

This rule does not have a significant economic impact on a substantial number of small entities; consequently, a regulatory flexibility analysis is not required (5 U.S.C. 601–612).

Paperwork Reduction Act

FSIS has reviewed this rule under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) and has determined that there is no new information collection related to this final rule. Under this final rule, the Agency is establishing January 1, 2028, as the uniform compliance date for new meat and poultry product labeling regulations that will be issued between January 1, 2025, and December 31, 2026. The relevant information collection or record keeping requirements are covered under OMB approval number 0583–0092, Marking, Labeling, and Packaging.

E-Government Act

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, *et seq.*) by, among other things, promoting the use of the internet and other information technologies and providing increased opportunities for citizen access to Government information and services, and for other purposes.

Executive Order 12988, Civil Justice Reform

This final action has been reviewed under E.O. 12988, Civil Justice Reform. Under this rule: (1) All State and local laws and regulations that are inconsistent with this action will be preempted; (2) no retroactive effect will be given to this action; and (3) no administrative proceedings will be required before parties may file suit in court challenging this rule. However, parties may be required to exhaust their administrative remedies before challenging in court any specific agency action that is the subject of an appeal pursuant to this action.

Executive Order 13175

This rule has been reviewed in accordance with the requirements of E.O. 13175, ''Consultation and Coordination with Indian Tribal Governments.'' E.O. 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

FSIS has assessed the impact of this action on Indian tribes and determined that this rule does not, to our knowledge, have tribal implications that require tribal consultation under E.O. 13175. If a tribe requests consultation, FSIS will work with the Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions, and modifications identified herein are not expressly mandated by Congress.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS web page located at: *https://www.fsis.usda.gov/federal-register.*

FSIS will also announce and provide a link to it through the FSIS *Constituent Update,* which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS web page. Through the web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: *http://www.fsis.usda.gov/subscribe.* Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves and have the option to password protect their accounts.

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To file a program discrimination complaint, a complainant should complete a Form AD–3027, USDA Program Discrimination Complaint Form, which can be obtained online at *https://www.usda.gov/forms/electronic-forms,* from any USDA office, by calling (866) 632–9992, or by writing a letter addressed to USDA. The letter must contain the complainant's name, address, telephone number, and a written description of the alleged discriminatory action in sufficient detail to inform the Assistant Secretary for Civil Rights about the nature and date of an alleged civil rights violation. The completed AD–3027 form or letter must be submitted to USDA by:

(1) *Mail:* U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250–9410;

(2) *Fax:* (833) 256–1665 or (202) 690–7442; or

(3) *Email: program.intake@usda.gov.*

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Done in Washington, DC.

Paul Kiecker,

Administrator.

[FR Doc. 2024–27864 Filed 11–26–24; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–2020; Project Identifier MCAI–2024–00303–A; Amendment 39–22877; AD 2024–22–06]

RIN 2120–AA64

Airworthiness Directives; Embraer S.A. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2023–21–06 for certain Embraer S.A. (Embraer) Model EMB–505 airplanes. AD 2023–21–06 required installing structural reinforcements on certain monuments and replacing certain floor support rivets. Since the FAA issued AD 2023–21–06, the FAA determined that certain airplanes need to be re-assigned to a different group and certain re-identified floor support part numbers need to be corrected. This AD requires installing structural reinforcements on monuments and replacing fasteners on the floor support, as specified in an Agência Nacional de Aviação Civil (ANAC) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 2, 2025.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of January 2, 2025.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2024–2020; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

• For ANAC material identified in this AD, contact ANAC, Continuing Airworthiness Technical Branch (GTAC), Rua Doutor Orlando Feirabend Filho, 230—Centro Empresarial Aquarius—Torre B—Andares 14 a 18, Parque Residencial Aquarius, CEP 12.246–190—São José dos Campos—SP, Brazil; phone: 55 (12) 3203–6600; email: *pac@anac.gov.br;* website: *anac.gov.br/en/.* You may find this material on the ANAC website at *sistemas.anac.gov.br/certificacao/DA/DAE.asp.*

• You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available at *regulations.gov* under Docket No. FAA–2024–2020.

FOR FURTHER INFORMATION CONTACT: Jim Rutherford, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (816) 329–4165; email: *jim.rutherford@faa.gov*.

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2023–21–06, Amendment 39–22578 (88 FR 76114, November 6, 2023; corrected December 7, 2023 (88 FR 85093)) (AD 2023–21–06). AD 2023–21–06 applied to certain serial-numbered Embraer Model EMB–505 airplanes. AD 2023–21–06 was prompted by an MCAI originated by ANAC, which is the aviation authority for Brazil. ANAC issued ANAC AD 2023–05–03, effective June 2, 2023 (ANAC AD 2023–05–03) to correct an unsafe condition.

AD 2023–21–06 required installing structural reinforcements on certain monuments and replacing certain floor support rivets. The FAA issued AD 2023–21–06 to address certain monuments (the right-hand refreshment center and left-hand forward cabinet) that might not withstand the loads expected for specific emergency landing conditions, which may cause the detachment of mass items and result in injuries to the airplane occupants.

Since the FAA issued AD 2023–21–06, ANAC superseded ANAC AD 2023–05–03 and issued ANAC AD 2023–05–03R01, effective March 8, 2024 (ANAC AD 2023–05–03R01) for certain serial-numbered Embraer Model EMB–505 airplanes. ANAC AD 2023–05–03R01 stated it was issued to incorporate Embraer Service Bulletin SB505–25–0046, Revision 02, dated February 19, 2024, which updates effectivity information, compliance information, and part number information.

ANAC superseded ANAC AD 2023–05–03R01 and issued ANAC AD 2023–05–03R02, effective May 17, 2024 (ANAC AD 2023–05–03R02) (also referred to as the MCAI) for certain serial-numbered Embraer Model EMB–505 airplanes. The MCAI states it was issued to incorporate Embraer Service Bulletin SB505–25–0046, Revision 03, dated May 6, 2024 (actual date May 7, 2024), which includes additional actions for certain airplane groups that had complied with the requirements of ANAC AD 2023–05–03R01 but had not yet installed part number 506–66837–001 and updates the effectivity information, compliance information, and part number information.

The NPRM published in the **Federal Register** on August 16, 2024 (89 FR 66642). The NPRM was prompted by ANAC AD 2023–05–03R02. In the NPRM, the FAA proposed to require installing structural reinforcements on monuments and replacing fasteners on the floor support, as specified in ANAC AD 2023–05–03R02.

The FAA is issuing this AD to address certain monuments that might not withstand the loads expected for specific emergency landing conditions, which may cause the detachment of mass items and result in injuries to the airplane occupants.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2024–2020.

Discussion of Final Airworthiness Directive

Comments

The FAA received no comments on the NPRM or on the determination of the costs.

Conclusion

These products have been approved by the aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA reviewed the relevant data and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. This AD is adopted as proposed in the NPRM.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed ANAC AD 2023–05–03R02, which specifies procedures for installing structural reinforcements on certain monuments and replacing certain fasteners on the floor support.

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

Differences Between This AD and the MCAI

The material specified in ANAC AD 2023–05–03R02 allows the use of alternative or similar parts in place of the ones specified in the kits, provided these alternative or similar parts are approved by Embraer, but this AD requires approval from either the Manager, International Validation Branch, FAA; ANAC; or ANAC's authorized Designee. If approved by the ANAC Designee, the approval must include the Designee's authorized signature.

Costs of Compliance

The FAA estimates that this AD affects 208 airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Airplane groups 1 and 2—install structural reinforcements.	22 work-hours × $85 per hour = $1,870.	$1,600	$3,470	$242,900 (70 airplanes).
Airplane groups 3, 4, and 5—install structural reinforcements and replace floor fasteners.	14 work-hours × $85 per hour = $1,190.	600	1,790	$200,480 (112 airplanes).
Airplane groups 6 and 8—install structural reinforcements and replace floor fasteners.	26 work-hours × $85 per hour = $2,210.	2,000	4,210	$84,200 (20 airplanes).
Airplane group 7—install structural reinforcements	20 work-hours × $85 per hour = $1,700.	1,600	3,300	$16,500 (5 airplanes).
Airplane group 9—install structural reinforcements	14 work-hours × $85 per hour = $1,190.	1,600	2,790	$2,790 (1 airplane).

The FAA estimates the following costs for the additional work that operators would be required to do for compliance with this AD if they completed the actions in the original version of Embraer Service Bulletin SB505–25–0046, dated March 31, 2021; Service Bulletin SB505–25–0046, Revision 01, dated May 8, 2023; or Service Bulletin SB505–25–0046, Revision 02, dated February 19, 2024. The agency has no way of determining the number of airplanes that might need these actions:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Inspect floor fasteners	9 work-hours × $85 per hour = $765	$50	$815
Replace floor fasteners	1 work-hour × $85 per hour = $85	50	135
Airplane groups 1 and 2 install reinforcement support on left-hand forward cabinet.	2 work-hours × $85 per hour = $170	200	370

The FAA has included all known costs in its cost estimate. According to the manufacturer, however, all of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected operators.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive 2023–21–06, Amendment 39–22578 (88 FR 76114, November 6, 2023; corrected December 7, 2023 (88 FR 85093)); and

■ b. Adding the following new airworthiness directive:

2024–22–06 Embraer S.A.: Amendment 39–22877; Docket No. FAA–2024–2020; Project Identifier MCAI–2024–00303–A.

(a) Effective Date

This airworthiness directive (AD) is effective January 2, 2025.

(b) Affected ADs

This AD replaces AD 2023–21–06, Amendment 39–22578 (88 FR 76114, November 6, 2023; corrected December 7, 2023 (88 FR 85093)).

(c) Applicability

This AD applies to Embraer S.A. Model EMB–505 airplanes, certificated in any category, as identified in Agência Nacional de Aviação Civil (ANAC) AD 2023–05–03R02, effective May 17, 2024 (ANAC AD 2023–05–03R02).

(d) Subject

Joint Aircraft System Component (JASC) Code 2500, Cabin Equipment/Furnishings.

(e) Unsafe Condition

This AD was prompted by the analysis of certain monuments (the right-hand refreshment center and left-hand forward cabinet) that identified the need for installing structural reinforcements and replacing applicable floor support rivets. The FAA is issuing this AD to address the unsafe condition. The unsafe condition, if not addressed, could result in a monument not withstanding the loads expected for specific emergency landing conditions, which may cause the detachment of mass items and result in injuries to the airplane occupants.

(f) Compliance

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

(g) Required Actions

Except as specified in paragraphs (h) and (i) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, ANAC AD 2023–05–03R02.

(h) Exceptions to ANAC AD 2023–05–03R02

(1) Where ANAC AD 2023–05–03R02 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where ANAC AD 2023–05–03R02 refers to Embraer Service Bulletin SB505–25–0046, Revision 03, as dated ''May 6, 2024,'' replace that text with ''May 7, 2024.''

(3) Where paragraph (b) of ANAC AD 2023–05–03R02 refers to ''June 2, 2023, the effective date of AD 2023–05–03, original revision,'' replace that text with ''December 11, 2023, the effective date of AD 2023–21–06.''

(4) Although the material referenced in ANAC AD 2023–05–03R02 allows the use of alternative or similar parts in place of the ones specified in the kits provided, this AD requires that alternative or similar parts be approved by the Manager, International Validation Branch, FAA; ANAC; or ANAC's authorized Designee. If approved by the ANAC Designee, the approval must include the Designee's authorized signature.

(5) Where the material referenced in ANAC AD 2023–05–03R02 specifies to ''discard'' certain parts, replace that text with ''remove from service.''

(6) This AD does not adopt paragraph (d)(1) of ANAC AD 2023–05–03R02.

(i) No Reporting Requirement

Although the material referenced in ANAC AD 2023–05–03R02 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Alternative Methods of Compliance (AMOCs)

The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, mail it to the address identified in paragraph (k) of this AD or email to: *AMOC@faa.gov.* If mailing information, also submit information by email. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(k) Additional Information

For more information about this AD, contact Jim Rutherford, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (816) 329–4165; email: *jim.rutherford@faa.gov.*

(l) Material Incorporated by Reference

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

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

(i) Agência Nacional de Aviação Civil (ANAC) AD 2023–05–03R02, effective May 17, 2024.

(ii) [Reserved]

(3) For ANAC material identified in this AD, contact ANAC, Continuing Airworthiness Technical Branch (GTAC), Rua Doutor Orlando Feirabend Filho, 230—Centro Empresarial Aquarius—Torre B—Andares 14 a 18, Parque Residencial Aquarius, CEP 12.246–190—São José dos Campos—SP, Brazil; phone: 55 (12) 3203–6600; email: *pac@anac.gov.br;* website: *anac.gov.br/en/.* You may find this material on the ANAC website at *sistemas.anac.gov.br/certificacao/DA/DAE.asp.*

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (817) 222–5110.

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

Issued on October 24, 2024.

Victor Wicklund,

Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2024–27709 Filed 11–26–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2024–1009]

RIN 1625–AA00

Safety Zone; Corpus Christi Bay, Corpus Christi, TX

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for certain navigable waters in the Laguna Madre, South Padre Island, Texas. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by fireworks display launched from a barge in Laguna Madre, South Padre Island, Texas. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port, Sector Corpus Christi or a designated representative.

DATES: This rule is effective from 9:30 p.m. through 11:59 p.m. on December 7, 2024.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2024–1009 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email Lieutenant Timothy Cardenas, Sector Corpus Christi Waterways Management Division, U.S. Coast Guard; telephone 361–939–5130, email *Timothy.J.Cardenas@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule under authority in 5

U.S.C. 553(b)(B). This statutory provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency, for good cause, finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. The Coast Guard was notified of this event on October 30, 2024, and must establish this safety zone by December 7, 2024, to protect personnel, vessels, and the marine environment from potential hazards created by the fireworks display, and therefore lack sufficient time to provide a reasonable comment period and then a period to consider those comments before issuing the rule.

Under 5 U.S.C. 553(d)(3), the Coast Guard also finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to the public interest because prompt action is needed to respond to the potential safety hazards associated with fireworks launched from a barge in the waters of the Laguna Madre.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port, Sector Corpus Christi (COTP) has determined that potential hazards associated with the fireworks display, occurring from 9:30 p.m. through 11:59 p.m. on December 7, 2024, will be a safety concern for anyone within the waters of the Laguna Madre area within a 700-yard radius of the barge from which the display will be launched. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while the fireworks display occurs in the Laguna Madre.

IV. Discussion of the Rule

This rule establishes a temporary safety zone from 9:30 p.m. to 11:59 p.m. on the night of December 7, 2024. The safety zone will encompass all navigable waters of the Laguna Madre and is defined by a 700-yard radius from the launch platform. The regulated area encompasses a 700-yard radius of the following point: 26°06′02.1″ N, 97°10′17.7″ W. The fireworks display will take place in waters of the Laguna Madre. No vessel or person is permitted to enter the temporary safety zone during the effective period without obtaining permission from the COTP or a designated representative, who may be contacted on Channel 16 VHF–FM (156.8 MHz) or by telephone at 361–939–0450. The Coast Guard will issue Broadcast Notices to Mariners and Safety Marine Information Broadcasts.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on the size, location, and duration of the safety zone. The temporary safety zone will be enforced for the short period of two and a half hours, on the night of December 7, 2024, when vessel traffic is normally low. The zone is limited to a 700-yard radius from the launching position in the navigable waters of the Laguna Madre. The rule does not completely restrict the traffic within a waterway and allows mariners to request permission to enter the zone.

B. Impact on Small Entities

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

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, and Environmental Planning, COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f) and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves establishment of a temporary safety zone for navigable waters of the Laguna Madre in a zone defined by a 700-yard radius around the fireworks barge, located at the following point: 26°06′02.1″ N, 97°10′17.7″ W. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165–REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

■ 2. Add § 165.T08–1009 to read as follows:

§ 165.T08–1009 Safety Zone; Corpus Christi Bay, Corpus Christi, TX.

(a) *Location.* The following area is a safety zone: all navigable waters of the Laguna Madre encompassed by a 700-yard radius around the fireworks barge, located at the following point: 26°06′02.1″ N, 97°10′17.7″ W.

(b) *Enforcement period.* This section is subject to enforcement from 9:30 p.m. through 11:59 p.m. on December 7, 2024.

(c) *Regulations.* (1) In accordance with the general regulations in subpart C of this part, entry into this temporary safety zone is prohibited unless authorized by the Captain of the Port Sector Corpus Christi (COTP) or a designated representative. They may be contacted on Channel 16 VHF–FM (156.8 MHz) or by telephone at 361–939–0450.

(2) If permission is granted, all persons and vessels shall comply with the instructions of the COTP or designated representative.

(d) *Information broadcasts.* The COTP or a designated representative will inform the public of the enforcement times and date for this safety zone through Broadcast Notices to Mariners and Safety Marine Information Broadcasts as appropriate.

Dated: November 21, 2024.

T.H. Bertheau,

Captain, U.S. Coast Guard, Captain of the Port, Sector Corpus Christi.

[FR Doc. 2024–27875 Filed 11–26–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2024–1020]

Safety Zone; City of Rockport, Rockport Tropical Christmas Festival Fireworks Display Show

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the safety zone for the Rockport Tropical Christmas Festival Fireworks Display Show on December 6, 2024, or December 7, 2024, to provide for the safety of persons, vessels, and the marine environment on navigable waterways during this event. Our regulation for marine events within the Eighth Coast Guard District identifies the safety zone for this event in Rockport, TX. During the enforcement periods, entry into this zone is prohibited unless authorized by the Captain of the Port Sector Corpus Christi (COTP) or a designated representative.

DATES: The regulations in 33 CFR 165.801, Table 4, Line 11, will be enforced from 8 p.m. through 8:45 p.m. on December 6, 2024, unless the event is postponed because of adverse weather, in which case this rule will be enforced from 8 p.m. through 8:45 p.m. on December 7, 2024.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email Lieutenant Timothy Cardenas, Sector Corpus Christi Waterways Management Division, U.S. Coast Guard; telephone 361–939–5130, email *timothy.j.cardenas@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zone in 33 CFR 165.801, Table 4, Line 11, for the Rockport Tropical Christmas Festival Fireworks Display Show from 8 p.m. through 8:45 p.m. on December 6, 2024, with a rain date set for December 7, 2024, from 8 p.m. through 8:45 p.m. This action is being taken to provide for the safety of persons, vessels, and the marine environment on navigable waterways during this event. Our regulation for marine events within the Eighth Coast Guard District, § 165.801, specifies the location of the safety zone for the Rockport Tropical Christmas Festival Fireworks Display Show, which encompasses portions of Little Bay in Rockport, TX. As reflected in § 165.23 and § 165.801(a), if you are the operator of a vessel in the regulated area you must comply with directions from the Captain of the Port Sector Corpus Christi (COTP) or any designated representative. Persons or vessels desiring to enter the zone must request permission from the COTP or a designated representative. They can be reached on VHF FM channel 16 or by telephone at (361) 939–0450.

If permission is granted, all persons and vessels shall comply with the instructions of the COTP or designated representative.

In addition to this notice of enforcement in the **Federal Register**, the COTP or a designated representative will inform the public through Broadcast Notice to Mariners (BNM) and Marine Safety Information Broadcasts (MSIBs) at least 24 hours in advance of each enforcement.

Dated: November 21, 2024.

T.H. Bertheau,

Captain, U.S. Coast Guard, Captain of the Port, Sector Corpus Christi.

[FR Doc. 2024–27870 Filed 11–26–24; 8:45 am]

BILLING CODE 9110–04–P

LIBRARY OF CONGRESS

Copyright Royalty Board

37 CFR Part 385

[Docket No. Docket No. 24–CRB–0010–PR–COLA (2025)]

Cost of Living Adjustment to Royalty Rates and Terms for Making and Distributing Phonorecords

AGENCY: Copyright Royalty Board, Library of Congress.

ACTION: Final rule; cost of living adjustment.

SUMMARY: The Copyright Royalty Judges announce a cost of living adjustment (COLA) in the royalty rates for the statutory license for making and distributing phonorecords of nondramatic musical works regarding physical phonorecords and Permanent Downloads.

DATES:

Effective date: November 27, 2024.

Applicability date: These rates and terms are applicable during the period from January 1, 2025, through December 31, 2025.

FOR FURTHER INFORMATION CONTACT: Anita Brown, Program Specialist, (202) 707–7658, *crb@loc.gov.*

SUPPLEMENTARY INFORMATION: Section 115 of the Copyright Act, title 17 of the United States Code, creates a statutory license for making and distributing phonorecords of nondramatic musical works. On December 16, 2022, the Copyright Royalty Judges (Judges) adopted final regulations governing the rates and terms of copyright royalty payments under that license for the license period 2024–2027 for making and distributing phonorecords of nondramatic musical works. *See* 87 FR 76942.

Pursuant to those regulations, at least 25 days before January 1 of each year, the Judges shall publish in the **Federal Register** notice of a cost of living adjustment (COLA) applicable to the royalty fees for making and distributing physical phonorecords and Permanent Downloads. *See* 37 CFR 385.11.

The adjustment in the royalty fee shall be based on a calculation of the percentage increase in the Consumer Price Index for All Urban Consumers (CPI–U) published in November 2022 (298.012) [1] (''base rate'') according to the following formulas: for the per-work rate, $(1 + (Cy - 298.012\ [2])/298.012) \times 12¢$, rounded to the nearest tenth of a cent; for the per-minute rate, $(1 + (Cy - 298.012)/298.012) \times 2.31¢$, rounded to the nearest hundredth of a cent; where Cy is the CPI–U published by the Secretary of Labor before December 1 of the preceding year. 37 CFR 385.11(a)(2). The CPI–U published by the Secretary of Labor from the most recent index published before December 1, 2024, is 315.664.[3] Applying the formulas in 37 CFR 385.11(a)(2) results in an increase in the rates for 2025.

The adjusted rates for 2025 are 12.7 cents for the per-work rate and 2.45 cents for the per-minute rate.

List of Subjects in 37 CFR Part 385

Copyright, Phonorecords, Recordings.

Final Regulations

In consideration of the foregoing, the Judges amend part 385 of title 37 of the Code of Federal Regulations as follows:

PART 385—RATES AND TERMS FOR USE OF NONDRAMATIC MUSICAL WORKS IN THE MAKING AND DISTRIBUTING OF PHYSICAL AND DIGITAL PHONORECORDS

■ 1. The authority citation for part 385 continues to read as follows:

Authority: 17 U.S.C. 115, 801(b)(1), 804(b)(4).

■ 2. Section 385.11 is amended by revising paragraph (a)(1) to read as follows:

§ 385.11 Royalty fees for the public performance of sound recordings and the making of ephemeral recordings.

(a) * * *

(1) *2025 rate.* For the year 2025 for every physical phonorecord and Permanent Download the Licensee makes and distributes or authorizes to be made and distributed, the royalty rate payable for each work embodied in the phonorecord or Permanent Download shall be either 12.7 cents or 2.45 cents per minute of playing time or fraction thereof, whichever amount is larger.

* * * * *

Dated: November 22, 2024.

David P. Shaw,

Chief Copyright Royalty Judge.

[FR Doc. 2024–27819 Filed 11–26–24; 8:45 am]

BILLING CODE 1410–72–P

[1] The CPI–U published in November 2022 is available at *https://www.bls.gov/news.release/archives/cpi_11102022.htm* at Table 1.

[2] Base rate.

[3] The CPI–U announced on November13, 2024, by the Bureau of Labor Statistics in its *Consumer Price Index News Release—Consumer Price Index,* is available at *https://www.bls.gov/news.release/archives/cpi_11142024.htm* at Table 1.

POSTAL SERVICE

39 CFR Part 111

Domestic Competitive Products Pricing and Mailing Standards Changes

AGENCY: Postal Service™.

ACTION: Final rule.

SUMMARY: The Postal Service is amending *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM®), to reflect changes to prices and mailing standards for competitive products.

DATES: *Effective* January 19, 2025.

FOR FURTHER INFORMATION CONTACT: Steven Jarboe at (202) 268–7690, Catherine Knox (202) 268–5636, or Garry Rodriguez at (202) 268–7281.

SUPPLEMENTARY INFORMATION: This final rule describes new prices and product features for competitive products, by class of mail, established by the Governors of the United States Postal Service®. New prices are available under Docket Number CP2025–1 on the Postal Regulatory Commission PRC website at *http://www.prc.gov,* and on the Postal Explorer® website at *http://pe.usps.com.*

The Postal Service will revise *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM), to reflect changes to certain prices and mailing standards for the following competitive products:

- Priority Mail Express®.
- Priority Mail®.
- USPS Ground Advantage®.
- Parcel Select®.
- Extra Services.
- Return Services.
- Mailer Services.
- Recipient Services.
- Other.

Competitive product prices and changes are identified by product as follows:

Priority Mail Express

Prices

Overall, Priority Mail Express prices will increase 3.2 percent. Priority Mail

Express will continue to offer zoned and Flat Rate, Retail and Commercial pricing.

Retail prices will increase an average of 3.2 percent. The Flat Rate Envelope price will increase to $31.40, the Legal Flat Rate Envelope will increase to $31.65, and the Padded Flat Rate Envelope will increase to $32.25.

Commercial prices will increase an average of 3.2 percent.

Priority Mail

Prices

Overall, Priority Mail prices will increase 3.2 percent. Priority Mail will continue to offer zoned and Flat Rate, Retail and Commercial pricing.

Retail prices will increase an average of 3.2 percent. The Flat Rate Envelope price will increase to $10.10, the Legal Flat Rate Envelope will increase to $10.40, and the Padded Flat Rate Envelope will increase to $10.85. The Small Flat Rate Box price will increase to $10.65, and the Medium Flat Rate Boxes will increase to $19.15. The Large Flat Rate Box will increase to $26.30 and the APO/FPO/DPO Large Flat Rate Box will increase to $25.05.

Commercial prices will increase an average of 3.2 percent.

USPS Ground Advantage

Prices

Overall, USPS Ground Advantage prices will increase 3.9 percent.

USPS Ground Advantage—Retail prices will increase 4.9 percent.

USPS Ground Advantage—Commercial prices will increase 3.2 percent.

Parcel Select

Prices

The prices for Parcel Select Destination Entry will increase an average of 9.2 percent.

The prices for USPS Connect® Local will increase 5.4 percent.

Extra Services

Adult Signature Service

Adult Signature Required and Adult Signature Restricted Delivery service prices are decreasing 10.2 and 10.4 percent respectively. The price for Adult Signature Required will decrease to $8.40 and Adult Signature Restricted Delivery will decrease to $8.65.

Return Services

USPS Returns Service

There are no structural changes to USPS Returns Service.

Mailer Services

Pickup on Demand Service

The Pickup on Demand® service fee will remain the same.

USPS Tracking Plus Service

The USPS Tracking Plus® service prices will increase on average between 11.1 and 152.5 percent.

USPS Label Delivery Service

The USPS Label Delivery Service™ prices will increase 24.0 percent to $1.55.

Recipient Services

Post Office Box Service

The competitive Post Office Box™ service prices will increase an average of 5.7 percent within the updated price ranges.

Premium Forwarding Service

Premium Forwarding Service® (PFS®) prices will increase between 2.5 and 6.1 percent depending on the specific price element. The enrollment fee paid at the retail counter for PFS-Residential will increase to $26.85 and the PFS-Residential, PFS-Commercial, and PFS-Local enrollment fee paid online will increase to $24.70 per application. The price of the weekly shipment charge for PFS-Residential and per container charge for PFS-Local will increase to $27.80.

USPS Package Intercept

The USPS Package Intercept® fee will increase 4.9 percent to $18.35.

Other

Address Enhancement Service

Address Enhancement Service competitive product prices will increase between 8.4 and 9.1 percent.

IMpb Noncompliance Fee Renamed

To encompass all the compliance qualities included under the current IMpb Noncompliance Fee, the Postal Service is renaming the IMpb Noncompliance Fee the Package Quality Noncompliance Fee.

Intelligent Mail Matrix Barcode

The Postal Service is requiring mailers to add a supplemental GS1-DataMatrix (2D) Intelligent Mail matrix barcode (IMmb) to domestic shipping labels to improve package visibility. The placement of the IMmb will be in the address block to the left of the delivery address. Optionally, a mailer may place a second IMmb in the lower right corner of the shipping label. The Postal Service recommends using the second IMmb on all labels. The addition of the IMmb barcode will provide the Postal Service with a greater opportunity for the package to be scanned providing customers with better visibility of their packages.

The Postal Service will also update Publication 52, Hazardous, Restricted, and Perishable, Matter, for consistency in barcode application.

Live Animal and Perishable Handling Fee

The Postal Service is implementing a Live Animal and Perishable Handling fee. This fee will be assessed on all live animals and perishables (*e.g.* fruit, meat), entered at retail and commercial Priority Mail Express, Priority Mail, and USPS Ground Advantage prices. The Live Animal and Perishable Handling fee is nonrefundable once the piece is entered in the network.

The Live Animal and Perishable Handling fee is in addition to the current Live Animal Transportation fee provided in the Notice 123—Price List, when applicable.

The Postal Service will also update Publication 52, Hazardous, Restricted, and Perishable, Matter, to provide detailed information on the fee requirement.

Hazardous Materials Shipping Label Markings

The Postal Service is revising the current requirement to include the hazardous materials icon (''H'') in lieu of the service icon on a shipping address label when mailing eligible hazardous materials. Items containing mailable hazardous materials addressed to an APO/FPO/DPO, the USPS territories and possessions, and the Freely Associated States, are excluded from the requirement to include the hazardous materials icon in lieu of the service icon on a shipping address label.

Overweight and Oversize Item Fee

The Postal Service is increasing the overweight and oversize item fee to $200.00, to continue to deter nonmailable volumes from being entered in the network.

Resources

The Postal Service provides additional resources to assist customers with this price change for competitive products. These tools include price lists, downloadable price files, and **Federal Register** Notices, which may be found on the Postal Explorer® website at *http://pe.usps.com.*

The Postal Service adopts the described changes to *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM),

incorporated by reference in the *Code of Federal Regulations.* We will publish an appropriate amendment to 39 CFR part 111 to reflect these changes.

List of Subjects in 39 CFR Part 111

Administrative practice and procedure, Postal Service.

Accordingly, the Postal Service amends *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM), incorporated by reference in the Code of Federal Regulations as follows (see 39 CFR part 111.1):

PART 111—GENERAL INFORMATION ON POSTAL SERVICE

■ 1. The authority citation for 39 CFR part 111 continues to read as follows:

Authority: 5 U.S.C. 552(a); 13 U.S.C. 301–307; 18 U.S.C. 1692–1737; 39 U.S.C. 101, 401–404, 414, 416, 3001–3018, 3201–3220, 3401–3406, 3621, 3622, 3626, 3629, 3631–3633, 3641, 3681–3685, and 5001.

■ 2. Revise *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM) as follows:

Mailing Standards of the United States Postal Service, Domestic Mail Manual (DMM)

* * * * *

100 Retail Mail Letters, Cards, Flats, and Parcels

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110 Retail Mail Priority Mail Express

113 Prices and Eligibility

1.0 Prices and Fees

* * * * *

[Add new 1.7 to read as follows:]

1.7 Live Animal and Perishable Handling Fee

Priority Mail Express pieces containing live animals or perishables (*e.g.* fruit, meat) are subject to the nonrefundable Live Animal and Perishable Handling fee (see Notice 123—Price List). This fee is in addition to the Live Animal Transportation fee provided in the Notice 123—Price List, when applicable. For additional information on the Live Animal and Perishable Handling fee see Publication 52, *Hazardous, Restricted, and Perishable, Mail,* (526).

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115 Mail Preparation

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2.0 Priority Mail Express 1-Day and 2-Day

2.1 Mailing Label

Priority Mail Express 1-Day and 2-Day items must be labeled as follows:

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[Revise the second sentence in item c to read as follows:]

c. * * * The Intelligent Mail package barcode (IMpb) and the Intelligent Mail matrix barcode (IMmb) on the shipping label must have the appropriate service-type code and banner text above the IMpb barcode used for cremated remains. * * *

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120 Retail Mail Priority Mail

123 Prices and Eligibility

1.0 Prices and Fees

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[Add new 1.7 to read as follows:]

1.7 Live Animal and Perishable Handling Fee

Priority Mail pieces containing live animals or perishables (*e.g.* fruit, meat) are subject to the nonrefundable Live Animal and Perishable Handling fee (see Notice 123—Price List). This fee is in addition to the Live Animal Transportation fee provided in the Notice 123—Price List, when applicable. For additional information on the Live Animal and Perishable Handling fee see Publication 52, *Hazardous, Restricted, and Perishable, Mail,* (526).

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130 Retail Mail First-Class Mail and USPS Ground Advantage—Retail

133 Prices and Eligibility

1.0 Prices and Fees

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[Add new 1.9 to read as follows:]

1.9 Live Animal and Perishable Handling Fee

USPS Ground advantage—Retail pieces containing live animals or perishables (*e.g.,* fruit, meat) are subject to the nonrefundable Live Animal and Perishable Handling fee (see Notice 123—Price List). This fee is in addition to the Live Animal Transportation fee provided in the Notice 123—Price List, when applicable. For additional information on the Live Animal and Perishable Handling fee see Publication 52, *Hazardous, Restricted, and Perishable, Mail,* (526).

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200 Commercial Letters, Cards, Flats, and Parcels

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202 Elements on the Face of a Mailpiece

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3.0 Placement and Content of Mail Markings

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3.9 Shipping Address Label Markings

3.9.1 General

[Revise the last sentence of 3.9.1 to read as follows:]

* * * Failure to comply may subject the piece to the Package Quality Noncompliance Fee.

3.9.2 Hazardous Materials

[Revise the text of 3.9.2 to read as follows:]

When a shipping address label is used on items containing mailable hazardous materials, except for items addressed to an APO/FPO/DPO, the USPS territories and possessions, and the Freely Associated States, it must include the hazardous materials icon in lieu of the service icon as provided in the Parcel Labeling Guide.

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6.0 Barcode Placement for Parcels

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[Delete 6.2 and 6.3 and add new 6.2 to read as follows:]

6.2 Intelligent Mail Matrix Barcode Location

In addition to the placement of the IMpb and GS1–128 Routing Barcodes locations provided in 6.1, the Intelligent Mail matrix barcode (IMmb) must be placed in the address block to the left of the delivery address. Optionally, a mailer may place a second IMmb in the lower right corner of the shipping label.

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204 Barcode Standards

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2.0 Standards for Package and Extra Service Barcodes

[Revise 2.1 to read as follows:]

2.1 Barcodes

2.1.1 Definition

The definition of an Intelligent Mail package barcode (IMpb) and an Intelligent Mail matrix barcode (IMmb) are as follows:

a. IMpb—An IMpb is the USPS-developed barcode that can be read by automated parcel processing equipment and scanning devices and consists of a

data string that generally follows the GS1–128 specification. These barcodes include a variable length format that is determined by the elements selected by the mailer, and supplies tracking and routing data for packages and extra service applications. Intelligent Mail package barcodes must be used on all commercial packages, and on other mailpieces of customers requesting extra services.

b. IMmb—An IMmb is supplemental GS1-DataMatrix (2D) barcode to improve package visibility. The IMmb contains the same data as the IMpb barcode using a space-efficient barcode symbology.

2.1.2 Specification Resources

Detailed Specifications on an IMpb and IMmb can be found on PostalPro at *https://postalpro.usps.com* as follows:

a. Publication 199, *Intelligent Mail Package Barcode (IMpb) Implementation Guide for Confirmation Services and Electronic Payment Systems.*

b. Parcel Labeling Guide.

c. Intelligent Mail Package Barcode Technical Specifications.

d. Intelligent Mail Matrix Barcode Technical Specifications.

2.1.3 Barcode Location

See 202.6.1 for barcode location standards.

2.1.4 Quality Assurance

Mailers must perform routine inspections and testing of labels and barcodes to ensure quality.

2.1.5 Electronic File

All mailers generating an IMpb and IMmb must transmit piece-level information to the USPS in an approved electronic file format (except for mailers generating barcodes for use on return services products, such as uninsured USPS Returns service packages).

2.1.6 Compliance Quality Thresholds

All mailers who enter commercial parcels must meet the established thresholds for Compliance Quality outlined in Exhibit 2.1.6 to avoid payment of the Package Quality Noncompliance Fee. Failure to meet any compliance quality threshold in Exhibit 2.1.6 will result in the assessment of the Package Quality Noncompliance Fee.

Exhibit 2.1.6 Compliance Quality Thresholds

Note: See Publication 199 for a list of validations for each Compliance Category (AQ, MQ, BQ).

Compliance categories	Compliance codes	Compliance thresholds
Address Quality: Checks for a timely address that validates to a unique 11-Digit DPV or passes the critical validation criteria in Pub 199.	AQ	90
Manifest Quality (Shipping Services file): Checks for a timely manifest file that passes the critical validation criteria in Pub 199.	MQ	94
Barcode Quality: Checks the barcode in the manifest that passes the critical validation criteria in Pub 199	BQ	98

2.1.7 Alternate Approval

Labels not meeting IMpb specifications or other label element standards, but still able to demonstrate acceptable functionality within USPS processes, may be allowed using an alternative approval process authorized by the vice president, Applied Engineering, (See 608.8.1 for contact information.).

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210 Commercial Mail Priority Mail Express

213 Prices and Eligibility

1.0 Prices and Fees

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1.7 Unmanifested Fee

[Revise the text of 1.7 to read as follows:]

Eligible Priority Mail Express pieces omitted from the manifest are subject to the unmanifested fee (see Notice 123—Price List), unless the piece is subject to the Package Quality Noncompliance Fee as specified in 3.2.

* * * * *

[Add new 1.10 to read as follows:]

1.10 Live Animal and Perishable Handling Fee

Priority Mail Express pieces containing live animals or perishables (*e.g.* fruit, meat) are subject to the nonrefundable Live Animal and Perishable Handling fee (see Notice 123—Price List). This fee is in addition to the Live Animal Transportation fee provided in the Notice 123—Price List, when applicable. For additional information on the Live Animal and Perishable Handling fee see Publication 52, *Hazardous, Restricted, and Perishable, Mail,* (526).

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3.0 Basic Eligibility Standards for Priority Mail Express

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[Revise the heading of 3.2 to read as follows:]

3.2 Barcode Standards

[Move the text from 3.2 under new heading 3.2.1 to read as follows:]

3.2.1 IMpb Standards

[Revise the renumbered text of 3.2.1 by deleting the second and last sentence.]

All Priority Mail Express pieces (outbound and returns) must bear an Intelligent Mail package barcode (IMpb) prepared under 204.2.0.

[Add new 3.2.2 and 3.2.3 to read as follows:]

3.2.2 IMmb Standards

In addition to the IMpb under 3.2.1, all Priority Mail Express pieces (outbound and returns) must bear an Intelligent Mail matrix barcode (IMmb) prepared under 204.2.0.

3.2.3 Package Quality Noncompliance Fee

Unless otherwise excepted, mailers of mailpieces not meeting the requirements for use of a unique IMpb, and IMmb as outlined in section 204.2.1.8 and Publication 199, Intelligent Mail Package Barcode (IMpb) Implementation Guide for: Confirmation Services and Electronic Payment Systems, will be assessed the Package Quality Noncompliance Fee (see Notice 123-Price List). For details see PostalPro at *https://postalpro.usps.com.*

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215 Mail Preparation

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2.0 Priority Mail Express 1-Day and 2-Day

2.1 Mailing Label

Priority Mail Express 1-Day and 2-Day items must be labeled as follows:

* * * * *

[Revise the second sentence in item c to read as follows:]

c. * * * The Intelligent Mail package barcode (IMpb) and the Intelligent Mail matrix barcode (IMmb) on the shipping label must have the appropriate service-

type code and banner text above the IMpb barcode used for cremated remains. * * *

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220 Commercial Mail Priority Mail

223 Prices and Eligibility

1.0 Prices and Fees

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1.9 Unmanifested Fee

[Revise the text of 1.9 to read as follows:]

Eligible Priority Mail pieces omitted from the manifest are subject to the unmanifested piece fee (see Notice 123—Price List), unless the piece is subject to the Package Quality Noncompliance Fee as specified in 3.2.

* * * * *

[Add new 1.12 to read as follows:]

1.12 Live Animal and Perishable Handling Fee

Priority Mail pieces containing live animals or perishables (*e.g.,* fruit, meat) are subject to the nonrefundable Live Animal and Perishable Handling fee (see Notice 123—Price List). This fee is in addition to the Live Animal Transportation fee provided in the Notice 123—Price List, when applicable. For additional information on the Live Animal and Perishable Handling fee see Publication 52, *Hazardous, Restricted, and Perishable, Mail,* (526).

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3.0 Basic Eligibility Standards for Priority Mail

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[Revise the heading of 3.2 to read as follows:]

3.2 Barcode Standards

[Move the text from 3.2 under new heading 3.2.1 to read as follows:]

3.2.1 IMpb Standards

[Revise the renumbered text of 3.2.1 by deleting the second and last sentence.]

Unless the mailer is authorized to use a unique IMb on Priority Mail letters and flats prepared in high-speed environments, all Priority Mail pieces (outbound and returns) must bear an Intelligent Mail package barcode prepared under 204.2.0. To obtain information on how to acquire an authorization to use an IMb on Priority Mail letters and flats, mailers can contact USPS Shipping Information Systems at *IMPB@usps.gov.*

[Add new 3.2.2 and 3.2.3 to read as follows:]

3.2.2 IMmb Standards

In addition to the IMpb under 3.2.1, all Priority Mail pieces (outbound and returns) must bear an Intelligent Mail matrix barcode (IMmb) prepared under 204.2.0.

3.2.3 Package Quality Noncompliance Fee

Unless otherwise excepted, mailers of mailpieces not meeting the requirements for use of a unique IMpb and IMmb, as outlined in section 204.2.1.8 and Publication 199, Intelligent Mail Package Barcode (IMpb) Implementation Guide for: Confirmation Services and Electronic Payment Systems, will be assessed the Package Quality Noncompliance Fee (see Notice 123—Price List). For details see PostalPro at *https://postalpro.usps.com.*

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240 Commercial Mail USPS Marketing Mail

243 Prices and Eligibility

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3.0 Basic Eligibility Standards for USPS Marketing Mail

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3.4 IMpb Standards

All USPS Marketing Mail parcels must bear an Intelligent Mail package barcode (IMpb) and an Intelligent Mail matrix barcode (IMmb) as outlined in section 204.2.0 and Publication 199, *Intelligent Mail Package Barcode (IMpb) Implementation Guide for: Confirmation Services and Electronic Payment Systems.* For details see PostalPro at *https://postalpro.usps.com.*

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250 Commercial Mail Parcel Select

253 Prices and Eligibility

1.0 Prices and Fees

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1.4 Unmanifested Fee

[Revise the text of 1.4 to read as follows:]

Eligible Parcel Select pieces omitted from the manifest are subject to the unmanifested fee (see Notice 123—Price List), unless the piece is subject to the Package Quality Noncompliance Fee specified in 3.3.

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3.0 Basic Eligibility Standards for Parcel Select Parcels

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[Revise the heading of 3.3 to read as follows:]

3.3 Barcode Standards

[Move the text from 3.3 under new heading 3.3.1 to read as follows:]

3.3.1 IMpb Standards

[Revise the renumbered text of 3.3.1 by deleting the second and last sentence.]

All Parcel Select mailpieces must bear an Intelligent Mail package barcode (IMpb) prepared under 204.2.0.

[Add new 3.3.2 and 3.3.3 to read as follows:]

3.3.2 IMmb Standards

In addition to the IMpb under 3.3.1, all Parcel Select pieces (outbound and returns) must bear an Intelligent Mail matrix barcode (IMmb) prepared under 204.2.0.

3.3.3 Package Quality Noncompliance Fee

Unless otherwise excepted, mailers of mailpieces not meeting the requirements for use of a unique IMpb and IMmb, as outlined in section 204.2.1.8 and Publication 199, *Intelligent Mail Package Barcode (IMpb) Implementation Guide for: Confirmation Services and Electronic Payment Systems,* will be assessed the Package Quality Noncompliance Fee (see Notice 123-Price List). For details see PostalPro at *https://postalpro.usps.com.*

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260 Commercial Mail Bound Printed Matter

263 Prices and Eligibility

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3.0 Basic Eligibility Standards for Bound Printed Matter

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[Revise the heading and text of 3.5 to read as follows:]

3.5 Barcode Standards

Presorted priced BPM parcels must bear an Intelligent Mail package barcode (IMpb) and an Intelligent Mail matrix barcode (IMmb) as outlined in section 204.2.0 and Publication 199, *Intelligent Mail Package Barcode (IMpb) Implementation Guide for: Confirmation Services and Electronic Payment Systems.* For details see PostalPro at *https://postalpro.usps.com.*

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270 Commercial Mail Media Mail and Library Mail

273 Prices and Eligibility

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5.0 Basic Eligibility Standards for Media Mail and Library Mail

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[Revise the heading and text of 5.5 to read as follows:]

5.5 Barcode Standards

All Media Mail and Library Mail parcels must bear an Intelligent Mail package barcode (IMpb) and an Intelligent Mail matrix barcode (IMmb) as outlined in section 204.2.0 and Publication 199, *Intelligent Mail Package Barcode (IMpb) Implementation Guide for: Confirmation Services and Electronic Payment Systems.* For details see PostalPro at *https://postalpro.usps.com.*

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280 Commercial Mail USPS Ground Advantage—Commercial

283 Prices and Eligibility

1.0 Prices and Fees

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1.6 Unmanifested Fee

[Revise the text of 1.6 to read as follows:]

Eligible USPS Ground Advantage—Commercial pieces omitted from the manifest are subject to the unmanifested fee (see Notice 123–Price List), unless the piece is subject to the Package Quality Noncompliance Fee as specified in 3.4.

* * * * *

[Add new 1.9 to read as follows:]

1.9 Live Animal and Perishable Handling Fee

USPS Ground advantage—Commercial pieces containing live animals or perishables (*e.g.,* fruit, meat) are subject to the nonrefundable Live Animal and Perishable Handling fee (see Notice 123—Price List). This fee is in addition to the Live Animal Transportation fee provided in the Notice 123—Price List, when applicable. For additional information on the Live Animal and Perishable Handling fee see Publication 52, *Hazardous, Restricted, and Perishable, Mail,* (526).

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3.0 Basic Eligibility Standards for USPS Ground Advantage—Commercial

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[Revise the heading of 3.4 to read as follows:]

3.4 Barcode Standards

[Move the text from 3.4 under new heading 3.4.1 to read as follows:]

3.4.1 IMpb Standards

[Revise the renumbered text of 3.4.1 by deleting the second and last sentence.]

All USPS Ground Advantage—Commercial parcels (outbound and returns) must bear an Intelligent Mail package barcode (IMpb) prepared under 204.2.0.

[Add new 3.4.2 and 3.4.3 to read as follows:]

3.4.2 IMmb Standards

In addition to the IMpb under 3.4.1, all USPS Ground Advantage pieces (outbound and returns) must bear an Intelligent Mail matrix barcode (IMmb) prepared under 204.2.0.

3.4.3 Package Quality Noncompliance Fee

Unless otherwise excepted, mailers of mailpieces not meeting the requirements for use of unique Intelligent Mail package barcodes or extra services barcodes, as outlined in section 204.2.1.8 and Publication 199, *Intelligent Mail Package Barcode (IMpb) Implementation Guide for: Confirmation Services and Electronic Payment Systems,* will be assessed the Package Quality Noncompliance Fee (see Notice 123—Price List). For details see PostalPro at *https://postalpro.usps.com.*

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500 Additional Mailing Services

503 Extra Services

1.0 Basic Standards for All Extra Services

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1.7 Forms and Labels

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1.7.2 Privately Printed Forms or Labels

[Revise the first and fourth sentence of 1.7.2 to read as follows:]

Except for Certificate of Mailing service using privately printed forms (*i.e.,* facsimiles) as provided under 5.0, if authorized, a mailer may use privately printed extra service forms and labels for domestic mail only, if the forms and labels are nearly identical in design elements and color to the USPS form, with an Intelligent Mail package barcode (IMpb) and human-readable numbers that meet USPS specifications, and an Intelligent Mail matrix barcode (IMmb), in 204.2.0.* * * * * * Mailers generating shipping labels bearing an IMpb and IMmb must also affix the appropriate colored non-barcoded color-coded label for Registered Mail (under 2.1.2) or Certified Mail (under 3.2.1).* * *

[Revise the heading and text of 1.7.3 to read as follows:]

1.7.3 Barcodes

Items for which extra services are added must bear a correct Intelligent Mail package barcode (IMpb) and Intelligent Mail matrix barcode (IMmb).

* * * * *

1.7.5 Legacy Extra-Service Forms

[Revise the last sentence in the introductory text of 1.7.5 to read as follows:]

* * * Mailers using noncompliant versions of the following extra-service forms will be subject to the Package Quality Noncompliance Fee (see Notice 123—Price List):

* * * * *

2.0 Registered Mail

2.1 Basic Standards

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2.1.2 Label 200

[Revise the first sentence of 2.1.2 to read as follows:]

Registered Mail must bear the barcoded red Label 200 (see forms at *https://pe.usps.com/*), or a non-barcoded red Label 200–N when a mailer-generated shipping label bearing an IMpb and IMmb under 204.2.0 is also affixed on the same mailpiece.* * *

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3.0 Certified Mail Services

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3.2 Mailing

3.2.1 PS Form 3800

[Revise the first sentence in the introductory text of 3.2.1 to read as follows:]

Certified Mail must bear the barcoded green label part of the Form 3800 (see forms at *https://pe.usps.com/*), or a non-barcoded green Label 3800–N when a mailer-generated shipping label bearing an IMpb and IMmb, under 204.2.0, is also affixed on the same mailpiece.* * *

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4.0 Insured Mail

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4.2 Insurance Coverage—Priority Mail, USPS Ground Advantage—Retail, and USPS Ground Advantage—Commercial

Priority Mail pieces (including Priority Mail Return service), USPS Ground Advantage—Retail, and USPS Ground Advantage—Commercial pieces (including USPS Ground Advantage Return service) are insured against loss,

damage, or missing contents, for no more than $100.00 in coverage, subject to the following:

[Revise the text of item a to read as follows:]

a. Insurance coverage is provided against loss, damage, or missing contents and is limited to a maximum liability of $100.00 when the pieces bear an Intelligent Mail package barcode (IMpb) and an Intelligent Mail matrix barcode (IMmb) or USPS retail tracking barcode (see 4.3.4) and the mailer pays retail or commercial prices.

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4.3 Basic Standards

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4.3.4 Markings and Forms

The treatment of pieces is determined by the insurance amount as described in 4.3.1c and under the following conditions:

[Revise the text of item a to read as follows:]

a. Retail Systems Software (RSS) sites—A label and a receipt will be provided at the retail counter. The label printed at the retail counter will include postage and an Intelligent Mail package barcode (IMpb) and an Intelligent Mail matrix barcode (IMmb) that contains the appropriate service type code for the product and extra service purchased.

* * * * *

7.0 USPS Tracking

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7.2 Labels

7.2.1 Types of Labels

* * * Mailers not printing their own privately printed labels must use one of the label options as follows:

* * * * *

[Revise the second sentence of item b to read as follows:]

b. * * * The labels are populated with the product service type code and customer's Mailer Identification (MID) number in the Intelligent Mail package barcode (IMpb) and Intelligent Mail matrix barcode (IMmb).

* * * * *

8.0 USPS Signature Services

8.1 Basic Standards

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8.1.2 Standards for Signature Confirmation

For Signature Confirmation with Media Mail, Library Mail, Bound Printed Matter, or Parcel Select pieces meeting the physical standards under 201.7.0, the parcel must meet these additional requirements:

* * * * *

d. Mailers must use one of the following labels:

[Revise the second sentence of item d1 to read as follows:]

1. Retail Systems Software (RSS) sites—* * * The label printed at the retail counter will include postage and an Intelligent Mail package barcode (IMpb) and an Intelligent Mail matrix barcode (IMmb) that contains the appropriate service type code for the product and extra service purchased.

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505 Return Services

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3.0 USPS Returns Service

3.1 Basic Standards

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3.1.3 Postage and Prices

Postage and prices are subject to the following:

[Revise the third and last sentence of item a to read as follows:]

a. * * * USPS Returns service packages are charged postage and fees based on the STC embedded in the IMpb and IMmb and as provided under 3.1.3c. If all or part of the barcodes are unreadable, or the package is unable to be priced based on the data collected, postage will be determined by the Postal Service based on historical data, or default data determined at time of enrollment.

* * * * *

c. The account holder or mailer may obtain extra and additional services as follows:

[Revise the third sentence of item c1 to read as follows:]

1. * * * Additional insurance for Priority Mail Return service and USPS Ground Advantage Return service is available to the account holder for a fee on packages that have the applicable STC embedded into the IMpb and IMmb on the label, and for which the account holder has provided electronic data that supports the value of the merchandise (see 503.4.1a).* * *

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3.1.4 Labels

Distribution and preparation of labels are subject to the following:

* * * * *

b. *Label Preparation.* The following provisions apply:

* * * * *

[Revise the text of item b2 to read as follows:]

2. The label must include an IMpb and IMmb (see 204.2.0), accommodate all required information, be legible, and be prepared in accordance with the standards in Publication 199, *Intelligent Mail Package Barcode (IMpb) Implementation Guide for Confirmation Services and Electronic Payment Systems,* available on the PostalPro website at *https://postalpro.usps.com.*

* * * * *

[Revise the text of item b4 to read as follows:]

4. Except for USPS Returns service labels generated by the USPS API or MRA, all returns labels must have a properly constructed IMpb (C01, C05, N02, or N05, as applicable) and IMmb approved by the NCSC.

* * * * *

3.1.5 Noncompliant Labels

[Revise the last sentence of 3.1.5 to read as follows:]

* * * When noncompliant labels, including discontinued labels, are affixed to USPS Returns service packages, the permit holder may be assessed the Package Quality Noncompliance Fee (see Notice 123—Price List), or the appropriate USPS Returns class of mail retail price (*i.e.,* permit holders of Priority Mail Express Returns service packages will be assessed the retail Priority Mail Express price) calculated from the package's initial entry point (first physical scan) in the USPS network to its delivery address.

3.1.6 Enter and Deposit

The following standards apply:

* * * * *

[Revise the last sentence of item b to read as follows:]

b * * * Any such packages deposited in collection boxes may be returned to the sender for the extra service to be purchased appropriately, or it will be processed and the sender charged postage and fees based on the STC embedded in the IMpb and IMmb on the label and as provided under 3.1.4c.

* * * * *

5.0 Bulk Parcel Return Service

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5.4 Optional BPRS Label

[Revise the last sentence of 5.4 to read as follows:]

* * * The label is prepared at the mailer's expense and must meet all format standards in the Parcel Labeling Guide available on PostalPro at *https://postalpro.usps.com,* including an IMpb

and IMmb meeting the standards in 204.2.0.

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507 Mailer Services

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5.0 Package Intercept

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5.3 Adding Extra Services

[Revise the third sentence in the introductory text of 5.3 to read as follows:]

* * * The relabeled item will be assigned a new barcode applicable to the extra service purchased.* * *

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600 Basic Standards for All Mailing Services

601 Mailability

1.0 General Standards

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1.2 Overweight Items or Oversize Items

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1.2.3 Fee

[Revise the text of 1.2.3 to read as follows:]

Except for an overweight or oversize item discovered and picked up at the same facility where it was entered, the overweight/oversize item fee of $200 will be assessed and must be paid before release of the item. The $200 overweight or oversize item fee may be paid by any authorized retail payment method or through *PostalOne!.*

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604 Postage Payment Methods and Refunds

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9.0 Exchanges and Refunds

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9.2 Postage and Fee Refunds

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9.2.4 Postage and Fee Refunds Not Available

Refunds are not made for the following:

* * * * *

[Revise 9.2.4 by adding an item j to read as follows:]

j. For the Package Intercept per-piece fee once the USPS successfully intercepts the mailpiece (507.5.2) or the Live Animal and Perishable Handling fee once the piece is entered in the network.

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609 Filing Indemnity Claims for Loss or Damage

1.0 General Filing Instructions

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1.2.2 Eligibilty

Eligibility for mailers to submit claims using the Bulk Indemnity Claims feature is based on the following:

* * * * *

[Revise the text of item b to read as follows:]

b. IMpb and IMmb compliance history.

* * * * *

1.3 Who May File

A claim may be filed by:

* * * * *

[Revise the text of item c to read as follows:]

c. Only the account holder, for USPS Returns packages that are insured as identified by the account holder's mailer identification (MID) and the applicable STC for insurance imbedded into the IMpb and IMmb on the label, and for which the account holder has provided electronic data that supports the value of the merchandise being returned (see 503.4.3.1a).

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700 Special Standards

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705 Advanced Preparation and Special Postage Payment Systems

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18.0 Priority Mail Express Open and Distribute and Priority Mail Open and Distribute

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18.5 Preparation

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18.5.7 Address Label Service Barcode Requirement

[Revise first and third through fifth sentences in the introductory text of 18.5.7 to read as follows:]

An electronic service barcode must include an Intelligent Mail package barcode (IMpb) and Intelligent Mail matrix barcode (IMmb) (eVS approved mailers) symbology for Priority Mail Express Open and Distribute, and the IMpb and IMmb symbology for Priority Mail Open and Distribute in the address label.* * * * * * Priority Mail Express Open and Distribute IMpb and IMmb labels must include service type code ''723.'' For Priority Mail Open and Distribute, the IMpb and IMmb must include service type code ''123.'' The human-readable text ''USPS SCAN ON ARRIVAL'' must appear above the IMpb barcode.* * *

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[Add an IMmb in the address block to the left of the delivery address to the label graphics in Exhibits 18.5.8 through 18.5.12.]

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Intelligent Mail

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[Revise the ''Intelligent Mail'' entry by alphabetically adding the following:]

matrix barcode, 204.2.0

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Notice 123 (Price List)

[Revise competitive prices as applicable.]

* * * * *

Colleen Hibbert-Kapler,

Attorney, Ethics and Legal Compliance.

[FR Doc. 2024–27463 Filed 11–26–24; 8:45 am]

BILLING CODE 7710–12–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 121

RIN 0937–AA13

Organ Procurement and Transplantation: Implementation of the HIV Organ Policy Equity (HOPE) Act

AGENCY: Office of the Assistant Secretary for Health (OASH) and Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services (HHS) amends the regulations implementing the National Organ Transplant Act of 1984, as amended (NOTA), to remove clinical research and institutional review board (IRB) requirements (''research and IRB requirements'') for transplantation of kidneys and livers from donors with human immunodeficiency virus (HIV) to recipients with HIV. As allowed by the HIV Organ Policy Equity (HOPE) Act, the Secretary of HHS determines that participation in such clinical research should no longer be a requirement for transplantation of kidneys and livers from donors with HIV to recipients with HIV. This final rule serves as publication of the

Secretary's determination and amends the regulations to reflect this determination. This final rule also serves as publication of the Secretary's direction to the Organ Procurement and Transplantation Network (OPTN) to adopt and use standards of quality with respect to kidneys and livers from donors with HIV to ensure that HOPE Act kidney and liver transplants are subject to OPTN policies that are consistent with NOTA, and in a way that ensures the revised requirements for transplantation of such organs will not reduce the safety of organ transplantation.

DATES: This rule is effective November 27, 2024.

FOR FURTHER INFORMATION CONTACT: Frank Holloman, Director, Division of Transplantation, Health Systems Bureau, HRSA, 5600 Fishers Lane, Room 08W63, Rockville, MD 20857; by email at *donation@hrsa.gov;* or by telephone (301) 443–7577.

SUPPLEMENTARY INFORMATION:

I. Public Participation

On September 12, 2024, HHS published a notice of proposed rulemaking (NPRM) in the **Federal Register** (89 FR 74174) proposing both that the Secretary of HHS determine that participation in clinical research should no longer be required for transplantation of kidneys and livers from donors with HIV to recipients with HIV, and that the HHS regulations at 42 CFR part 121 implementing the HOPE Act be amended consistent with this proposed determination. The NPRM provided for a 30-day comment period, and HHS received 56 comments raising a variety of issues. HHS has carefully considered all comments in developing this rule, as outlined in section III, below, and presents a summary of all significant comments and Departmental responses.

II. Background

A. HHS Oversight of Organ Allocation and Transplantation

Within HHS, HRSA is responsible for overseeing the operation of the Nation's OPTN, including assisting in the equitable allocation of donor organs for transplantation. 42 U.S.C. 274(b)(2)(D). The allocation of organs is guided by the OPTN in accordance with NOTA and with the HHS regulations governing the operation of the OPTN in 42 CFR part 121. The OPTN is also charged with developing policies on many subjects related to organ donation, procurement, and transplantation, which include establishing standards of quality pertaining to organs procured for use in transplantation. 42 U.S.C. 274(b)(2)(E).

B. HOPE Act Requirements and Implementation

The enactment of the HOPE Act in 2013, Public Law 113–51, amended NOTA to eliminate the prohibition in the United States on transplantation of organs from persons with HIV, allowing transplantation of these organs if certain requirements are satisfied. Under the HOPE Act, organs from donors with HIV may be transplanted only in recipients living with HIV prior to receiving such an organ. 42 U.S.C. 274(b)(3)(A). Further, the HOPE Act requires that transplants of HIV-positive organs occur only in recipients with HIV who are participating in IRB-approved research protocols that adhere to certain criteria, standards, and regulations. 42 U.S.C. 274(b)(3)(B)(i). However, the Secretary may lift the research and IRB requirements if the Secretary has determined that participation in such clinical research, as a requirement for such transplants, is no longer warranted. 42 U.S.C. 274(b)(3)(B)(ii).

The HOPE Act outlines the process by which the Secretary may make such a determination under 42 U.S.C. 274(b)(3)(B)(ii). Specifically, the Secretary must routinely review the results of scientific research, in conjunction with the OPTN, to determine whether the results warrant revision of the OPTN standards of quality regarding organs from donors with HIV. If the Secretary determines that those standards of quality should be revised, the Secretary must direct the OPTN to revise the standards. 42 U.S.C. 274f–5(c)(2). The Secretary is also required to revise the regulatory provision implementing the HOPE Act, 42 CFR 121.6, upon determining that revisions to the OPTN standards of quality are warranted. 42 U.S.C. 274f–5(c)(3).

HRSA published a final rule implementing the HOPE Act on May 8, 2015. 80 FR 26464.[1] The 2015 rule amended 42 CFR 121.6 to permit transplants of organs from donors with HIV in accordance with the HOPE Act requirements.

The HOPE Act also directs the Secretary to develop and publish criteria for the conduct of research relating to transplantation of organs from donors with HIV into persons who are living with HIV before receiving an HIV-positive organ. 42 U.S.C. 274f–5(a). Subsequent to publication of the 2015 rule implementing the HOPE Act, the National Institutes of Health (NIH) published the *Final Human Immunodeficiency Virus (HIV) Organ Policy Equity (HOPE) Act Safeguards and Research Criteria for Transplantation of Organs Infected With HIV,* on November 25, 2015. 80 FR 73785.[2]

In general, the NIH Research Criteria include safeguards designed to protect both donors and recipients, as well as healthcare providers at Organ Procurement Organizations (OPOs) and transplant centers. Specifically, and in addition to the requirements in established OPTN transplant policies, donors with HIV must not have evidence of opportunistic infections and recipients must have a stable CD4+ T-cell count and established HIV suppression and control on effective antiretroviral therapy (ART). The study team must describe the anticipated effective HIV treatment plan and ART regimen for patients receiving an organ with a potentially different HIV strain. Antiretroviral drugs suppress viral replication; however, HIV may develop resistance to a specific drug necessitating a different medication regimen to maintain effectiveness. Transplant hospitals conducting HOPE Act operations are required to have expertise in transplants provided to recipients with HIV. OPOs are required to have procedures in place to address working with families of deceased donors who lived with HIV and a biohazard plan to address viral exposure and potential transmission. Finally, the Research Criteria establish uniform outcome measures that must be incorporated in the research design so that data on HOPE Act transplants can be analyzed consistently and data collection is harmonized to inform future implementation of the HOPE Act.

Publication of both the final rule implementing the HOPE Act and the NIH Research Criteria necessitated that the OPTN update its standards of quality for HIV-positive organ transplants and coordinate related OPTN policies. On November 21, 2015, the OPTN published an open variance (an experimental policy that tests

[1] **Federal Register**. Organ Procurement and Transplantation: Implementation of the HIV Organ Policy Equity (HOPE) Act. 80 FR 26464 (May 8, 2015). *https://www.federalregister.gov/documents/2015/05/08/2015-11048/organ-procurement-and-transplantation-implementation-of-the-hiv-organ-policy-equity-act.*

[2] **Federal Register**. Final Human Immunodeficiency Virus (HIV) Organ Policy Equity (HOPE) Act Safeguards and Research Criteria for Transplantation of Organs Infected With HIV. 80 FR 73785 (Nov. 25, 2015). *https://www.federalregister.gov/documents/2015/11/25/2015-30172/final-human-immunodeficiency-virus-hiv-organ-policy-equity-hope-act-safeguards-and-research-criteria.*

methods of improving organ allocation) providing standards for transplant hospitals conducting HOPE Act transplants.[3] The OPTN expanded the variance in 2019 to include all solid organs,[4] and extended the variance through January 2026, to provide for the gathering of data and subsequent evaluation of the outcomes of HOPE Act transplants.[5]

C. Review of Research Results

The Secretary, in conjunction with the OPTN, reviewed the results of scientific research to determine whether the results warrant revision to the OPTN standards of quality with respect to organs from donors with HIV and the safety of transplanting an organ from a donor with a particular strain of HIV into a recipient with a different strain of HIV. 42 U.S.C. 274f–5(c)(1). This review allowed the Secretary to determine if the safety and efficacy of HOPE Act transplants are comparable to non-HOPE Act transplants and, if warranted, to further determine whether such transplants should be conducted outside of a research setting.

1. OPTN Review and Recommendations

In 2018, the OPTN initiated a review of research results and data relevant to HOPE Act transplants, forming a working group for this purpose.[6] The OPTN's assessment as to whether revision is warranted for the OPTN standards of quality applicable to HOPE Act transplants was based primarily on (1) the review of studies demonstrating the safety and outcomes of organ transplantation in recipients with HIV and (2) a recognition that the removal of the general research and IRB requirements for HOPE Act transplants could expand access to organ transplantation for all patients regardless of their HIV status. In this context, safety is measured by accidental or inadvertent transmission of HIV in the performance of HOPE Act transplants. (Of note, there were no recorded accidental or inadvertent transmission events in the data reviewed by the OPTN.) Outcomes are determined primarily by transplant recipient or graft survival, compared to non-HOPE Act transplants or transplant recipients without HIV. Measures (*e.g.,* CD4+ T-cell counts, ART resistance, and detectable HIV viral loads) or variables such as opportunistic infections, HIV superinfection, malignancy, rejection, or graft failure may also factor into comparative outcomes in the short and long term.

The OPTN used three primary sources of data to assess HOPE Act transplants, each of which contributed to the recommendation the OPTN provided to the Secretary: (1) the research results of two pilot studies evaluating HOPE Act kidney transplants and liver transplants, and the progress of two ongoing NIH-funded clinical trials evaluating HOPE Act kidney transplants and liver transplants, (2) the research results of an older clinical trial analyzing safety and efficacy of kidney transplants in a small cohort of transplant recipients with HIV, and (3) OPTN data on the outcomes of all HOPE Act transplants.

Pilot Studies

A multicenter pilot study was launched in 2016 to determine safety and efficacy of HOPE Act kidney transplants. The HOPE In Action Consortium of 14 transplant centers conducting HOPE Act kidney transplants found no major differences between HOPE Act transplants of a kidney from a donor with HIV to a recipient with HIV and non-HOPE Act kidney transplants from a donor without HIV to a recipient with HIV.[7] Rates of opportunistic infections and infections requiring hospitalization post-transplant did not differ significantly across the study arms. Rejection was common for the study participants in the first year after transplant, occurring in 50 percent of recipients who received a kidney from a donor with HIV and 29 percent of recipients who received a kidney from a donor without HIV, but this result was not statistically significant. The insignificance of the result is due, in part, to the relatively small sample size. This finding is consistent with the earlier clinical trial of kidney transplantation in recipients with HIV, discussed in the next subsection of this preamble, which also found higher rejection rates in HIV allografts. The pilot study investigators noted that despite rejection rates, 1-year renal function was excellent for both study populations. Limitations of the pilot study include study size (75 transplants), which investigators attributed to the lower number of HOPE Act transplants conducted than the projected potential. In general, the study authors concluded that there is a survival benefit of transplantation for kidneys from donors with HIV to recipients with HIV, and that the availability of HOPE Act kidney transplants has the potential to mitigate disparities for a vulnerable population that faces lower access to transplant and higher waitlist mortality. The investigators further concluded that the observed trend toward higher rejection, albeit not statistically significant, for transplanted organs from donors with HIV merited further investigation.

A separate pilot study conducted by HOPE In Action Consortium participants compared HOPE Act transplants of a liver from a donor with HIV to a recipient with HIV and non-HOPE Act liver transplants from a donor without HIV to a recipient with HIV, and found that there were no differences in one-year graft survival, rejections, HIV breakthrough or severe adverse events. While the recipients of HOPE Act liver transplants presented with more opportunistic infections, infectious hospitalizations, and cancer, compared to non-HOPE Act liver transplants, the investigators determined that these findings warrant further investigation and perhaps consideration of additional donor and recipient infection and malignancy monitoring. In general, the investigators concluded that the transplant outcomes were more favorable compared to historical data on liver transplantation in recipients with HIV, who are known to experience higher rates of opportunistic infections and other complications. In addition, it was noted that co-infections are more common among both donors and recipients with HIV and confound the results. (Results of non-HOPE Act transplants have confirmed that recipients with both HIV and a co-infection have lower survival rates. Therefore, the presence of co-infections could independently impact survival and other variables measured by studies on HOPE Act transplants.)

[3] Organ Procurement and Transplantation Network. Policy Notice: Modifications to the Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors. 2016 Sep 1: *https://optn.transplant.hrsa.gov/media/1872/dtac_policynotice_hope_201606.pdf.*

[4] Organ Procurement and Transplantation Network. Policy Notice: Modify HOPE Act Variance to Include Other Organs. 2019 Jun 10: *https://optn.transplant.hrsa.gov/media/3000/dtac_policynotice_201906.pdf.*

[5] Organ Procurement and Transplantation Network. Policy Notice: Extend HIV Organ Policy Equity (HOPE) Act Variance. 2021 Dec 6: *https://optn.transplant.hrsa.gov/media/t1sdej22/policy-notice_dtac_hope_variance.pdf.*

[6] Organ Procurement and Transplantation Network. Public Comment Proposal: Modify the HOPE Act Variance to Include Other Organs. 2019 Jan 22: *https://optn.transplant.hrsa.gov/media/2800/dtac_publiccomment_20190122.pdf.*

[7] Durand CM, Zhang W, Brown DM, Yu S, Desai N, Redd AD, Bagnasco SM, Naqvi FF, Seaman S, Doby BL, Ostrander D, Bowring MG, Eby Y, Fernandez RE, Friedman-Moraco R, Turgeon N, Stock P, Chin-Hong P, Mehta S, Stosor V, Small CB, Gupta G, Mehta SA, Wolfe CR, Husson J, Gilbert A, Cooper M, Adebiyi O, Agarwal A, Muller E, Quinn TC, Odim J, Huprikar S, Florman S, Massie AB, Tobian AAR, Segev DL; HOPE in Action Investigators. A prospective multicenter pilot study of HIV-positive deceased donor to HIV-positive recipient kidney transplantation: HOPE in action. Am J Transplant. 2021 May;21(5):1754–1764.

This pilot study was the first multicenter prospective study reporting results of U.S. transplants of livers from donors with HIV to recipients with HIV and comparing outcomes according to donor HIV status in order to assess attributable risk. The investigators recognized as a limitation that the pilot study was relatively small (45 transplants), and noted that increases among HOPE Act liver transplant recipients in mortality, cytomegalovirus (CMV) viremia, infectious hospitalizations, and cancer, were observed. However, they note that these results should be considered in light of the relatively high rate of mortality for recipients awaiting liver transplant. For these patients, the benefit of undergoing a HOPE Act liver transplant may outweigh the risks of living with HIV and end stage liver disease.[8]

Ongoing Clinical Trials

The OPTN further considered the progress of an NIH-funded study on HOPE Act kidney transplants that was ongoing at the time of the OPTN's analysis. The NIH-funded U01 HOPE Act kidney transplant clinical trial was designed to analyze rejection and long-term outcomes of kidney transplantation for recipients with HIV. While the study was subsequently expanded, at the time of the OPTN's consideration the study was designed to compare outcomes of 100 HOPE Act kidney transplant recipients to 100 kidney transplant recipients with HIV who received an HIV-negative organ at 15 transplant centers, adding to the cohort accrued from the pilot studies discussed in the immediately preceding section of this preamble.[9] The results from this clinical trial were published in October 2024 and are described in section 3, ''Additional Research Results Published Subsequent to Issuance of the NPRM,'' below. Of note, these investigators were awarded an expansion grant to evaluate longer-term outcomes in HOPE Act kidney transplants.

Similarly, the OPTN considered the progress of an ongoing U01 HOPE Act liver transplant clinical trial designed to compare outcomes between HOPE Act transplants and non-HOPE Act transplants of livers from donors without HIV. The study has enrolled 40 individuals in each group over 3 years at 16 transplant centers,[10] reaching target enrollment, and now is in the phase of patient follow-up. The final results are not yet published.

Other Research Results

Prior to the initiation of the pilot studies and clinical trials discussed previously, a clinical trial examined outcomes of 150 kidney transplants in recipients with HIV conducted between November 2003 and June 2009. The investigators found both recipient and graft survival rates were high with no important increases in complications associated with HIV.[11] As noted in the description of the findings of the HOPE Act kidney transplant pilot study described in the immediately preceding subsection of this preamble, the investigators observed what they described as ''unexpectedly higher'' rejection rates in the transplant recipients with HIV participating in the study, compared with kidney transplant recipients who are not living with HIV. This higher rejection rate was blunted in transplant recipients that received anti-T-cell antibody medication at the time of transplantation. Studies of non-HOPE Act transplants have confirmed that such immunosuppressive regimens can reduce the risk of rejection for kidney transplant recipients with HIV.[12]

OPTN Data—HOPE Act Transplant Outcomes

Data from HOPE Act transplants is compiled by the OPTN on a quarterly basis, including waitlist registrations and counts of HOPE Act transplants, and is routinely reviewed. Prior to issuing its recommendation to the Secretary, the OPTN reviewed data on over 300 patients included in the HOPE Act research variance for which no case was halted, paused, or substantially amended to address safety concerns.

OPTN Recommendations

Based on the assessment of the above-described research results and data, in 2021 the OPTN recommended to the Secretary that the research and IRB requirements of the HOPE Act be removed for all organs.[13] The OPTN specifically noted that in its review of the data safety monitoring review board (DSMB) reports from five years of HOPE Act transplants, with over 300 persons with HIV receiving HOPE Act transplants, no DSMB identified patient safety concerns in HOPE Act research. Further, there have been no reports made to the OPTN of safety issues regarding HOPE Act transplants among OPO, hospital, or transplant center personnel or in patients, in donor hospitals, or transplant hospitals. The OPTN noted that it was the opinion of the OPTN Safety Review Group that the research and IRB requirements for HOPE Act transplants present a barrier to fully realizing the potential of organ transplantation from donors with HIV to recipients with HIV, as the research and IRB requirements limit access to such transplants.[14] [15]

2. Additional Research Results Published Subsequent to the OPTN Assessment

Prior to publication of the NPRM, the Secretary further considered additional research published providing more evidence for the safety of organ transplantation from donors with HIV to recipients with HIV. In general, this research demonstrates that the safety and outcomes of kidney and liver HOPE Act transplants are well established, with over 517 HOPE Act kidney and liver transplants conducted to date.

One prospective study published in 2022, examined 92 HOPE Act donors contributing 177 organs, which included 131 kidneys and 46 livers, to understand the characteristics of donors with HIV in terms of clinical,

[8] Durand CM, Florman S, Motter JD, Brown D, Ostrander D, Yu S, Liang T, Werbel WA, Cameron A, Ottmann S, Hamilton JP, Redd AD, Bowring MG, Eby Y, Fernandez RE, Doby B, Labo N, Whitby D, Miley W, Friedman-Moraco R, Turgeon N, Price JC, Chin-Hong P, Stock P, Stosor V, Kirchner VA, Pruett T, Wojciechowski D, Elias N, Wolfe C, Quinn TC, Odim J, Morsheimer M, Mehta SA, Rana MM, Huprikar S, Massie A, Tobian AAR, Segev DL; HOPE in Action Investigators. HOPE in action: A prospective multicenter pilot study of liver transplantation from donors with HIV to recipients with HIV. Am J Transplant. 2022 Mar;22(3):853–864.

[9] National Institutes of Health RePORT. Kidney Transplantation from Donors with HIV: Impact on Rejection and Long-term Outcomes. Project No. 5U01AI177211–02. Accessed 21 May 2024. *https://reporter.nih.gov/search/kcWJ0GeT8kigjO2_LU8R2g/project-details/10848468.*

[10] National Institutes of Health RePORT. Hope In Action: A Clinical Trial of HIV-to-HIV Liver Transplantation. Project No. 5U01AI138897–05. Accessed 21 May 2024. *https://reporter.nih.gov/project-details/10459319.*

[11] Stock PG, Barin B, Murphy B, Hanto D, Diego JM, Light J, Davis C, Blumberg E, Simon D, Subramanian A, Millis JM, Lyon GM, Brayman K, Slakey D, Shapiro R, Melancon J, Jacobson JM, Stosor V, Olson JL, Stablein DM, Roland ME. Outcomes of kidney transplantation in HIV-infected recipients. N Engl J Med. 2010 Nov 18;363(21):2004–14.

[12] Locke JE, James NT, Mannon RB, Mehta SG, Pappas PG, Baddley JW, Desai NM, Montgomery RA, Segev DL. Immunosuppression Regimen and the Risk of Acute Rejection in HIV-Infected Kidney Transplant Recipients. Transplantation. 2014 Feb 27;97(4):p 446–450.

[13] Cooper M. ''OPTN Letter to Secretary Becerra on the HOPE Act.'' 2021 Oct 29. *https://optn.transplant.hrsa.gov/media/ueyjdfnd/hope-act-letter.pdf.*

[14] McCauley J. ''Fifty Sixth ACBTSA Meeting, Written Public Comment—November 17, 2022 Meeting.'' 2022 Nov 8. *https://optn.transplant.hrsa.gov/media/hwgncda2/optn-executive-committee_acbtsa-letter.pdf.*

[15] Chandran S, Stock PG, Roll GR. Expanding Access to Organ Transplant for People Living With HIV: Can Policy Catch Up to Outcomes Data? Transplantation. 2024 Apr 1;108(4):874–883.

immunologic, and virologic profiles to ensure the safety of transplantation. Of these donors, 58 were donors with HIV and 34 were donors without HIV. For those donors with known HIV infection, 90 percent received ART treatment. The study concluded that although drug resistant mutations (DRMs) were common, DRMs that could compromise the effectiveness of certain ART were rare, reassuring the safety of using organs from donors with HIV in recipients with HIV. Further, the study also found that there were no major differences in comorbidities between recipient groups that received an organ from a donor with HIV compared to those that received an organ from a donor without HIV.[16]

In a March 2024 analysis of the impact of the HOPE Act on access to kidney transplantation for recipients with HIV, the authors found 70 percent of HOPE Act recipients received a kidney transplant during the 4.5 year study period versus 43 percent of non-HOPE Act transplant candidates at the same center.[17] Furthermore, those who received transplants in HOPE Act trials had shorter estimated wait times (median 10.3 months versus 60.8 months), and after adjusting for relevant allocation factors including time on dialysis, kidney transplantation was 3.3-fold higher for those who received an organ from a donor with HIV.[18] These findings suggest that the availability of kidneys from donors with HIV increases access to transplantation among people with HIV. Given that people with HIV who are living with end stage renal disease (ESRD) have higher mortality than people with ESRD who are not also living with HIV,[19] in HHS's view, this data illustrates the benefit of HOPE Act kidney transplants for this vulnerable population.

The HOPE in Action Consortium also has published information on the positive outcomes of living HOPE Act kidney donors. In a case series of three transplants, investigators reported that two of the three donors developed adverse events, but findings suggested these were medically managed and that HIV RNA copies and CD4+ T-cell counts were stable at two to four years post-transplant.[20]

There is significantly less data on non-kidney and non-liver HOPE Act transplants. Since 2019, when the OPTN's HOPE Act policy was expanded to include all solid organs, only three heart transplant programs have received approval to perform HOPE Act transplants. To date, just three heart transplants have been conducted, including one heart-kidney transplant.[21] [22] No HOPE Act transplants have been recorded among recipients in need of other organs. The lack of data makes it difficult to assess the safety and outcomes of HOPE Act transplants other than kidney and liver HOPE Act transplants.

3. Additional Research Results Published Subsequent to Issuance of the NPRM

Since publication of the NPRM, results from a new, groundbreaking study were published in October 2024.[23] In the largest prospective, observational, multicenter study to date, researchers compared transplantation of kidneys at 26 U.S. centers from deceased donors with HIV and donors without HIV to recipients with HIV. The study enrolled 408 transplantation candidates, of whom 198 received a kidney from a deceased donor; 99 received a kidney from a donor with HIV and 99 from a donor without HIV. This study was larger than the HOPE Act pilot study, described above, and was designed to assess whether kidney transplantation from donors with HIV to recipients with HIV would be noninferior to transplantation from donors without HIV. The study further assessed safety and post-transplantation complications.

The primary outcome assessed was a safety outcome (a composite of death from any cause, graft loss, serious adverse event, HIV breakthrough infection, persistent failure of HIV treatment, or opportunistic infection) for noninferiority (margin for the upper bound of the 95% confidence interval, 3.00). Researchers found an adjusted hazard ratio of 1.00 for the primary composite outcome, demonstrating noninferiority of kidney transplantation from donors with HIV as compared to kidney transplantation from donors without HIV.

Secondary outcomes included overall survival, survival without graft loss, rejection, infection, cancer, and HIV superinfection. The following secondary outcomes were similar whether the donor had HIV or not: overall survival at 1 year (94% vs. 95%) and 3 years (85% vs. 87%), survival without graft loss at 1 year (93% vs. 90%) and 3 years (84% vs. 81%), and rejection at 1 year (13% vs. 21%) and 3 years (21% vs. 24%).

The incidence of serious adverse events, infections, and cancer was similar in all groups studied. Of note, the incidence of HIV breakthrough infection was approximately three times higher among HOPE Act transplants (incidence rate ratio, 3.14; 95% CI, 1.02 to 9.63), which the researchers attributed to non-adherence to antiretroviral therapy. In all participants with HIV breakthrough infection, viral suppression was regained. A single case of potential HIV superinfection or dual infection occurred among the 58 recipients in this group, without HIV breakthrough infection or clinical consequences.

[16] Werbel WA, Brown DM, Kusemiju OT, Doby BL, Seaman SM, Redd AD, Eby Y, Fernandez RE, Desai NM, Miller J, Bismut GA, Kirby CS, Schmidt HA, Clarke WA, Seisa M, Petropoulos CJ, Quinn TC, Florman SS, Huprikar S, Rana MM, Friedman-Moraco RJ, Mehta AK, Stock PG, Price JC, Stosor V, Mehta SG, Gilbert AJ, Elias N, Morris MI, Mehta SA, Small CB, Haidar G, Malinis M, Husson JS, Pereira MR, Gupta G, Hand J, Kirchner VA, Agarwal A, Aslam S, Blumberg EA, Wolfe CR, Myer K, Wood RP, Neidlinger N, Strell S, Shuck M, Wilkins H, Wadsworth M, Motter JD, Odim J, Segev DL, Durand CM, Tobian AAR; HOPE in Action Investigators. National Landscape of Human Immunodeficiency Virus-Positive Deceased Organ Donors in the United States. Clin Infect Dis. 2022 Jun 10;74(11):2010–2019.

[17] Motter JD, Hussain S, Brown DM, Florman S, Rana MM, Friedman-Moraco R, Gilbert AJ, Stock P, Mehta S, Mehta SA, Stosor V, Elias N, Pereira MR, Haidar G, Malinis M, Morris MI, Hand J, Aslam S, Schaenman JM, Baddley J, Small CB, Wojciechowski D, Santos CAQ, Blumberg EA, Odim J, Apewokin SK, Giorgakis E, Bowring MG, Werbel WA, Desai NM, Tobian AAR, Segev DL, Massie AB, Durand CM; HOPE in Action Investigators. Wait Time Advantage for Transplant Candidates With HIV Who Accept Kidneys From Donors With HIV Under the HOPE Act. Transplantation. 2024 Mar 1;108(3):759–767.

[18] Motter JD, et al, on behalf of the HOPE in Action Investigators. Wait Time Advantage for Transplant Candidates With HIV Who Accept Kidneys From Donors With HIV Under the HOPE Act. Transplantation. 2024 Mar 1;108(3):759–767.

[19] Motter JD, et al., on behalf of the HOPE in Action Investigators. Wait Time Advantage for Transplant Candidates With HIV Who Accept Kidneys From Donors With HIV Under the HOPE Act. Transplantation. 2024 Mar 1;108(3):759–767.

[20] Durand CM, et al., on behalf of the HOPE in Action Investigators. Living Kidney Donors with HIV: Experience and Outcomes from a Case Series by the HOPE in Action Consortium. The Lancet Regional Health Americas. 2023 Jul;24:100553.

[21] Montefiore News Releases. World's First HIV-Positive to HIV-Positive Heart Transplant Performed at Montefiore Health System. 2022 Jul 22. *https://www.montefiore.org/body.cfm?id=1738&action=detail&ref=2194.*

[22] Hemmige V, Saeed O, Puius YA, Azzi Y, Colovai A, Borgi J, Goldstein DJ, Rahmanian M, Carlese A, Jorde UP, Patel S. HIV D+/R+ heart/kidney transplantation: First case report. J Heart Lung Transplant. 2023 Mar;42(3):406–408.

[23] C.M. Durand, A. Massie, S. Florman, T. Liang, M.M. Rana, R. Friedman-Moraco, A. Gilbert, P. Stock, S.A. Mehta, S. Mehta, V. Stosor, M.R. Pereira, M.I. Morris, J. Hand, S. Aslam, M. Malinis, G. Haidar, C.B. Small, C.A.Q. Santos, J. Schaenman, J. Baddley, D. Wojciechowski, E.A. Blumberg, K. Ranganna, O. Adebiyi, N. Elias, J.A. Castillo-Lugo, E. Giorgakis, S. Apewokin, D. Brown, D. Ostrander, Y. Eby, N. Desai, F. Naqvi, S. Bagnasco, N. Watson, E. Brittain, J. Odim, A.D. Redd, A.A.R. Tobian, and D.L. Segev, for the HOPE in Action Investigators. Safety of Kidney Transplantation from Donors with HIV. New England Journal of Medicine. 2024 Oct 17; 391(15): 1390–1401.

Among the acknowledged limitations of this study are the lack of true randomization, which the authors note was not possible due to the U.S. national organ allocation process. The authors further note that study participants were equally eligible for a kidney from a donor with or a donor without HIV, and that study group assignment was determined according to whichever organ was available first. The study group whose donors did not have HIV served as a control group and included 27 donors who were treated as having HIV during allocation but did not; in the authors' estimation, recipients of kidneys from these donors represent an ideal counterfactual control group. Immunosuppression and prophylaxis were heterogeneous; however, these factors were balanced between the two groups and reflect real-world practice, which the authors assert increases the generalizability of the study results.

This study is an important addition to the evidence base for HOPE Act kidney transplants in that the finding that kidney transplantation from donors with HIV was noninferior to kidney transplantation from donors without HIV with respect to the primary safety outcome, and that the incidence of serious adverse events, infections, surgical or vascular complications, and cancer was similar in the two groups, supporting the safety of HOPE Act kidney transplants.

4. HHS Advisory Committee on Blood and Tissue Safety and Availability Recommendations

The Secretary also considered the HHS Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) recommendation that the Secretary eliminate research and IRB requirements for all HOPE Act transplants. The ACBTSA working group developing this recommendation considered the OPTN recommendation and the results of relevant scientific research. While the ACBTSA working group proposed that the full committee recommend that the Secretary eliminate research and IRB requirements for all HOPE Act transplants, the working group expressed concern about the elimination of research and IRB requirements for non-kidney and non-liver HOPE Act transplants,[24] and whether there was sufficient data collected on other organs to justify a full adoption of the OPTN's recommendation.

The ACBTSA subsequently recommended that the Secretary act to lift the statutory research and IRB requirements for all HOPE Act transplants and at the same time recommended that the Secretary direct the OPTN to adopt, for HOPE Act transplants of organs other than kidneys and livers, organ-specific policies imposing additional requirements for the conduct of these transplants, including collecting safety and outcomes data for transplant candidates and recipients of such transplants through an IRB-approved research protocol.

These recommendations were later approved by the HHS Blood, Organ, and Tissue Senior Executive Council (BOTSEC), an advisory forum for senior leadership from HHS entities involved in blood, organ, and tissue safety and availability.

Upon review of the OPTN, ACBTSA and BOTSEC recommendations, and in consideration of the results of relevant scientific research, the Secretary proposed to determine that the research and IRB requirements for kidney and liver HOPE Act transplants are no longer warranted. The NPRM incorporated this approach, publishing the Secretary's proposed determination for comment, and proposing regulatory changes to exempt HOPE Act kidney and liver transplants from research and IRB requirements. In an effort to avoid the use of stigmatizing language, the NPRM further proposed wording changes to references to persons, donors, and recipients with HIV, and organs from individuals with HIV.

III. Discussion of Public Comment

HHS received 56 comments from individuals and organizations involved in healthcare, organ transplantation, HIV advocacy, health equity, LGTBQIA+ health, and HOPE Act clinical research. The comments received expressed overwhelming support for the finalization of this rule. A total of 55 of the 56 commenters expressed support for the proposed rule. One commenter did not support the proposed rule. Additional consideration was given to comments that were expressed by multiple individuals and entities. HHS has considered all of the comments, and, in response to comments regarding the use of non-stigmatizing language, made changes to the final rule as suggested by commenters.

Themes identified in many comments include that the proposed rule, if finalized, could reduce morbidity and mortality for people with HIV, reduce barriers to organ transplantation, increase organ utilization, reduce wait times for people on organ transplant wait lists, and reduce stigma and discrimination associated with HIV. One commenter indicated that, given that only 31 of the 250 transplant centers in the U.S. currently participate in HOPE Act clinical trials, access to these vital transplants is geographically limited: the proposed rule would encourage more transplant centers to offer HOPE Act transplants, enabling more equitable access to life-saving care for people with HIV across the country and helping to generate additional clinical data to enhance understanding and inform best practices in transplant care for people with HIV. In addition, numerous commenters noted that research has sufficiently demonstrated that HOPE Act kidney and liver transplants are both safe and effective.

The NPRM specifically invited public comment on the future Secretarial direction to the OPTN to revise the standards of quality concerning kidneys and livers from donors with HIV. Some commenters provided specific suggestions for the Secretary's direction, and other comments received appear relevant to HHS's consideration as to the content of the direction to the OPTN. These comments are noted below in both the subheading discussing the comments specifically provided on the content of the direction to the OPTN, and the subheadings relating to the subject matter of the comment. HHS has considered these comments in the development of the Secretary's direction to the OPTN, which is provided in section V, ''Implementation Considerations,'' below.

Multiple commenters also provided specific suggestions for the content of the revised NIH Research Criteria, and other comments received appear relevant to the content of the Research Criteria. These comments are noted below in both the subheading discussing the comments specifically provided on the Research Criteria, as well as in the subheadings relating to the subject matter of the comment when the commenter did not specifically reference the Research Criteria. All comments relating to the content of the revised Research Criteria were provided to NIH for consideration in the development of the revised Research Criteria.

Detailed descriptions of comments on specific aspects of the NPRM preamble and the proposed regulation, and HHS's responses to these comments, are provided below.

[24] HHS Advisory Committee on Blood and Tissue Safety and Availability. 2022. Fifty-Sixth ACBTSA Meeting November 17, 2022—Meeting Summary. *https://www.hhs.gov/oidp/advisory-committee/blood-tissue-safety-availability/meeting-summary/2022-11-17/index.html.*

Removal of Research and IRB Requirements for All Organs

Several commenters suggested that the Secretary should consider in this rule, or in a future rulemaking, the removal of research and IRB requirements for all HOPE Act organ transplants instead of removing research and IRB requirements only for kidney and liver transplants. Some of these commenters referenced the October 2021 letter from the OPTN to the Secretary providing that the OPTN had not identified any patient safety concerns involving HOPE Act transplants and that no research protocols applicable to HOPE Act transplants had been stopped, paused, or substantially altered due to patient safety concerns.[25] Many of these comments suggested that the available data was sufficient to prove the safety and efficacy of HOPE Act transplantation for all organ transplants, not only kidney and liver transplants. Others suggested that HHS should continue supporting research on HOPE Act transplants with the goal of generating sufficient evidence to make the case for a future Secretarial determination and rulemaking process that would remove the research and IRB requirements for all HOPE Act transplants.

HHS response: In the process leading up to the development of the NPRM, the Secretary considered whether to eliminate research and IRB requirements for all HOPE Act transplants. As a part of this process, the Secretary considered the October 2021 communication from the OPTN referenced by commenters, recommendations of advisory bodies, and research results and outcomes data on HOPE Act transplants. The vast majority of this data was generated from kidney and liver transplants, and, as discussed in the NPRM preamble, the Secretary notes the limited evidence demonstrating safety and efficacy of non-kidney and non-liver HOPE Act transplants. In order to lift the research and IRB requirements for HOPE Act transplants, the HOPE Act requires that the Secretary must determine that participation in clinical research is no longer warranted. 42 U.S.C. 274(b)(3)(B)(ii). In the absence of research results and robust outcomes data relevant to HOPE Act transplants of organs other than kidneys and livers, the Secretary does not have sufficient information about transplants of organs other than kidneys and livers on which to base the statutorily required determination. For this reason, the NPRM proposal to lift the research and IRB requirements only for HOPE Act kidney and liver transplants is incorporated in this final rule. As required by the HOPE Act, the Secretary will periodically review the results of additional scientific research relevant to transplants of organs other than kidneys and livers, and will reevaluate in the future whether the evidence is robust enough to demonstrate that other types of HOPE Act transplants need not be conducted in the research context. HHS makes no changes to the regulatory proposal in response to these comments.

Language Regarding HIV

Many commenters expressed support for the proposed revisions to the regulatory language used when referencing people, donors, and recipients with HIV. In general, commenters suggested that the proposed changes are more respectful, reflect a person-centered approach, and help to combat stigma associated with HIV. Others noted that these wording changes help to create a more inclusive healthcare environment.

One commenter requested that the proposed modification to 42 CFR 121.6 regarding references to donor organs be changed from ''donor organ(s) with HIV'' to ''organ(s) from donors with HIV.'' The commenter stated that, in their view, the term ''organs from donors with HIV'' is accurate and precise, stigma-reducing, and reflects a person-first approach in describing these donated organs.

HHS response: HHS appreciates this feedback, and includes the regulatory revisions in this final rule as proposed with regard to references to people, donors, and recipients with HIV. Further, HHS concurs with the suggested revision provided by the commenter with respect to the references to donor organs, and has incorporated this suggested revision and other similar revisions in the final rule at 42 CFR 121.6(b)(1)(ii)(B) introductory text, (b)(1)(ii)(B)(*1*) and (*2*), and (b)(2).

Ongoing Data Monitoring

Multiple commenters expressed support for efforts to monitor outcomes of HOPE Act transplants, both for patient safety and to develop evidence for the safety and efficacy of HOPE Act transplants.

Commenters addressing patient safety indicated that while the proposed rule may streamline the transplant process and increase the availability of organs, patient safety must be the top priority and rigorous safety standards must continue to apply. Several commenters noted that areas needing further attention, such as monitoring for rejection, malignancy, and infection, do not overshadow the overall favorable outcomes for HOPE Act kidney and liver transplants. Commenters emphasized the importance of continued monitoring of outcomes for these transplants by the OPTN, and that transparency and public communication of these outcomes are critical to maintaining trust and ensuring the ongoing success of HOPE Act transplant programs. Commenters indicated that application of the NIH Research Criteria has provided essential protections with regard to outcomes monitoring for HOPE Act kidney and liver transplants, and urged continued monitoring of HOPE Act transplants to ensure these protections are maintained.

Other commenters expressed that data monitoring could help HOPE Act transplant recipients and HOPE Act living donors who may need to be monitored for the development of chronic or end-stage conditions. For example, one commenter noted that living kidney donors ''are already at higher risk of kidney disease and will now only have one kidney.''

Commenters addressing evidence development noted that monitoring and evaluation of HOPE Act transplants may help develop evidence that will inform future policy, including a potential future implementation of the HOPE Act to remove research and IRB requirements for all HOPE Act organ transplants.

Several commenters indicated that current data monitoring requirements applicable to all organ transplants are sufficient. One commenter indicated that there is no reason to continue monitoring HOPE Act kidney and liver transplant outcomes above and beyond the baseline safety and outcomes monitoring for all organ transplants in the United States. One commenter indicated that the OPTN structure and outcome data collected are sufficient in their current state to provide oversight for all organs. Another commenter indicated comfort with appropriate oversight and data management by the organizations designated to oversee transplant services on a national level, which could include comprehensive reporting systems to track outcomes and address any issues promptly. The commenter further expressed an expectation that this information be made available to the public is a transparent manner.

HHS response: HHS notes that the final rule does not affect existing data

[25] Cooper M. ''OPTN Letter to Secretary Becerra on the HOPE Act.'' 2021 Oct 29. *https://optn.transplant.hrsa.gov/media/ueyjdfnd/hope-act-letter.pdf.*

monitoring or evaluation requirements for HOPE Act transplants, as these are determined by OPTN policy and the NIH Research Criteria. HHS agrees that patient safety remains a paramount concern and that appropriate safety standards apply to protect organ donors and transplant recipients. Further, HHS expects to utilize data on HOPE Act transplant outcomes in its ongoing evaluation of the HOPE Act. These comments were provided to the NIH working group for consideration in the development of revisions to the Research Criteria. Further, HHS considered these comments in developing the Secretary's direction to the OPTN to revise the OPTN standards of quality embodied in OPTN policy regarding organs from donors with HIV. HHS makes no changes to the regulatory proposal in response to these comments.

Standards for Transplant Centers Performing HOPE Act Transplants

Several commenters provided suggestions for transplant centers that are seeking to participate in HOPE Act transplants. One commenter requested that HHS evaluate all outstanding requests by transplant centers to participate in HOPE Act transplants, and approve qualifying transplant centers as soon as possible to both expand access to care and to generate additional data on the HOPE Act transplants they perform. The commenter further requested that HHS explore providing grants designed to build the capacity at transplant centers such that more transplant centers will be able to meet the minimum requirements necessary to become HOPE Act transplant centers.

HHS response: Thank you for these suggestions. While no changes have been made to the regulatory proposal in response to these comments, HHS will consider these suggestions in the Department's ongoing approach to implementation of the HOPE Act.

Informed Consent and Autonomy of Transplant Recipients

Some commenters expressed the desire that, if HHS finalizes the proposed rule, that HHS take steps to prioritize ethical considerations relevant to the autonomy of donors and recipients. In particular, commenters asked that transplant centers maintain meaningful processes to provide patients with the opportunity to provide informed consent, and that transplant candidates with HIV retain the option to elect a non-HOPE Act transplant instead of a HOPE Act transplant.

HHS response: This rule does not affect existing OPTN policies that require that informed consent is obtained from all transplant candidates, including HOPE Act transplant candidates,[26] or the informed consent policies or practices at hospitals providing clinical care to potential organ donors, OPOs, or individual transplant centers. HHS supports retaining the existing approach in OPTN policy that requires informed consent.

Further, existing OPTN policies do not prohibit transplant candidates eligible for a HOPE Act transplant to choose a non-HOPE Act transplant.[27] There are no revisions made in this rule that would force a transplant candidate to receive an organ from a donor with HIV. HHS supports retaining the existing approach in OPTN policy that permits transplant candidates eligible for a HOPE Act kidney or liver transplant to choose a non-HOPE Act kidney or liver transplant.

HHS considered these comments in developing the Secretary's direction to the OPTN to revise the OPTN standards of quality embodied in OPTN policy regarding organs from donors with HIV, as provided below in this preamble in the discussion of implementation considerations. HHS makes no changes to the regulatory proposal in response to these comments.

Education

Commenters expressed the desire for additional educational efforts regarding HOPE Act transplantation. Some commenters suggested that HRSA collaborate with the OPTN and work with OPOs to ensure that transplant centers are making compassionate efforts to seek authorization from potential kidney donors with HIV. Commenters further suggested that HRSA partner with the Centers for Medicare & Medicaid Services (CMS) to ensure that donor hospitals recognize every opportunity for organ donation for patients with an HIV-positive diagnosis and make referrals to the local OPO for an organ donation evaluation as mandated by the CMS Conditions of Participation. Other commenters asked for educational efforts aimed at people with HIV, healthcare professionals, students of health sciences, transplant centers, OPOs, and the public at large to increase awareness of the HOPE Act and opportunities to elect organ donation regardless of HIV status.

HHS response: HHS is supportive of any and all efforts to increase awareness and education about HOPE Act transplants, opportunities for persons with HIV to participate as organ donors, and transplant candidates with HIV to receive a HOPE Act transplant. While HHS is not making any revisions to the regulatory proposal in response to these comments, HHS will consider additional educational efforts along the lines of those suggested by the commenters.

NIH Research Criteria

Several commenters provided specific suggestions for the content and development of the revised NIH Research Criteria:

- Commenters requested the elimination of the current requirement that a transplant team perform at least five transplants within a four-year period between any donor and a recipient with HIV for all organs, as, in the commenters' estimation, this requirement is not necessary for organs from donors with HIV to be used safely.
- Commenters suggested that each transplant team should include infectious disease specialists with expertise in HIV care.
- One commenter requested the elimination of the biopsy requirement.
- One commenter noted that, in revising the Research Criteria, NIH should both maintain the strong patient safety record for HOPE Act transplants, while actively seeking to reduce burdens that may be slowing the establishment of non-kidney and non-liver HOPE Act transplant programs.
- One commenter requested that NIH include people with HIV, HIV researchers, physicians, and healthcare providers in the process of developing revised Research Criteria, and indicated that these individuals can provide invaluable insights that can only come from lived experience.

HHS response: HHS appreciates these suggestions, and agrees that these comments are relevant to the content of the NIH Research Criteria. These comments were provided to the NIH working group for consideration in the development of revisions to the Research Criteria. HHS makes no changes to the regulatory proposal in response to these comments.

Secretarial Direction to the OPTN

While multiple commenters provided suggestions that appear relevant to the Secretary's future direction to the OPTN to revise the standards of quality concerning kidneys and livers from donors with HIV, only a few commenters specifically referenced the

[26] Organ Procurement and Transplantation Network. OPTN Policies. Updated October 31, 2024. *https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf.*

[27] Organ Procurement and Transplantation Network. OPTN Policies. Updated October 31, 2024. *https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf.*

content of the Secretarial direction and provided recommendations. One commenter indicated that they defer to health care professionals as to the content of such direction, and further urged HHS to make sure that the final OPTN policies do not create additional barriers or lead to unintended consequences that make it more difficult for individuals to access these organs. One commenter requested that the direction to the OPTN require intensive and multi-disciplinary counseling and discussions to be conducted with the solid organ recipient, with ongoing care before, during, and after the transplant, to ensure that solid organ recipients understand the complexities of the transplant procedure while also receiving the emotional and physical care they need throughout the entirety of the process. The commenter further noted the opportunity for the OPTN to define transplant program collaboration on a more formal basis, recommending that the structure of the transplant team include nephrologists and/or hepatologists, infectious diseases experts, and transplant pharmacy members, and that requirements be instituted for providing counseling or any specific transplant training recommendations for infectious disease experts.

The commenters who provided views and suggestions that are relevant to the Secretary's direction to the OPTN, while not specifically referencing the content of the Secretary's direction, generally indicated that the current requirements applicable to all organ transplants are sufficient to appropriately ensure the safety of HOPE Act kidney and liver transplants conducted outside of the research context. One commenter indicated that there is no reason to impose special monitoring requirements for HOPE Act kidney and liver transplant outcomes, as appropriately protective standards are already included in the baseline safety and outcomes monitoring for all organ transplants in the United States. One commenter indicated that the OPTN structure and outcome data collected are sufficient in their current state to provide appropriate oversight for all organ transplants, regardless of whether the transplant involves organs from donors with HIV to recipients with HIV. Another commenter indicated comfort with appropriate oversight and data management by the organizations designated to oversee transplant services on a national level, indicating that such oversight may include stringent medical protocols, regular follow-ups, and comprehensive reporting systems to track outcomes and address any issues promptly. The commenter further expressed an expectation that safety and outcomes information be made available to the public is a transparent manner.

One commenter noted that HHS stated in the NPRM that scientific evidence demonstrates that transplants of kidneys and livers from donors with HIV to recipients with HIV are safe and effective. Given this view, the commenter opined that the current clinical standards of care for non-HOPE Act organ transplants are sufficient to apply to transplants of all kidneys and livers, of any HIV serostatus. The commenter further expressed that additional scrutiny of transplants of kidneys and livers from donors with HIV to recipients with HIV could be viewed as discrimination against recipients with HIV who are willing to accept offers of an organ from a donor with HIV, and infringes on patient autonomy. The commenter noted that the OPTN already is responsible for safety and outcomes monitoring for transplants that involve donors or recipients with viruses other than HIV, including cytomegalovirus, Epstein-Barr virus, hepatitis B and C viruses, and severe acute respiratory syndrome coronavirus 2.

HHS response: HHS appreciates all of the comments and suggestions regarding the content of the Secretary's direction to the OPTN. HHS has carefully considered these comments in developing the Secretary's direction to the OPTN to revise the OPTN standards of quality embodied in OPTN policy regarding organs from donors with HIV. As discussed below in section V, ''Implementation Considerations,'' through publication of this final rule, the Secretary directs the OPTN to adopt and use standards of quality with respect to kidneys and livers from donors with HIV to ensure that HOPE Act kidney and liver transplants are subject to OPTN policies that, from the OPTN's expertise, will not reduce the safety of HOPE Act kidney and liver transplants, provide appropriate oversight for these transplants, and require sufficient data collection and outcomes monitoring.

Health Equity and Patient Experience

Many comments positively noted the health equity component of the proposed rule and the potential impact to populations that are disproportionately impacted by HIV and end-stage chronic diseases. Several commenters requested that HHS consider the insights and experiences of HOPE Act patients in this and future rulemaking efforts.

HHS response: We agree. HHS supports efforts to better address health equity in organ transplantation and believes this rule will help to increase access to care among populations that are disadvantaged. HHS also is supportive of efforts to incorporate patient experience into policy, and we have received, and considered, comments from HOPE Act patients during this rulemaking process, including a comment from a self-identified living donor of a kidney used in a HOPE Act transplant. HHS makes no changes to the regulatory proposal in response to these comments.

Approach to Patient Care

Several commenters suggested changes to clinical care standards for HOPE Act transplant patients. One commenter requested that the Department encourage transplant centers to incorporate syndemic care approaches to address the complex needs of people with HIV. Syndemic care aims to provide more holistic service delivery to prevention and care, including by addressing the social determinants of health that allow for health conditions to cluster and interact. Several commenters requested that additional safety protocols be developed for transplant centers, such as post-operative care guidelines for HOPE Act transplant recipients.

HHS response: HHS is supportive of efforts to incorporate syndemic care approaches within the organ transplantation domain. Regarding the establishment of additional safety protocols for transplant centers, currently safety protocols beyond those included in the NIH Research Criteria are determined by individual transplant centers. These comments were provided to the NIH working group for consideration in the development of revisions to the Research Criteria. Further, HHS considered these comments in developing the Secretary's direction to the OPTN to revise the OPTN standards of quality embodied in OPTN policy regarding organs from donors with HIV, as provided below in the discussion of implementation considerations. HHS makes no changes to the regulatory proposal in response to these comments.

Addressing Diverse Needs

Several commenters requested that HHS consider the unique challenges of patients who are Black, Indigenous, and people of color and patients living in rural areas. A commenter indicated that post-transplant care is essential for

positive patient outcomes and factors such as implicit bias in medical settings, socioeconomic disparities, and geographic limitations frequently hinder equitable access to post-transplant care, especially for people experiencing both geographic isolation and medical racism. Long travel distances to transplant centers and lacking local healthcare options can impede consistent follow-up care and medication compliance.

HHS response: HHS is supportive of efforts to improve health equity in organ transplantation and believes this rule will contribute to improving access to care for patients who are Black, Indigenous, and people of color and patients living in rural areas by allowing HOPE Act kidney and liver transplants to be conducted at any transplant center in the United States. HHS makes no changes to the regulatory proposal in response to this comment.

Standards for Transplant Candidates

One commenter noted his opposition to lengthy sobriety requirements for liver transplant candidates.

HHS response: Currently, sobriety requirements for transplant candidates are determined by individual transplant centers. This comment was provided to the NIH working group for consideration in the development of revisions to the Research Criteria. Further, HHS considered this comment in developing the Secretary's direction to the OPTN to revise the OPTN standards of quality embodied in OPTN policy regarding organs from donors with HIV, as provided below in this preamble in the discussion of implementation considerations. HHS makes no changes to the regulatory proposal in response to this comment.

Future Research on HOPE Act Transplants

Multiple commenters expressed support for additional research evaluating the safety and efficacy of HOPE Act transplants. One commenter suggested that the experience of HOPE Act transplant patients should help inform the direction of future research on HOPE Act transplants.

HHS response: HHS is supportive of additional research evaluating the safety and efficacy of HOPE Act transplants, and considering patient experiences in informing the direction of future research. While no changes are made to the regulatory proposal in response to these comments, HHS will consider these comments in further efforts to implement the HOPE Act.

Beyond Scope

Some commenters provided comments or made suggestions that are beyond the scope of the proposed rule.

One commenter requested that HHS establish a program to provide technical assistance to state, local, and tribal health departments with the goal of adopting policies to prevent health information from being used in a criminal, civil, or immigration legal proceeding.

One commenter noted that none of the other comments provided on the NPRM highlight that there will be a conflict between a majority of expressly prohibitive or potentially permissive State laws and expressly permissive Federal law when this proposed rule is finalized. The commenter indicated that State laws that are silent on or prohibitive of organ transplantation between people diagnosed with HIV can and do preclude performance of HOPE Act transplants within a given jurisdiction regardless of permissive Federal laws, and despite Congress and Federal regulators having the authority to preempt state and local health laws.

Multiple commenters noted that State criminal laws that prohibit persons with HIV for donating or attempting to donate organs, blood, tissue, and other bodily fluids are a legal barrier to implementation of the HOPE Act.

HHS response: As these comments are not within the scope of the proposed rule, these comments have not altered HHS's proposed approach to lifting the research and IRB requirements for HOPE Act kidney and liver transplants.

Opposition

One commenter opposed the proposed rule, suggesting that organs from donors with HIV are not the same as organs from donors without HIV, and expressing concern regarding the transmission of HIV through organ transplantation to recipients without HIV.

HHS response: HHS notes that there have been no reported cases of inadvertent HIV transmission resulting from HOPE Act transplants. Further, under the requirements of the HOPE Act, transplantation of organs from donors with HIV to recipients without HIV is prohibited. HHS makes no changes to the regulatory proposal in response to this comment.

IV. Secretarial Determination

The Secretary has reviewed the recommendations of the OPTN, the ACBTSA, and the BOTSEC on implementation of the HOPE Act, the results of research on HOPE Act transplants conducted to date as well as results of other relevant research on organ transplants in recipients with HIV, and public comment received on the NPRM. Pursuant to his authority under the HOPE Act, 42 U.S.C. 274(b)(3)(B)(ii), and consistent with the implementing regulations at 42 CFR 121.6, the Secretary determines that participation in clinical research, and therefore adherence to research and IRB requirements, as a requirement for transplants of kidneys and livers from persons with HIV, is no longer warranted. Through publication of this final rule, the Secretary is lifting the statutory research and IRB requirements for such transplants.

HHS anticipates that the Secretary's determination and publication of this final rule will increase access to kidney and liver transplants by allowing more transplant centers to perform HOPE Act kidney and liver transplants. Currently, only a limited number of centers can perform HOPE Act transplants, because there are specific requirements stipulated by the NIH Research Criteria for such transplant centers. These requirements include expertise in HIV infection management, minimum organ-specific transplant team experience of five transplants of organs from donors without HIV to recipients with HIV over four years and an independent advocate for both recipients with HIV and prospective living donors with HIV. The requirements for centers conducting HOPE Act transplants have been subject to critique and have been viewed by some as a barrier to participation in HOPE Act transplant programs, which may impact equity and access to organ transplantation throughout the United States.[28] By eliminating the requirement that HOPE Act kidney and liver transplants are conducted in the research context, HHS expects that a larger number of transplant centers will be able to conduct such transplants. This rule will enable more transplant centers to transplant kidneys and livers donated by both living and deceased donors with HIV, in recipients with HIV, thereby expanding opportunities for people with HIV and end-stage diseases.

Further, HHS expects this rule will expand access to organ transplantation for all patients, regardless of their HIV status. When eligible for transplant, a

[28] Bowring, M.G., Ruck, J.M., Bryski, M.G., Werbel, W., Tobian, A.A.R., Massie, A.B., Segev, D.L., & Durand, C.M. (2023). Impact of expanding HOPE Act experience criteria on program eligibility for transplantation from donors with human immunodeficiency virus to recipients with human immunodeficiency virus. American Journal of Transplantation, 23(6), 860–864.

person with HIV is added to the waiting list. That patient may elect to receive an organ from a donor with HIV, as a HOPE Act transplant, should it become available, or may choose to wait for an organ from a donor who did not have HIV. If the patient with HIV chooses the HOPE Act transplant, this will allow another patient on the waiting list to receive the next available organ from a donor who does not have HIV, which would reduce the time spent waiting for a transplant. Of note, patients who do not have HIV will not be offered an organ from a donor who has HIV, as such transplants are not allowed under Federal law.

As of February 16, 2024, more than 103,000 men, women, and children were on the national organ transplant waiting list.[29] Every 10 minutes another person is added to the waiting list, and nearly 20 people die every day while waiting for a transplant.[30] HHS expects that the Secretary's determination and publication of this rule will improve access to kidney and liver transplants both by increasing the number of kidneys and livers available for transplant, and by allowing more transplant centers to perform HOPE Act kidney and liver transplants. This anticipated positive result is consistent with the Department's commitment to reducing the number of persons on the organ transplant waiting list.

V. Implementation Considerations

A. NIH Research Criteria

The HOPE Act provides the Secretary with the discretion to determine what research criteria should apply to HOPE Act transplants. 42 U.S.C. 274f–5(a). NIH, in consultation with HRSA and the OPTN, and including the input of other relevant Federal stakeholders, formed a working group to develop revised NIH Research Criteria. The NIH Research Criteria, as originally drafted, include a strong focus on HOPE Act kidney and liver transplants, as these are the most common types of HOPE Act transplants: as this rule removes HOPE Act kidney and liver transplants from the research context, it is necessary that the revised NIH Research Criteria appropriately address non-kidney and non-liver HOPE Act transplantation.

Further, HHS recognizes the revised NIH Research Criteria should reflect advances in research in the time since HOPE Act transplants began, including the current needs of various entities involved in non-kidney and non-liver HOPE Act transplants in consideration of input from transplant centers, transplant surgeons, OPOs, HIV clinicians, donors, recipients, HIV advocates, the OPTN, and individuals affected by the HOPE Act.

HHS has considered the comments submitted in response to the NPRM that are relevant to the revised NIH Research Criteria, as summarized in the discussion of public comment in section III, *supra.* These comments have been provided to NIH for consideration in developing the revised NIH Research Criteria. HHS will publish updated Research Criteria in the **Federal Register** for public comment.

B. Secretary's Direction To Revise OPTN Policies

As part of the implementation of the Secretary's determination that participation in clinical research as a requirement for transplants of kidneys and livers from persons with HIV is no longer warranted, the Secretary must direct the OPTN to update its policies to clarify that HOPE Act kidney and liver transplants may be conducted in a way consistent with the statutory requirements at 42 U.S.C. 274, and that ensures the revisions to the policies will not reduce the safety of organ transplantation. 42 U.S.C. 274f–5(c)(2); 42 CFR 121.6(b)(3).

In the NPRM preceding publication of this final rule, HHS specifically sought public comment on the nature and content of the Secretary's direction to the OPTN, including the level of specificity in the direction and the extent of the OPTN's discretion in developing the revised policies; what factors should be considered in assessing whether the revised policies are consistent with 42 U.S.C. 274; and what factors should be considered in assessing whether the revisions to the OPTN policies will not reduce the safety of organ transplantation. HHS further welcomed comment on any other aspects relating to the Secretary's direction to the OPTN to revise its standards of quality as required by the HOPE Act.

As described in the discussion of public comment in section III, *supra,* HHS received multiple comments relating to HHS's consideration as to the direction to the OPTN. The vast majority of commenters agreed that scientific evidence clearly demonstrates that HOPE Act kidney and liver transplants are safe and effective. Many of those commenters indicated that the current requirements applicable to all organ transplants are sufficient to appropriately ensure the continued safety of HOPE Act kidney and liver transplants conducted outside of the research context. HHS has carefully considered all comments received in the development of the Secretary's direction to the OPTN.

Through publication of this final rule, the Secretary directs the OPTN to adopt and use standards of quality with respect to kidneys and livers from donors with HIV to ensure that HOPE Act kidney and liver transplants are subject to OPTN policies that are consistent with 42 U.S.C. 274, and from the OPTN's expertise, will not reduce the safety of HOPE Act kidney and liver transplants, provide appropriate oversight for these transplants, and require sufficient data collection and outcomes monitoring.

In consideration of the public comments received, HHS notes that it may be appropriate for the OPTN to determine that current OPTN policies that are generally applicable to kidney and liver transplants provide appropriate safety and oversight standards for HOPE Act kidney and liver transplants. Alternatively, the OPTN may choose to revise OPTN policies to provide additional standards for HOPE Act kidney and liver transplants.

This rule provides the Secretary's determination that that participation in clinical research as a requirement for transplants of kidneys and livers from persons with HIV is no longer warranted; revises 42 CFR 121.6 to reflect the removal of the statutory research and IRB requirements for HOPE Act kidney and liver transplants; and directs the OPTN to revise its standards of quality with respect to kidneys and livers from donors with HIV consistent with 42 U.S.C. 274 and in a way that ensures the changes will not reduce the safety of organ transplantation policies as required by the HOPE Act. The final implementation step is for the OPTN to adopt and use standards of quality as directed by the Secretary to reflect that HOPE Act kidney and liver transplants no longer are subject to research and IRB requirements.

As was stated in the NPRM, HHS expects that the OPTN will solicit public comment on a proposed revision to relevant OPTN policies, and update the OPTN policies containing standards of quality with respect to kidneys and livers from donors with HIV, within 15 months from the publication of this final rule. As publication of this final rule has obviated current OPTN policies requiring HOPE Act kidney and liver transplants to be conducted in accordance with research and IRB requirements, HHS encourages the OPTN to act expeditiously to revise these policies. This will allow transplant centers that had not

previously been performing HOPE Act kidney and liver transplants in the research context to begin performing HOPE Act kidney and liver transplants in accordance with the revised OPTN policies.

VI. Final Rule Requirements

A. Removal of Research and IRB Requirements for HOPE Act Kidney and Liver Transplants

Consistent with the Secretary's determination under the HOPE Act, this rule revises 42 CFR 121.6 to reflect the removal of the statutory research and IRB requirements for kidney and liver HOPE Act transplants. Section 121.6(b)(1)(ii)(B) provides that participation in clinical research is no longer warranted for the following categories of transplants:

- Transplant of a kidney from a donor with HIV; and
- Transplant of a liver from a donor with HIV.

In implementation, this means that HOPE Act kidney and liver transplants will no longer be required to be conducted as research, and instead will be conducted in accordance with OPTN policies applicable to HOPE Act kidney and liver transplants. As noted above, the OPTN may decide that OPTN policies that generally apply to kidney and liver transplants are appropriate to apply to HOPE Act kidney and liver transplants, or may create different policies for HOPE Act kidney and liver transplants.

B. Revised Terminology: Persons With HIV

HHS is aware that previous language used in enacting and implementing the HOPE Act contained vocabulary and phrases that some people find stigmatizing—namely, references to ''infected with HIV'' when the regulatory language encompasses both living and deceased donors with HIV, or recipients with HIV. For the references to both living and deceased donors with HIV, HHS revises all current references in 42 CFR 121.6(b) from ''individuals infected with human immunodeficiency virus (HIV)'' and ''individuals infected with HIV'' to ''donors with HIV'' or, when discussing organs donated, ''organs from donors with HIV'' and specifically ''kidneys from donors with HIV'' and ''livers from donors with HIV.'' Further, HHS revises the current reference in 42 CFR 121.6(b)(1)(i) describing the allowable recipients of HOPE Act transplants from individuals who are ''infected with HIV before receiving such organ(s)'' to instead refer to individuals who are ''living with HIV before receiving such organ(s).'' This is consistent with the Centers for Disease Control and Prevention's (CDC) Stigma Language Guide.[31] These changed regulatory references are to avoid stigmatizing language, and do not change the groups of people referenced in 42 CFR 121.6.

VII. Effective Date

HHS finds that there is good cause for this rule to be effective upon publication in accordance with 5 U.S.C. 553(d)(3) of the Administrative Procedure Act and 5 U.S.C. 808(2) of the Congressional Review Act.

The waiting list for kidney transplant in the U.S. currently exceeds 88,700 candidates.[32] The 2022 OPTN/U.S. Scientific Registry of Transplant Recipients (SRTR) Annual Data Report indicated that over the course of a year more than 4,400 adults died while waiting for a kidney transplant, and an additional 4,500 persons were removed from the waiting list because they became too sick to receive a transplant.[33] Most transplant candidates wait years for a kidney transplant, often requiring dialysis or other interventions.

In addition, thousands of Americans suffer from conditions requiring liver transplant. As of November 8, 2024, 13,170 candidates were added to the waiting list in 2024.[34] In 2022, more than 1,031 liver patients died while awaiting transplant, according to the OPTN/SRTR Annual Data Report.[35]

HHS expects that this final rule will have the effect of decreasing the time all candidates for kidney and liver transplants spend on the waiting list, regardless of their HIV status. As described in section IV, above, a transplant candidate with HIV may choose to receive a HOPE Act kidney or liver transplant if an organ from a donor with HIV becomes available, or may choose to wait for an organ from a donor without HIV. Research has demonstrated that candidates with HIV who accept a HOPE Act kidney transplant spend significantly less time awaiting transplant than candidates on the waiting list for an kidney from a donor without HIV. A 2023 study found that median wait time for a HOPE Act kidney transplant was 10.8 months compared to 60.8 months—a 3.3-fold higher rate of transplant compared to non-HOPE Act transplants.[36] When candidates with HIV choose a HOPE Act transplant, this data suggests that this will decrease the time they spent on the waiting list. Additionally, this will have the effect of allowing a candidate further down the waiting list to receive the next available organ from a donor who does not have HIV, both reducing the time that candidate spends waiting for a transplant and decreasing the time all other candidates spend on the waiting list.

Moreover, HHS expects that this final rule also will increase access to organ transplantation. Thirty-one transplant centers are qualified to perform HOPE Act kidney and liver transplants as research in conformance with the requirements of the NIH Research Criteria, while 250 transplant centers operate nationwide. As, pursuant to this rule, HOPE Act kidney and liver transplants no longer need to be conducted as research, it can be reasonably expected that more transplant centers than in the past will be able to offer HOPE Act kidney and liver transplants to appropriate candidates on the transplant center's waiting list. It also is reasonable to expect that if a greater number of transplant centers will be able to offer HOPE Act transplants, this will allow more candidates with HIV on the waiting list to receive HOPE Act kidney and liver transplants.

Lastly, HHS believes that a delayed effective date is unnecessary to afford affected parties a reasonable time to adjust practices in accordance with this rule. From the economic analysis of impacts, provided below in section IX, this final rule will have a minimal direct impact on affected entities with regard to preparing for implementation. The direct effect of this final rule on transplant centers is considered to be limited to the time spent by transplant centers to read and understand the final rule, educate their staff on the content of this final rule, and review and update

[31] Centers for Disease Control and Prevention. Let's Stop HIV Together: Stigma Language Guide. *https://www.cdc.gov/stophivtogether/hiv-stigma/ways-to-stop.html.* Accessed 2/23/2024.

[32] Organ Procurement and Transplantation Network. Dashboard and metrics. *https://insights.unos.org/OPTN-metrics/.* Accessed Feb 2024.

[33] Organ Procurement and Transplantation Network (OPTN)/Scientific Registry of Transplant Recipients (SRTR). 2022. ''Annual Data Report.'' Accessed November 2024. *https://srtr.transplant.hrsa.gov/ADR/Chapter?name=Liver&year=2022.*

[34] Organ Procurement and Transplantation Network. Dashboard and metrics. *https://optn.transplant.hrsa.gov/data/dashboards-metrics/.* Accessed November 2024.

[35] Organ Procurement and Transplantation Network (OPTN)/Scientific Registry of Transplant Recipients (SRTR). 2021. ''Annual Data Report.'' Accessed February 2024. *https://srtr.transplant.hrsa.gov/annual_reports/2021_ADR_Preview.aspx.*

[36] Motter JD, et al; HOPE in Action Investigators. Wait Time Advantage for Transplant Candidates With HIV Who Accept Kidneys From Donors With HIV Under the HOPE Act. Transplantation. 2024 Mar 1;108(3):759–767.

internal policies. This rule does not impose obligations on transplant centers, and rather increases available flexibilities in that transplant centers are no longer required to conduct HOPE Act kidney and liver transplants in the research context. Further, as described above in section V(B), the final implementation step for HOPE Act kidney and liver transplants to begin occurring outside of the research context is for the OPTN to revise its policies to reflect that HOPE Act kidney and liver transplants no longer are subject to research and IRB requirements. HHS is encouraging the OPTN to act expeditiously to revise these policies, and it is likely that transplant centers will educate their staff and review and update internal policies relevant to the content of this final rule after the OPTN has published its revised policies for HOPE Act kidney and liver transplants. Transplant centers do not have any obligations stemming from this rule until the OPTN revises its policies. In light of this context, a delayed effective date for this rule is unnecessary for implementation purposes.

Given that, and the expected positive effects on time candidates spend on the waiting list and the increase in access to HOPE Act transplants resulting from this rule, pursuant to 5 U.S.C. 553(d)(3) and 5 U.S.C. 808(2) HHS finds that there is good cause for this rule to be effective upon publication.

VIII. Paperwork Reduction Act of 1995

This rule does not impose any additional information collection burden under the Paperwork Reduction Act and does not contain any information collection requirements beyond those already imposed by current regulations, which have been approved by the Office of Management and Budget (OMB). The current data collection requirements in the OPTN final rule approved by OMB under the Paperwork Reduction Act of 1995 are assigned control numbers OMB No. 0915–0157 (for organ donors, candidates, and recipients) and OMB No. 0915–0184 (for OPTN membership application data).

IX. Final Economic Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, Executive Order 14094, the Regulatory Flexibility Act (5 U.S.C. 601–612), the Congressional Review Act (5 U.S.C. 801, Pub. L. 104–121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866, 13563, and 14094 direct us to assess all benefits, costs, and transfers of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Rules are ''significant'' under Executive Order 12866, section 3(f)(1) (as amended by Executive Order 14094), if they have an annual effect on the economy of $200 million or more (adjusted every 3 years by the Administrator of the Office of Information and Regulatory Affairs (OIRA) for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities. The regulatory impact analysis indicates, and OIRA has determined, that the final rule is a significant regulatory action under Executive Order 12866, section 3(f)(1), and that it meets the criteria set forth in 5 U.S.C. 804(2) under the Congressional Review Act.

The Regulatory Flexibility Act (RFA) requires agencies to consider the impact of their regulatory proposals on small entities. Because the impacts on kidney and liver transplants are small relative to the number of transplants performed annually, and because the economic impacts on affected small entities are small relative to the average payroll of firms in the smallest enterprise size category, HHS certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (UMRA) generally requires that each agency conduct a cost-benefit analysis; identify and consider a reasonable number of regulatory alternatives; and select the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the final rule before promulgating any proposed or final rule that includes a Federal mandate that may result in expenditures of more than $100 million (adjusted for inflation) in at least one year by State, local, and tribal governments, in the aggregate, or by the private sector. Each agency issuing a final rule with relevant effects over that threshold must also seek input from State, local, and tribal governments. The current threshold after adjustment for inflation using the Implicit Price Deflator for the Gross Domestic Product is $183 million, reported in 2023 dollars. The final rule will not result in an unfunded mandate in any year that meets or exceeds this amount.

The final rule removes the current research and IRB requirements for the transplantation of kidneys and livers from donors with HIV. We have assessed the likely impacts of the final rule, and report in the regulatory impact analysis (RIA) several sources of monetized, quantified, and unquantified benefits, costs, or transfers. Most of the monetized or quantified impacts relate to the incremental increases in the number of kidney and liver transplants that will be performed annually as a result of the final rule.

We report monetized benefits from increases in life expectancy for both kidney and liver transplant recipients; and for kidney transplant recipients, we also report monetized benefits from quality-of-life improvements and time savings from fewer kidney dialysis visits. We also anticipate quality-of-life improvements for liver transplant recipients, and quantify the number of people affected who might experience those benefits. We also identify several sources of unquantified benefits, which could potentially be quantified through additional research or data, including time savings for caregivers, and cost savings for transplant centers from removing the research and institutional review board requirements. We also identify difficult-to-quantify benefits associated with revising vocabulary and phrases that some people find stigmatizing through adoption of language that is intended be respectful of people living with HIV, and living and deceased donors with HIV. These changes may result in people living with HIV experiencing more inclusive interactions when accessing healthcare, generating additional benefits beyond the increases in life expectancy and improvements in quality of life from improved access to liver and kidney transplantation.

We report monetized costs from increases in medical expenditures associated with organ transplantation; for kidney transplants, we report net costs that account for reductions in medical expenditures associated with kidney dialysis. We report this shift in expenditures from kidney dialysis to kidney transplantation as a monetized transfer. We also monetize the opportunity costs of the time spent by transplant centers reading and understanding the final rule, reviewing policies and procedures, and training staff.

Table 1 summarizes our estimates of the benefits, costs, and transfers of the final rule, annualizing impacts over a 10-year analytic time horizon covering 2025 through 2034 using a 2 percent real discount rate, and reporting all

monetary estimates in constant 2023 dollars. Annualized benefits range from $381 million to $858 million, with a primary estimate of $612 million; costs range from $73 million to $92 million, with a primary estimate of $83 million; and transfers range from $24 million to $37 million, with a primary estimate of $30 million. Table 1 also reports our estimates of the annualized net benefits of the final rule, which range from $301 million to $772 million, with a primary estimate of $530 million. The RIA concludes that the monetized net benefits, combined with the quantified, but non-monetized, and unquantified impacts, indicate that the final rule is highly likely to generate net benefits to society. This finding is further supported through additional quantitative assessments of uncertainty and sensitivity analyses contained in the RIA. The full RIA is available in the docket for this final rule at *https://www.regulations.gov/docket/HRSA-2024-0001/document.*

TABLE 1—SUMMARY OF IMPACTS OF THE FINAL RULE

[Millions of constant 2023 dollars]

Category	Primary estimate	Low estimate	High estimate	Dollar year or unit	Discount rate (%)	Time horizon	Notes
BENEFITS							
Annualized monetized benefits.	$612	$381	$858	2023	2	2025–2034	Increased life expectancy for organ transplant recipients; improved quality of life for kidney transplant recipients; time savings from fewer kidney dialysis visits.
Annualized quantified, but non-monetized, benefits.	72	64	81	People affected	2	2025–2034	Improved quality of life for liver transplant recipients.
Unquantified benefits						2025–2034	Time savings for caregivers; cost savings for transplant centers from removing the research and institutional review board requirements; difficult-to-quantify benefits associated with stigma-reducing terminology.
COSTS							
Annualized monetized costs.	83	73	92	2023	2	2025–2034	Medical expenditures associated with transplantation; time spent by transplant centers to read and understand the final rule, review policies and procedures, and train staff.
TRANSFERS							
Annualized monetized transfers.	30	24	37	2023	2	2025–2034	Shift in expenditures from kidney dialysis to kidney transplantation.
NET BENEFITS							
Annualized monetized net benefits.	530	301	772	2023	2	2025–2034	

Note: primary, low, and high estimates correspond to the mean, 5th percentile, and 95th percentile of the outcomes of a Monte Carlo simulation.

List of Subjects in 42 CFR Part 121

Health care, Hospitals, Organ transplantation, Reporting and recordkeeping requirements, Transplant centers.

Accordingly, by the authority vested in me as the Secretary of Health and Human Services, and for the reasons set forth in the preamble, 42 CFR part 121 is amended as follows:

PART 121—ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

■ 1. The authority citation for part 121 continues to read as follows:

Authority: Sections 215, 371–377, and 377E of the PHS Act (42 U.S.C. 216, 273–274d, 274f–5); sections 1102, 1106, 1138 and 1871 of the Social Security Act (42 U.S.C. 1302, 1306, 1320b–8, and 1395hh); section 301 of the National Organ Transplant Act, as amended (42 U.S.C. 274e); and E.O. 13879, 84 FR 33817.

■ 2. In § 121.6, revise paragraph (b) to read as follows:

§ 121.6 Organ procurement.

* * * * *

(b) *HIV.* (1) Organs from donors with human immunodeficiency virus (HIV) may be transplanted only into individuals who—

(i) Are living with HIV before receiving such organ(s); and

(ii)(A) Are participating in clinical research approved by an institutional review board, as defined in 45 CFR part 46, under the research criteria published by the Secretary under subsection (a) of section 377E of the Public Health Service Act, as amended; or

(B) The Secretary has published, through appropriate procedures, a determination under section 377E(c) of the Public Health Service Act, as amended, that participation in such clinical research, as a requirement for transplantation of organs from donors with HIV, is no longer warranted. The Secretary has determined that participation in such clinical research is no longer warranted for the following categories of transplants:

(*1*) Transplant of a kidney from a donor with HIV; and

(*2*) Transplant of a liver from a donor with HIV.

(2) Except as provided in paragraph (b)(3) of this section, the OPTN shall adopt and use standards of quality with respect to organs from donors with HIV to the extent the Secretary determines necessary to allow the conduct of research in accordance with the criteria described in paragraph (b)(1)(ii)(A) of this section.

(3) If the Secretary has determined under paragraph (b)(1)(ii)(B) of this section that participation in clinical research is no longer warranted as a requirement for transplantation of organs from donors with HIV, the OPTN shall adopt and use standards of quality with respect to organs from donors with HIV as directed by the Secretary, consistent with 42 U.S.C. 274, and in a way that ensures the changes will not reduce the safety of organ transplantation.

* * * * *

Dated: November 19, 2024.

Xavier Becerra,

Secretary.

[FR Doc. 2024–27410 Filed 11–26–24; 8:45 am]

BILLING CODE 4150–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

45 CFR Part 412

RIN 0970–AD10

Investigations of Child Abuse and Neglect Rule

AGENCY: Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS).

ACTION: Interim final rule with comment period (IFR).

SUMMARY: This IFR describes how ORR shall investigate and substantiate allegations of child abuse and neglect occurring in certain ORR care provider facilities, and maintain a registry of perpetrators relating to certain sustained allegations.

DATES: This IFR is effective December 27, 2024. Comments on this IFR must be received on or before January 27, 2025.

ADDRESSES: You may send comments, identified by [docket number and/or Regulatory Information Number (RIN)], by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: UCPolicy-RegulatoryAffairs@acf.hhs.gov.* Include [docket number and/or RIN] in the subject line of the message.

Instructions: All submissions received must include the agency name and docket number or RIN for this rulemaking. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Toby Biswas, Director of Policy, Division of Unaccompanied Children Policy, Unaccompanied Children Bureau, Office of Refugee Resettlement, Administration for Children and Families, Department of Health and Human Services, Washington, DC, (202) 205–4440 or *UCPolicy-RegulatoryAffairs@acf.hhs.gov.*

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I. Public Participation

ORR encourages all interested parties to participate in this rulemaking by submitting written comments, views, and data on any or all aspects of this interim final rule. ORR also invites comments that relate to the economic, environmental, or federalism effects that might result from this interim final rule. ORR will review all comments received, but ORR will only post comments that address the topic of the interim final rule. All comments ORR posts to *https://www.regulations.gov* will include any personal or commercial information you provide.

A. Submitting Comments

Comments that will provide the most assistance to ORR will reference a specific portion of the interim final rule, explain the reason for any recommended change, and include data, information, or authority that support such recommended change. If you submit comments, please indicate the specific section of this document to which each comment applies and provide a reason for each suggestion or recommendation. You may submit your comments and materials online or by email, but please use only one of these means. If you submit a comment online via *https://www.regulations.gov,* it will be considered received when it is received at the Docket Management Facility.

Instructions: To submit your comments online, go to *https://www.regulations.gov* and insert ''XXXX–XXXX–XXXX'' in the ''Search'' box. Click on the ''Comment Now!'' box and input your comment in the text box provided. Click the ''Continue'' box, and if you are satisfied with your comment, follow the prompts to submit it.

For additional information, please read the ''Privacy and Security Notice'' that is available via the link in the footer of *https://www.regulations.gov.*

ORR will consider all comments and materials received during the comment period and may change this rule based on your comments.

B. Viewing Comments and Documents

Docket: To view posted comments, as well as documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov* and insert ''XXXX–XXXX–XXXX'' in the ''Search'' box. Click on the ''Open Docket Folder,'' and you can click on ''View Comment'' or ''View All'' under the ''Comments'' section of the page. Individuals without internet access can make alternate arrangements for viewing comments and documents related to this rulemaking by contacting ORR through the **FOR FURTHER INFORMATION CONTACT** section above. You may sign up for email alerts on the online docket to be notified when comments are posted, or a final rule is published.

C. Privacy Act

As stated in the Submitting Comments section above, please be aware that anyone can search the electronic form of comments received into any dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.).

II. Table of Abbreviations

ACF—Administration for Children and Families
ALJ—Administrative Law Judge
CAPTA—Child Abuse Prevention and Treatment Act
CWT—ORR's Child Welfare Team
DAB—HHS Departmental Appeals Board
DOJ—U.S. Department of Justice
EIF—Emergency or Influx Facility
FBI—Federal Bureau of Investigation
FSA—Flores Settlement Agreement
HHS—U.S. Department of Health and Human Services

HSA—Homeland Security Act of 2002
OIG—Office of the Inspector General
OMB—Office of Management and Budget
ORR—Office of Refugee Resettlement, U.S. Department of Health and Human Services
PCAN Team—ORR's Prevention of Child Abuse and Neglect Team
PSA IFR—Standards To Prevent, Detect, and Respond to Sexual Abuse and Sexual Harassment Involving Unaccompanied Children, Interim Final Rule
TVPRA—William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008
UC Bureau—Unaccompanied Children Bureau
VCAA—Victims of Child Abuse Act

III. Executive Summary

This interim final rule provides standards and processes for the Department of Health and Human Services (HHS), Administration for Children and Families (ACF), Office of Refugee Resettlement (ORR), to apply when it conducts investigations into allegations of child abuse and neglect that occur in certain care provider facilities funded by ORR to provide residential and other services for unaccompanied children; [1] describes a process for appeal and review of substantiated allegations; and establishes an ORR Central Registry to list individuals with certain findings of child abuse and neglect that have been substantiated and sustained after exhausting the appeal and review process. This rule describes how and in what circumstances ORR may conduct investigations, and impose certain consequences with respect to sustained allegations of child abuse and neglect by care provider facility staff, contractors or sub-grantees of the care provider facility, care provider facility volunteers, and other individuals with access to unaccompanied children in ORR care through contracts or grants with ORR. Specifically, the investigations and required consequences described in this rule shall apply in two circumstances: (1) where the State or local authority that would otherwise be responsible for such investigations will not investigate allegations arising at ORR care provider facilities that care for or propose to care for unaccompanied children; and (2) at ORR emergency or influx facilities (EIFs).

Child abuse and neglect can have devastating lifelong mental and physical effects on an individual. ORR is committed to preventing and mitigating child abuse and neglect in its care provider facilities and seeks to ensure the safety, well-being, and security of all unaccompanied children in its care.

IV. Background and Purpose

A. Background and History

On March 1, 2003, section 462 of the Homeland Security Act of 2002 (HSA) transferred responsibilities for the care and placement of unaccompanied children from the Commissioner of the former Immigration and Naturalization Service to the Director of ORR. Since that time, ORR has provided for the day-to-day care of over 700,000 unaccompanied children in ORR care provider facilities that are currently administered through a nationwide network of providers (funded via cooperative agreements or contracts, or sub-awards thereof).[2]

As further detailed below in section IV.B., ORR oversees its care provider facilities through its Unaccompanied Children Bureau [3] pursuant to its responsibilities under the HSA,[4] the Trafficking Victims Protection Reauthorization Act of 2008 (TVPRA),[5] the Unaccompanied Children (UC) Program Foundational Rule,[6] the *Flores* Settlement Agreement (FSA) as relevant,[7] [8] and ORR's regulatory Standards To Prevent, Detect, and Respond to Sexual Abuse and Sexual Harassment Involving Unaccompanied Children interim final rule (PSA IFR).[9]

Consistent with the HSA and TVPRA, ORR is responsible for the care, custody, and placement of unaccompanied children who are in Federal custody by reason of their immigration status.[10] Any department or agency of the Federal government that has an unaccompanied child from a non-contiguous country in its custody is required to transfer custody of such child to HHS.[11] Typically, ORR places unaccompanied children in care provider facilities it funds to provide these children with residential and other services, until the children can be safely released to qualified and vetted sponsors (individuals or entities to whom ORR releases unaccompanied children out of ORR custody, in accordance with ORR's sponsor suitability assessment process and release procedures),[12] are repatriated to their home country, obtain legal status, or otherwise no longer meet the statutory definition of an unaccompanied child (*e.g.,* turn 18 years old). In accordance with the UC Program Foundational Rule (and consistent with the FSA), ORR makes reasonable efforts to place unaccompanied children in State-licensed facilities in those geographical areas where the majority of children are apprehended [13]—except in cases of emergency or influx, when ORR may utilize EIFs.[14] EIFs are Federally contracted facilities that ORR may need to stand up quickly to accommodate placements for children that exceed its standard capacity. Consistent with ORR's UC Program Foundational Rule (and the FSA), EIFs are not required to be State-licensed.[15]

As of the publication date of this rulemaking, ORR has built a network of nearly 300 care provider facilities in 27 States, funded through cooperative agreements and grants between ORR and the care provider facilities. As discussed below, a significant number of ORR care provider facilities are in Texas, which has decided to no longer conduct investigations of reported abuse and neglect arising at ORR-funded care provider facilities housing unaccompanied children.

In addition, as of the publication date of this rulemaking, ORR oversees three influx care facilities, funded through contracts, that currently have no children in care but are ready to commence or resume operations within certain timeframes if needed.[16] ORR does not currently have formal written agreements with the relevant State or local authorities to investigate reports of

[1] An unaccompanied child is defined as a child who has no lawful immigration status in the United States; has not attained 18 years of age; and with respect to whom there is no parent or legal guardian in the United States, or no parent or legal guardian in the United States available to provide care and physical custody. *See* 6 U.S.C. 279(g)(2).

[2] Unaccompanied Children Bureau Fact Sheet. (July 5, 2024). Retrieved from: *https://www.acf.hhs.gov/orr/fact-sheet/programs/uc/fact-sheet.*

[3] *See* Statement of Organization, Functions, and Delegations of Authority, 89 FR 49889 (Jun. 12, 2014) (redesignating the former ''Unaccompanied Children Program'' as the ''Unaccompanied Children Bureau'').

[4] 6 U.S.C. 279.

[5] 8 U.S.C. 1232.

[6] 45 CFR part 410.

[7] Stipulated Settlement Agreement, *Flores* v. *Reno,* No. CV 85–4544–RJK(Px) (C.D. Cal. Jul. 17, 1997).

[8] As of the publication of this rule, the *Flores* Settlement Agreement (FSA) has been partially and conditionally terminated as to ORR, as a result of the publication of the UC Program Foundational Rule. *See* Order Re Defendants' Motion to Terminate the *Flores* Settlement Agreement as to Defendant HHS, *Flores* v. *Garland,* No. 2:85–cv–04544 (C.D. Cal. Jun. 28, 2024), ECF No. 1447.

[9] 45 CFR part 411.

[10] *See* 6 U.S.C. 279(b)(1)(A); 8 U.S.C. 1232(b)(1).

[11] *See* 8 U.S.C. 1232(b)(3).

[12] *See* 45 CFR 410.1001.

[13] 45 CFR 410.1103(e); *see also* FSA par. 6.

[14] *See* 45 CFR part 410, subpart I; *see also* FSA Exhibit 3.

[15] *See* 45 CFR 410.1001.

[16] ORR Influx Care Facilities for Unaccompanied Children Fact Sheet. (July 29, 2024). Retrieved from: *https://www.acf.hhs.gov/orr/fact-sheet/programs/uc/influx-care-facilities-fact-sheet.*

child abuse and neglect at these facilities. If such agreements are executed, ORR may in its discretion elect not to exercise its investigative authority and instead rely on the relevant State or local authorities (consistent with its approach to sexual abuse as described at 45 CFR part 411).[17] Nevertheless, even in these circumstances, ORR retains statutory authority to conduct investigations at EIFs, and in these situations could do so consistent with this rule. If ORR were to conduct its own investigation concurrently with a State or local authority's investigation, ORR would cooperate with such authority and ORR's investigation would not conflict with such investigation. Further, ORR would conduct its investigation in such a manner as to minimize potential trauma to the alleged victim (*e.g.,* by not interviewing a child where the State or local authority has already interviewed the child for the same information).

To ensure that reports of child abuse and neglect at Texas care provider facilities and EIFs (as relevant) do not go uninvestigated, and pursuant to ORR's statutory responsibilities, on June 12, 2024, ORR established a Division of Unaccompanied Child Protection Investigations (DCPI) to, among other things, receive reports of alleged abuse or neglect involving unaccompanied children in ORR custody and investigate those claims where it has jurisdiction.[18] DCPI began conducting investigations of alleged child abuse and neglect in ORR-funded care provider facilities in Texas as of July 2024. This interim final rule describes the procedures DCPI uses when it performs child welfare investigations of alleged child abuse and neglect at ORR care provider facilities; and establishes employment consequences for care provider facility staff and volunteers based on ORR investigation dispositions, including relevant due process protections for alleged perpetrators of abuse and neglect.

B. Authority

ORR's statutory authority enables it to perform investigations of alleged child abuse and neglect occurring at its care provider facilities, and to establish disciplinary consequences, including employment consequences, for individuals it determines to have perpetrated abuse or neglect. The HSA transferred to the Director of ORR functions under the immigration laws of the United States with respect to the care of unaccompanied children that were vested by statute in, or performed by, the Commissioner of the Immigration and Naturalization Service. Pursuant to such transfer, the ORR Director is ''responsible for,'' among other things, ''ensuring that the interests of the child are considered in decisions and actions relating to the care and custody of an [unaccompanied child],'' [19] ''implementing policies with respect to the care and placement of [unaccompanied children],'' [20] and ''identifying a sufficient number of qualified individuals, entities, and facilities to house [unaccompanied children].'' [21] In addition, the HSA makes the ORR Director responsible for ''overseeing the infrastructure and personnel of facilities in which [unaccompanied children] reside,'' [22] and ''conducting investigations and inspections of facilities and other entities in which [unaccompanied children] reside, including regular follow-up visits to such facilities, placements, and other entities, to assess the continued suitability of such placements.'' [23]

Necessarily, a fundamental aspect of ensuring that there are qualified individuals, entities, and care provider facilities to care for and house unaccompanied children is ensuring that care provider facility staff, contractors, or sub-grantees of the care provider facility, along with care provider facility volunteers and other individuals who have access to children in ORR care through contracts or grants with ORR, do not engage in abuse or neglect of children in ORR care; that such individuals who are alleged to have engaged in such abuse or neglect are reported and identified; that allegations of child abuse or neglect against such individuals are properly and thoroughly investigated; and that if the allegations are found to be substantiated and are sustained pursuant to an appeal and review process, actions are taken to ensure that such individuals are prohibited from working or volunteering in any way on ORR-funded grants or contracts and do not have contact with children in ORR custody. Thus, the rule described here is a crucial aspect of implementing ORR's statutory mandates under the HSA, which expressly delegates authority to the ORR Director to administer the UC Bureau.

Pursuant to these authorities, this rule describes the circumstances in which ORR will investigate allegations of child abuse and neglect; the procedures for such investigations; and steps ORR may take in response to findings that individuals who work or volunteer at ORR-funded care provider facilities have perpetrated abuse or neglect against children in its custody, including due process requirements that would apply to such steps.

In addition to the HSA, ORR's Interim Final Rule regarding the Prevention of Sexual Abuse [24] (PSA IFR), which ORR promulgated in 2014 pursuant to the Violence Against Women Reauthorization Act of 2013 (VAWA),[25] describes requirements concerning sexual abuse of unaccompanied children in ORR custody. Though the PSA IFR specifically applies to the prevention of *sexual* abuse of unaccompanied children, it describes requirements that inform this IFR regarding the prevention of abuse and neglect, including requirements for staff background checks; suspension of staff, contractors, and volunteers suspected of perpetrating sexual abuse or sexual harassment from all duties that would involve or allow access to unaccompanied children pending the outcome of an investigation; and requirements for restricting the employment of care provider facility staff against whom allegations of child abuse or neglect have been substantiated.[26]

The standards in the PSA IFR also require care provider facilities to refer allegations of sexual abuse and sexual harassment to proper investigating authorities (*i.e.,* State and local law enforcement, child protective services, and licensing authorities), and to remain informed of ongoing investigations and fully cooperate with outside investigators as necessary.[27] ORR notes that nothing in this rule is intended to replace or prohibit investigations of sexual abuse and sexual harassment under other civil rights laws. The PSA IFR also states that ORR will refer allegations to the Department of Justice

[17] *See infra* Section IV.B.

[18] *See* 89 FR 49889, 49892.

[19] 6 U.S.C. 279(b)(1)(B).

[20] 6 U.S.C. 279(b)(1)(E).

[21] 6 U.S.C. 279(b)(1)(F).

[22] 6 U.S.C. 279(b)(1)(G).

[23] 6 U.S.C. 279(b)(1)(L).

[24] *Standards To Prevent, Detect, and Respond to Sexual Abuse and Sexual Harassment Involving Unaccompanied Children,* 79 FR 77768 (Dec. 24, 2014) (codified at 45 CFR part 411).

[25] *See* Public Law 113–4, 1101(d), 127 Stat. 134, 135 (2013) (codified at 34 U.S.C. 30307(d)) (directing the Secretary of HHS to ''publish a final rule adopting national standards for the detection, prevention, reduction, and punishment of rape and sexual assault in facilities that maintain custody of unaccompanied alien children (as defined in section 279(g) of Title 6)'').

[26] *See generally* Standards to Prevent, Detect, and Respond to Sexual Assault and Sexual Harassment Involving Unaccompanied Children, codified at 45 CFR part 411 (PSA IFR); *see also* the ORR Policy Guide at Section 4.3.

[27] *See* 45 CFR 411.22(a); 411.71(c), (d).

or other investigating authority for further investigation where such reporting is in accordance with its policies and procedures and any memoranda of understanding.[28]

At the time the PSA IFR was published, ORR assumed that all States or localities would maintain their historic practices of investigating alleged child abuse and neglect in ORR State-licensed care provider facilities. Accordingly, the PSA IFR only contemplates scenarios where a State or local authority is the investigating authority for allegations of sexual abuse and harassment occurring at ORR care provider facilities. This rule describes a new system of ORR investigations and actions to be taken based on investigation findings, which ORR would apply, as needed, at care provider facilities as described at § 412.100(c).

Finally, the Victims of Child Abuse Act (VCAA) and its implementing regulations [29] impose reporting requirements on ORR-contracted facilities (*e.g.,* EIFs). Under the VCAA, child abuse (as defined in the Act) occurring at Federally-operated or contracted facilities must be reported to local law enforcement or child protective services agencies with jurisdiction to investigate reports of child abuse or to protect child abuse victims in the land area or facility in question, ''provided that such agencies, if non-federal, enter into formal written agreements to do so. . . .'' [30] If there is no such formal written agreement, the Federal Bureau of Investigation (FBI) is the agency designated to receive such reports.[31] However, ORR is advised that the FBI's jurisdiction is limited to Federal crimes (*i.e.,* the FBI cannot investigate conduct that does not rise to the level of a Federal crime)—and many child abuse and neglect allegations that nonetheless warrant investigation do not constitute Federal crimes. Upon receipt of such reports of child abuse, agencies designated under the VCAA—which can include other federal agencies or non-federal agencies that are designated pursuant to a formal written agreement—may conduct investigations of the alleged abuse and neglect. This IFR does not conflict with any agency duties under the VCAA. If ORR executes formal written agreements with relevant local authorities to investigate child abuse and neglect at EIFs, it reserves discretion under its statutory authorities to conduct its own investigations as well. In such cases, ORR intends under this rule that any ORR investigation will not conflict with investigations performed by other authorities in connection with the VCAA.

C. Basis and Scope of Regulatory Action

1. Discontinuation of Investigations of Child Abuse and Neglect at Care Provider Facilities That Care for Unaccompanied Children.

For years, ORR has relied on States or localities both to license its care provider facilities and to investigate any allegations of child abuse and neglect.[32] Since 2021, however, three States—Texas, Florida, and South Carolina—have ceased licensing childcare facilities that serve or propose to serve unaccompanied children under grant or contract with ORR. As of publication of this rule, Florida and South Carolina continue to provide for State-based investigations of alleged child abuse and neglect in ORR-funded care provider facilities.[33] In contrast, in connection with the State's decision to end licensing of care provider facilities housing unaccompanied children, the Texas State agency that would otherwise be responsible for such investigations no longer conducts them at ORR care provider facilities (except foster care providers).

Pursuant to a proclamation by Texas's Governor Abbott,[34] on July 13, 2021, the Texas Health and Human Services Commission (HHSC) issued an emergency rule temporarily exempting Texas's childcare facilities that shelter unaccompanied children in Federal custody from Texas's licensing requirement.[35] The exemption went through a series of renewals until, on July 22, 2022, Texas amended the emergency rule to make the licensure exemption ongoing.[36]

ORR understands that, pursuant to this change in Texas law, neither Texas HHSC nor the Texas Department of Family and Protective Services (DFPS) currently conducts child abuse and neglect investigations in facilities that house unaccompanied children due to their lack of jurisdiction over license-exempt childcare facilities. Because DFPS is not investigating, substantiating, or sustaining these allegations pursuant to administrative reviews as appropriate, DFPS does not list potential sustained perpetrators in the Texas child abuse and neglect registry,[37] and thus such perpetrators will not be identified as having committed abuse or neglect in a background check by an ORR-funded or other provider. State and local law enforcement continue to investigate reported child abuse and neglect that rises to the level of a crime, but in many instances, actions involving abuse or neglect constitute civil violations, but not criminal violations. Depending on circumstances, this may include physical abuse, verbal/emotional abuse, and sexual harassment.

As discussed above, ORR has historically relied on State and local authorities to investigate allegations of child abuse and neglect arising at its care provider facilities. However, a significant gap in investigative capacity has resulted from Texas's decision to cease DFPS investigations at ORR care provider facilities. ORR was unable to immediately fill this gap by conducting its own investigations because such investigations necessitate the use of skilled and trained investigators, and historically ORR had not played this role.

However, ORR took immediate and ongoing steps after determining that Texas planned to cease its investigations into alleged child abuse and neglect at ORR-funded care provider facilities housing unaccompanied children. Soon after it became clear that Texas DFPS was not going to resume its long-standing child welfare and investigative functions when it extended its emergency declaration in 2022, ORR began examining the operational feasibility, capacity, and expertise that would be required to permanently absorb the investigative responsibilities once performed by Texas DFPS. Such an endeavor represented an unexpected

[28] *See* 45 CFR 411.22(d).

[29] *See* 34 U.S.C. 20341; *see also* 28 CFR part 81.

[30] 28 CFR 81.2

[31] 28 CFR 81.3.

[32] *See, e.g.,* 79 FR 77768, 77776 (''. . . ORR does not conduct investigations regarding the substance of an allegation. Instead, as stated in the previous paragraphs, ORR requires that all care provider facilities refer all allegations, regardless of how an allegation is made or who it comes from, to the proper investigating authorities.'').

[33] ORR notes that Florida continues to investigate child abuse and neglect in care provider facilities housing unaccompanied children, and ORR only operates foster family home care settings in South Carolina. Foster care licensing has not been impacted by South Carolina's action to not license residential care.

[34] Proclamation by the Governor of the State of Texas. (May 31, 2021). Available at: *https://gov.texas.gov/uploads/files/press/DISASTER_border_security_IMAGE_05-31-2021.pdf.*

[35] 46 Tex. Reg. 4407. (July 23, 2021). (Adopting on an emergency basis in Texas Administrative Code title 26 part 1, chapter 745, Licensing, new § 745.10301 and amended § 745.115). The emergency rule—and the exemption it provides—were only effective for 120 days and could only be renewed for an additional 60 days. Available at: *https://texashistory.unt.edu/ark:/67531/metapth1362781/m2/1/high_res_d/0723is.pdf.*

[36] Texas HHS Agenda Item. (May 19, 2022). Available at: *https://www.hhs.texas.gov/sites/default/files/documents/may-2022-ec-agenda-item-2bvi.docx.*

[37] Tex. Fam. Code § 261.002.

and significant expansion of ORR's operations, as ORR had successfully relied on relevant state child welfare entities to fulfill that role for years up to this point. ORR's work over the past two years has included, but not been strictly limited to: communicating with Texas state officials to confirm their position regarding investigations into alleged child abuse and neglect at ORR care providers and attempt to reach a resolution with the state directly; consulting with other federal agencies to evaluate available options to address the lack of investigations and seek feedback on ORR's proposed approach; researching and planning how ORR would develop the necessary expertise and capacity to conduct investigations; developing policies and procedures to inform how investigations are conducted; obtaining administrative approval for new agency positions; creating of new comprehensive technical systems for recording and tracking investigations; and, eventually, the hiring, onboarding, and training of qualified investigative staff.

In addition, while engaged in these efforts, ORR directed its care provider facilities in Texas to continue reporting abuse and neglect allegations to State child welfare agencies, State licensing agencies, State and local law enforcement, and where appropriate, the HHS Office of the Inspector General and the FBI. ORR also established a framework, utilizing its child welfare team or CWT (later becoming known as the ORR Prevention of Child Abuse and Neglect or PCAN Team) for conducting in-depth reviews of care provider facility responses to each individual allegation of abuse and neglect. In these reviews, ORR staff receive and review documentation concerning the allegation, assess whether proper interventions and reporting requirements under ORR policies and procedures were followed, and make recommendations for appropriate follow-up actions regarding the alleged victim's medical and mental health needs.

While ORR's in-depth reviews have played an important role in filling some of the investigations-related gaps like ensuring compliance with reporting requirements and following up on appropriate interventions for staff and children, there remained a need for a separate entity other than the care provider facilities themselves—that would ensure independent oversight and response—to investigate allegations of abuse and neglect that do not constitute criminal violations. Accordingly, pursuant to its statutory responsibilities to oversee the personnel and infrastructure of care provider facilities and to conduct investigations (see discussion under section IV.B. Authority), ORR established the Division of Unaccompanied Child Protection Investigations (DCPI) in June 2024.[38] DCPI began conducting investigations of alleged child abuse and neglect at care provider facilities in Texas in July 2024.

However, investigations without more do not fully fill the gap left by Texas DFPS's decision not to investigate allegations of child abuse and neglect, including by substantiating and sustaining such allegations so that perpetrators may be identified and precluded from working with unaccompanied children in ORR's care. The statutory provisions authorizing ORR to establish its investigative division do not specify the particular procedures ORR should follow in conducting investigations and taking action to protect children from individuals with pending or sustained allegations of sexual abuse or neglect. Thus, ORR has determined that in order to fully address the protection of children in its custody, consistent with its statutory responsibility, it is important to establish a mechanism to ensure that individuals with sustained Tier I allegations (as defined in this rule) investigated by DCPI are terminated from employment in ORR-funded programs, prevented from having contact with children in ORR programs, and barred from employment in any ORR-funded program in the future. To accomplish this goal with appropriate due process protections, ORR has adopted this rule.

2. Need for ORR To Investigate Child Abuse and Neglect at Emergency or Influx Facilities

In addition, this rulemaking provides needed clarity with respect to investigations of child abuse and neglect at EIFs. Responsibility for investigating allegations of child abuse and neglect at EIFs is unique to each EIF based on a number of factors, including the willingness of States or local authorities to investigate child abuse and neglect at care provider facilities housing unaccompanied children or enter into a formal written agreement with ORR to do so; the unique size, capacity, and scope of EIFs; and the urgent timelines under which EIFs may be activated. Because EIFs are activated in times of influx, which arise based on unpredictable migration patterns, there may not be sufficient time to establish formal written agreements with local authorities to conduct child abuse and neglect investigations when ORR activates such facilities. For example, referrals of unaccompanied children to ORR increased dramatically from Federal fiscal year (FFY) 2020 (15,381 children) to FFY 2021 (122,731 children), continued to increase in FFY 2022 (128,904 children), but then decreased in FFY 2023 (118,938 children).[39] ORR believes, as a result, that it is appropriate to include EIFs within the scope of this rule—to ensure that reports of child abuse and neglect arising at EIFs are consistently investigated and that ORR may take actions to protect unaccompanied children from those with pending or sustained allegations.[40]

ORR prefers that State and local authorities exercise their long-standing authority under State and local laws and regulations to investigate allegations of child abuse and neglect and will continue to seek to establish agreements with States and local authorities to investigate child abuse and neglect at EIFs. However, as noted above, as of the date of publication, ORR does not currently have written agreements with State or local authorities to conduct child welfare investigations at EIFs, and as noted above, FBI investigations are limited to allegations that potentially rise to the level of Federal crimes. Further, with DCPI investigations of alleged child abuse and neglect underway, there is also a need to maintain an ORR central registry to document substantiated abuse and neglect findings based on its own investigations. As in States that do not to provide an investigative infrastructure for ORR-funded facilities housing unaccompanied children, both investigations and the maintenance of a central registry are required at EIFs—particularly where no State or local investigative infrastructure is available (*e.g.,* pursuant to a formal written agreement with ORR).

ORR notes that any ORR investigations into allegations of child abuse and neglect at EIFs under this rule would be separate from any other investigations that may occur by other authorities, whether pursuant to the VCAA or otherwise, and will not conflict with investigations by those other authorities.

[38] *See* Statement of Organization, Functions, and Delegations of Authority, 89 FR 49889 (June 24, 2024).

[39] ORR Unaccompanied Children Facts and Data. (July 5, 2024). Retrieved from: *https://www.acf.hhs.gov/orr/about/ucs/facts-and-data.*

[40] *See also infra* Section VI (discussing good cause for issuing this IFR).

3. Scope of Rulemaking

This IFR describes the circumstances in which ORR will investigate and substantiate child abuse and neglect allegations. It also delineates further steps ORR may take upon conducting such investigations to protect unaccompanied children, such as ensuring that certain individuals against whom allegations of child abuse and neglect have been substantiated and upheld after an appeal and review process are prevented from working or volunteering in any way on ORR-funded grants or contracts, and that alleged perpetrators with pending allegations do not have continued access to children. As discussed below at section VI, considering ORR's recent establishment of the DCPI, there is good cause to issue an IFR both to describe the nature and scope of ORR investigations, and critically, to establish required consequences for certain investigative findings, with appropriate due process protections.

This IFR:

- Describes the responsibilities of ORR to conduct investigations into allegations of child abuse and neglect of unaccompanied children at (1) care provider facilities located in States where the State agency responsible for investigating child abuse and neglect allegations will not investigate such allegations in ORR-funded care provider facilities, and at (2) EIFs;
- Defines the applicable burden of proof as a preponderance of the evidence and describes the investigation disposition types as substantiated-Tier I; substantiated-Tier II; not substantiated; unfounded; or administratively closed;
- Describes notification requirements of the findings of investigations;
- Describes an appeal and review process for individuals with substantiated allegations of child abuse and neglect at ORR care provider facilities in States that will not investigate allegations of abuse or neglect in facilities housing unaccompanied children and at emergency or influx facilities;
- Creates an ORR Central Registry, and associated processes and sanctions, for individuals with sustained Tier I allegations of child abuse and neglect at EIFs and at ORR care provider facilities in States that will not investigate allegations of abuse or neglect in facilities housing unaccompanied children; and
- Describes requirements for care provider facilities to cooperate with investigations.

D. Severability

The different parts of this interim final rule address distinct aspects of investigations of child abuse and neglect. These include: the investigation of allegations of child abuse and neglect occurring at care provider facilities that do not conduct their own investigations, and investigations at EIFs (§ 412.100); interventions and discipline, including an ORR Central Registry of perpetrators relating to certain sustained allegations (§ 412.101); the appeal and review process (§ 412.102); and obligations of care provider facilities (§ 412.103) in cooperating with investigations. To the extent any section or subsection of the rule is declared invalid by a court, ORR intends for all remaining sections and subsections to remain in effect, as they would continue to function sensibly. As an illustration, ORR expects that if a court were to invalidate § 412.100(c)(2), which makes the requirements of § 412.100 relating to investigations into allegations of child abuse and neglect applicable to EIFs, the standards, requirements, and procedures under § 412.100 would continue to be applicable to care provider facilities housing unaccompanied children in States where the State agency responsible for investigating child abuse and neglect allegations will not investigate such allegations in ORR-funded care provider facilities, as provided in § 412.100(c)(1). Likewise, ORR expects that if a court were to declare that the ORR Central Registry as defined at § 412.001 and described at § 412.101(a) is invalid, the requirements of § 412.100 relating to investigations into allegations of child abuse and neglect at certain facilities, and the obligations of care facilities delineated at § 412.103 will remain in effect.

V. Discussion of Elements of the Interim Final Rule

Section 412.001 Definitions

ORR, in § 412.001, is codifying the definitions of terms that apply to this part. Many terms used in this rule are defined in other authorities, including statutes and ORR regulations, and this rule uses these terms consistently with those definitions. For example, this rule uses the term ''unaccompanied child'' consistently with the definition provided in the UC Program Foundational Rule, at 45 CFR 410.1001 (which is further consistent with the definition of ''unaccompanied alien child'' found in the Homeland Security Act (HSA), at 6 U.S.C. 279(g)(2)). Below, ORR further explains its rationale for certain definitions applied in this rule.

The definition of ''administrative closure'' describes when ORR determines it will not make a finding regarding an allegation of child abuse or neglect. Administrative closure does not imply that ORR would have found an allegation of abuse or neglect to be substantiated or not substantiated. ORR may assign an intake report for administrative closure if ORR determines it is not appropriate for investigation. Reasons for administrative closure before an investigation may include, but are not limited to, lack of jurisdiction to conduct an investigation of the allegation (*e.g.,* if the alleged abuse or neglect occurred in a State where the State agency responsible for investigating child abuse and neglect continues to investigate such reports of unaccompanied children in ORR care); transfer of the report to another jurisdiction or agency; an allegation not rising to the level of child abuse or neglect; duplication of an existing report; or an allegation is otherwise outside the scope of this rule, as described at § 412.100(c). ORR may also make a disposition of administrative closure after investigation. Reasons for administrative closure after an investigation may include, but are not limited to, inability to contact the child; insufficient information to proceed with the investigation; or transfer to another jurisdiction or agency. If ORR administratively closes an intake report or investigation, it may consider further investigation related to the initial allegation if new information becomes available.

The definition of ''alleged perpetrator'' means a person who is alleged to have abused or neglected a child within the scope of this part as described at § 412.100(a) and (c). The term encompasses individuals who are identified in an intake report, and subject to an investigation under this part, but does not include individuals who have been subject to an investigation which resulted in a not substantiated allegation, unfounded allegation, or administrative closure. Per the definition of child abuse and neglect set out at § 412.001, alleged perpetrators can include individuals who observed, permitted, or otherwise allowed a child to be mistreated and knowingly failed to act to protect the child. Alleged perpetrators do not become sustained perpetrators until all appropriate investigative steps have been completed and they have exhausted all administrative remedies, including waiving their right to appeal, as

applicable and as specified in § 412.102(c).

The definition of ''child abuse and neglect'' in this IFR is based on ORR's review of Federal laws, consultation with the Administration on Children, Youth, and Families, including the Children's Bureau, and on its experience operating the UC Bureau. For example, ORR intends that this definition capture the types of behaviors identified at 22 U.S.C. 7102, 34 U.S.C. 20341, and 42 U.S.C. 5106g, Note § 3, to the extent they describe behaviors and situations that are relevant to unaccompanied children for purposes of this rule. At the same time, the definition of ''child abuse and neglect'' and related definitions (*e.g.,* medical neglect, verbal or emotional abuse) in this rule provide additional granularity relevant to the UC Bureau. The definitions of sexual abuse and sexual harassment used in this rule are the same as the PSA IFR at 45 CFR 411.6. ORR developed other related definitions to appropriately capture incidents and circumstances that raise child welfare concerns, and also reflect how abuse or neglect has historically been identified within the UC Bureau (*e.g.,* based on historical significant incident reporting to ORR, input from subject matter experts in child welfare including ORR's CWT, Prevention of Sexual Abuse Team, Division of Health for Unaccompanied Children, Federal field specialists, and Data Analytics and Information Management team). For example, this IFR provides separate definitions distinguishing neglect and medical neglect, and child abuse from child neglect, in contrast to 34 U.S.C. 20341, which groups these concepts together. Having separate definitions in this rule also enables ORR to have accurate data on specific kinds of abuse or neglect that may occur with respect to children in its care.

The definition of ''inappropriate sexual behavior'' refers to inappropriate sexual, derogatory, or offensive conduct that does not rise to the level of sexual abuse or sexual harassment. ORR intends that this term, which is also used in current ORR policies, capture conduct that falls outside of other relevant definitions, but still merits reporting and response.

The definition of ''medical neglect'' draws in part from ORR's review of other Federal authorities. For example, it is meant to include concerns described in the definition of ''negligent treatment'' from 34 U.S.C. 20341(c)(7), and the definition of ''neglect'' from 42 CFR 483.5. ORR found that these authorities described the types of issues from which it seeks to protect unaccompanied children in its custody, and, to that extent, these authorities informed the definition of ''medical neglect'' in this rule. ORR is providing a separate definition for medical neglect, distinct from other forms of neglect, based on its experience operating the UC Bureau, including knowledge of the forms of neglect historically reported within the context of the UC Bureau, and the importance of having sufficient granularity in data reporting and monitoring to appropriately capture and address the types of incidents and circumstances that raise child welfare concerns.

''Multidisciplinary team'' is defined as a group of individuals comprised of ORR staff, including subject matter experts. Multidisciplinary teams provide input to ORR's Child Welfare Investigators by assessing reported allegations of child abuse and neglect at care provider facilities and making recommendations regarding physical and behavioral healthcare needs of unaccompanied children potentially impacted by child abuse and neglect at these facilities. Notably, the multidisciplinary team may include, but is not limited to, child welfare experts, forensic interviewers, mental health practitioners, child development and disability practitioners, pediatricians and other medical experts as needed, policy advisors, Federal program analysts, Federal program management staff, or other subject matter experts. The multidisciplinary team will also focus on the physical and behavioral healthcare needs of unaccompanied children potentially impacted by, and during the course of, the investigation of child abuse or neglect. Importantly, this team is different from, and in addition to, the ORR Child Welfare Investigator. The ORR Child Welfare Investigator sits within the DCPI, which will have the option to consult with the separate multidisciplinary team as necessary and appropriate. ORR believes that this collaborative approach to the investigation will lead to a coordinated response, representing a variety of fields and disciplines to support unaccompanied children while also ensuring a more efficient and thorough investigation.

The definition of ''not substantiated allegation'' means a disposition that there is not a preponderance of the evidence establishing that the alleged perpetrator committed child abuse or neglect (as defined in this section), but there is at least some evidence that the unaccompanied child was harmed or placed at risk of harm, whether or not by the alleged perpetrator. This term does not include administratively closed allegations. ORR notes that this definition differs from its definition of ''unsubstantiated allegation'' under the PSA IFR at 45 CFR 411.5 (''an allegation that was investigated and the investigation produced insufficient evidence to make a final determination as to whether or not the event occurred''). This investigation disposition, as well as the other defined dispositions, are further described in § 412.100.

The definition of ''physical abuse'' in this IFR aligns with the types of behaviors identified at 34 U.S.C. 20341 and described at 42 U.S.C. 5106g, Note § 3, to the extent that those provisions describe behaviors and situations that are relevant to unaccompanied children for the purposes of this rule. Further, the definition of ''physical abuse'' provided in this rule includes specific non-exhaustive examples, based on ORR's experience operating the UC Bureau and the forms of physical abuse historically reported, as well as feedback from care provider facilities that definitions with greater specificity better support effective reporting and monitoring.

The definition of ''preponderance of the evidence'' describes the burden of proof used to substantiate allegations of child abuse and neglect. ORR notes that this definition is based on 42 CFR 93.219, and that this definition means something is more likely than not to be true.

The definition of ''sexual abuse,'' has the same meaning as that term is defined in 45 CFR 411.6.

The definition of ''sexual harassment,'' has the same meaning as that term is defined in 45 CFR 411.6. ORR notes that this definition indicates that prohibited conduct ''includes'' repeated actions; however, the definition is not intended to be exhaustive, and a single instance may constitute sexual harassment.

The definition of ''sub-grantee'' is based on the definition of the term ''subrecipient'' from 45 CFR 75.2. ORR is using the term sub-grantee instead of subrecipient for consistency with existing ORR policies and guidance.

The definition of ''substantiated allegation-Tier I'' means a disposition that there is a preponderance of the evidence establishing that the alleged perpetrator committed child abuse or neglect, and the investigation indicates one or more automatic Tier I substantiating circumstances have been found pursuant to § 412.100(e)(7) or substantiation at Tier I is warranted based on consideration of aggravating and mitigating factors pursuant to § 412.100(e)(8). ORR notes that this

definition differs from its definition of ''substantiated allegation'' under the PSA IFR at 45 CFR 411.5 (''an allegation that was investigated and determined to have occurred'') to incorporate that ORR, as the investigating entity, is using the preponderance of evidence standard to establish a disposition of ''substantiated'' and to incorporate the consideration of automatic Tier I substantiating circumstances, aggravating factors, and mitigating factors.

The definition of ''substantiated allegation-Tier II'' means a disposition that there is a preponderance of the evidence establishing that the alleged perpetrator committed child abuse or neglect, and that based on consideration of aggravating and mitigating factors pursuant to § 412.100(e)(8), the evidence does not warrant a finding of ''Substantiated Allegation-Tier I.'' ORR notes that this definition differs from its definition of ''substantiated allegation'' under the PSA IFR at 45 CFR 411.5 (''an allegation that was investigated and determined to have occurred'') to incorporate that ORR, as the investigating entity, is using the preponderance of the evidence standard to establish a disposition of ''substantiated'' and to incorporate the consideration of whether a disposition of substantiated allegation-Tier I is warranted, including in consideration of the aggravating and mitigating factors.

The definition of ''substantiated perpetrator'' means a person against whom an allegation of child abuse or neglect has been substantiated by ORR at Tier I or Tier II, but who has not exhausted the applicable appeal and review process for such allegations. Substantiated perpetrators at both Tier I and Tier II may appeal the disposition made by ORR to an Administrative Law Judge (ALJ) of the HHS Departmental Appeals Board (DAB) pursuant to § 412.102(c) and subsequently to the HHS Assistant Secretary for Children and Families pursuant to § 412.102(e).

The definition of ''sustained allegation'' means an allegation that was substantiated by ORR at Tier I or Tier II and that was upheld pursuant to the appeal and review process described in this rule or for which an appeal and review process was dismissed, including when the substantiated perpetrator waives their right to appeal by failing to make a timely request or by waiving those rights as specified in § 412.102(c).

The definition of ''sustained perpetrator'' means a substantiated perpetrator at Tier I or Tier II whose child abuse or neglect finding was upheld in the appeal and review process or whose appeal and review process was dismissed, including due to the sustained perpetrator's waiver of their right to appeal by failing to timely request appeal, or by otherwise waiving those rights as specified at § 412.102(c). Tier I Sustained perpetrators shall be prohibited from working in any way in connection with ORR-funded grants or contracts, including working or volunteering at any ORR care provider facility; may not have access to or contact with any unaccompanied child in ORR custody; will be added to the ORR Central Registry; and will be referred to appropriate law enforcement agencies. Information concerning Tier II sustained perpetrators will be recorded and maintained in agency records.

The definition of ''unfounded allegation'' means a disposition that there is not a preponderance of the evidence establishing that the alleged perpetrator committed child abuse or neglect, and the evidence indicates that the unaccompanied child was not harmed or placed at risk of harm. ORR notes that this definition differs from its definition of ''unfounded allegation'' under 45 CFR 411.5 (''an allegation that was investigated and determined not to have occurred'') to incorporate that ORR, as the investigating entity, is using the preponderance of evidence standard to establish a disposition of ''unfounded allegation.'' ORR also notes that records regarding unfounded allegations are maintained and disposed of in accordance with the applicable federal records management requirements.

The definition of ''verbal or emotional abuse'' aligns with the definition of ''mental injury'' at 34 U.S.C. 20341 and described at 42 U.S.C. 5106g, Note § 3, to the extent that those authorities describe behaviors and situations that are relevant to unaccompanied children for the purposes of this rule. The definition also includes specific non-exhaustive examples, based on ORR's experience operating the UC Bureau and the forms of verbal and emotional abuse historically reported, as well as feedback from care provider facilities that definitions with greater specificity will better support effective reporting and monitoring.

Section 412.100 Investigations Into Allegations of Child Abuse and Neglect

ORR describes the purpose of this IFR at § 412.100(a). This rule establishes the standards, requirements, and procedures for investigations by ORR of allegations of child abuse and neglect of unaccompanied children in ORR custody alleged to have been committed by care provider facility staff, contractors or sub-grantees of the care provider facility, care provider facility volunteers, or other individuals who have access to children in ORR care through contracts or grants with ORR, subject to § 412.100(c). ORR may also investigate individuals including those who are affiliated with legal service providers, child advocates, or other contractors engaged by ORR or the relevant care provider facility, to the extent allegations of abuse or neglect concern unaccompanied children who were in ORR custody at the time of the alleged incident. ORR believes these regulations will reduce the risk of child abuse and neglect of unaccompanied children in ORR care.

Section 412.100(b) provides that the provisions of this part are separate and severable from one another and that if any provision is stayed or determined to be invalid in a final judgment by a court of law, the remaining provisions shall continue in effect. This provision is meant to be consistent with the discussion of severability provided in the preamble at section IV.D.

Section 412.100(c) states that this rule applies in two circumstances. First, it applies to care provider facilities located in States where the State agency otherwise responsible for investigating child abuse and neglect allegations will not, as a matter of policy, investigate allegations of abuse or neglect concerning unaccompanied children at ORR-funded care provider facilities.[41] Second, this rule applies to EIFs. ORR notes this regulation implements ORR's statutory authority to conduct investigations and inspections of care provider facilities and other entities in which unaccompanied children reside while in ORR custody, regardless of the alleged perpetrator's particular role or job at the care provider facility—*i.e.,* regardless of whether they are employed directly by the care provider facility, are employed by a contractor or sub-grantee of the care provider facility, are caring for unaccompanied children through a cooperative agreement with ORR, or are volunteers at a care provider facility. Finally, this regulation provides ORR the authority to investigate any allegations of child abuse and neglect that occurred during a child's stay at an ORR care provider facility, even if the allegation is reported after the unaccompanied child has been released from ORR care and custody. In the event that a child is transferred to another care provider facility, ORR will continue to investigate any allegations of child abuse and neglect that occurred at the

[41] As of the publication of this rule, the only such state is Texas.

care provider facility for which the allegation was submitted.

ORR believes that it is critical to ensure that allegations of child abuse and neglect are reported to ORR. For example, ORR's existing policies and procedures require care provider facilities to report all allegations of child abuse and neglect of an unaccompanied child in ORR custody to ORR and to Federal, State, and local authorities in accordance with any applicable Federal, State, and local reporting and licensing laws.[42] Further, 45 CFR 411.61 requires care provider facilities to report to ORR any allegation, suspicion, knowledge, or information regarding an incident of sexual abuse or sexual harassment occurring in ORR care, along with any retaliatory actions resulting from reporting such incidents. The UC Program Foundational Rule requires at 45 CFR 410.1303(g) that all care provider facilities report to ORR any emergency incident, significant incident, or program-level event, in accordance with any applicable Federal, State, and local reporting laws. These existing requirements apply to all ORR care provider facilities. The requirements outlined in this rule at § 412.100(d) further provide that any person may report an allegation of child abuse and neglect to ORR directly, to the care provider facility, or to a designated entity or office that is not part of the care provider facility. To ensure clarity and consistency, ORR believes it is important to outline these additional reporting requirements for care provider facilities subject to this rule.

ORR believes that ensuring individuals can report allegations of child abuse and neglect without fear of retaliation is key to ensuring that such reports are made. Therefore, under § 412.100(d), care provider facilities to which this part applies must have written policies and procedures that allow children, care provider facility staff, contractors or sub-grantees of the care provider facility, care provider facility volunteers, families of unaccompanied children, legal service providers, child advocates, attorneys of record, and any other persons to report allegations of child abuse and neglect to ORR directly, to the care provider facility, or to a designated entity or office that is not part of the care provider facility. Under § 412.100(d), the written policies and procedures must minimally address three topics. First, under § 412.100(d)(1), the care provider facilities' policies and procedures must at minimum provide unaccompanied children and other individuals with methods for reporting and inform them of how they can report an allegation of child abuse and neglect to a designated entity or office that is not part of the care provider facility. Such entity or office must be able to receive allegations of child abuse and neglect and to immediately forward them to ORR, allowing unaccompanied children to remain anonymous upon request. Second, under § 412.100(d)(2), all the methods of reporting must be accessible to all unaccompanied children including those with disabilities and those with limited English proficiency. This can include, for example, ensuring unaccompanied children are aware of, and are able to call, ORR's National Call Center.[43] In order to be accessible to unaccompanied children with disabilities, the method of reporting must provide effective communication consistent with section 504 of the Rehabilitation Act of 1973. In addition, ORR notes that the requirements for language access for unaccompanied children with disabilities under the UC Program Foundational Rule must also be met, at 45 CFR 410.1306 and 45 CFR 410.1311 respectively. Third, under § 412.100(d)(3), the care provider facility policies and procedures must include protections to prevent retaliation against unaccompanied children and others who report allegations of child abuse and neglect.

At § 412.100(e), ORR is establishing requirements for the screening and intake of reports of allegations of child abuse and neglect, conducting investigations, assigning dispositions to the allegations, and documenting investigations. When receiving reports of allegations of child abuse and neglect and conducting investigations, ORR must ensure the health and safety of unaccompanied children while making every effort to reduce further trauma to the alleged victim(s).

ORR is requiring at § 412.100(e)(1), that when it receives a report of alleged child abuse or neglect, ORR must generate an intake report and determine whether the report includes an allegation that, if found to be true, would meet the definition of child abuse and neglect in this part and is consistent with § 412.100(a) and (c). If so, ORR will assign the intake report for investigation. If not, ORR will assign the intake report for administrative closure. ORR will assign an intake report for investigation where the allegation meets the requirements of § 412.100(a) and (c); but ORR may in its discretion elect not to investigate an allegation at an EIF if it has a formal written agreement with the relevant State or local authority to perform such investigations. ORR may administratively close an intake report when it determines it is not appropriate for an investigation, which may include circumstances such as those described in the definition of administrative closure in § 412.001. ORR notes that it will assign an intake report for investigation in accordance with the requirements at § 412.100(e) even if the child is no longer in ORR care, as long as the alleged abuse or neglect occurred while the child was in ORR care. This could include, for example, instances in which an unaccompanied child reports an allegation of abuse or neglect to ORR after they have been released, or if the child has been transferred to another care provider facility. In the event that a child has been transferred to a new care provider facility in a State that conducts investigations, ORR will continue its investigation in the State in which the alleged child abuse or neglect occurred, as the alleged perpetrator may still pose a risk to other children in the care provider facility from which the child was transferred. ORR will document and assess the report to determine the timeline for assigning the report for investigation based on the level of risk of harm to the alleged victim and assign different response times based on the level of risk of harm. ORR will document and maintain a record of every allegation received at care provider facilities that fall under this IFR, whether it is ultimately assigned for investigation and a disposition rendered or assigned for administrative closure. ORR's decision and rationale about whether to classify the allegation as an intake report and assign it for investigation (or for administrative closure) will also be documented.

After an intake report is assigned for investigation, under § 412.100(e)(2), ORR shall assign an ORR Child Welfare Investigator to make a prompt and thorough investigation of the report to obtain sufficient information to determine whether the allegation is substantiated based on a preponderance of the evidence. The preponderance of the evidence standard for ORR investigations shall be applied in determining whether the alleged perpetrator committed child abuse or neglect. As such, the investigation prescribed in this section relates to the

[42] *See,* ORR Policy Guide Section 5.8.2 Significant Incidents.

[43] *See* ORR, Office of Refugee Resettlement National Call Center, *https://www.acf.hhs.gov/orr/outreach-material/office-refugee-resettlement-national-call-center* (date accessed Sept. 6, 2024).

underlying allegation of abuse or neglect to a child, in addition to focusing on the individual perpetrator(s) involved. ORR will communicate its disposition to the alleged perpetrator, consistent with the requirements set forth at § 412.100(g), specifying whether the investigation determined that the alleged perpetrator committed abuse or neglect as defined in this rule. ORR emphasizes that this child-centered approach comports with common child welfare best practices seen across State systems.

ORR is requiring, at § 412.100(e)(3), that ORR shall provide notification that an allegation of child abuse and neglect will be investigated by ORR. This notification shall be provided to the alleged perpetrator; care provider facility; alleged victim; alleged victim's attorney of record (if the child has an attorney of record); and the alleged victim's parent(s), legal guardian(s), or sponsor(s) (as appropriate), unless ORR has evidence showing the parents, legal guardians, or sponsors should not be notified. If the alleged victim is 14 years old or older and ORR has determined that the alleged victim is able to make an independent decision, the alleged victim can affirmatively consent to disclosure. ORR notes that this notification requirement to the alleged victim, their attorney of record, and their parents, legal guardians, or sponsors is consistent with ORR's existing subregulatory notification policies and the PSA IFR requirements at 45 CFR 411.61(e) that are specific to sexual abuse and sexual harassment. To be clear, ORR also notes that the requirements of 45 CFR 411.61(f) continue to apply with respect to allegations of sexual abuse and harassment.

ORR is requiring, at § 412.100(e)(4), that the care provider facility must take immediate responsive measures to protect child welfare when notified that an investigation has been initiated, confirm the actions to ORR, and notify the alleged perpetrator, as appropriate. Such responsive measures may extend throughout the pendency of an investigation, and during the pendency of appeal and review processes, as necessary and applicable. ORR believes that this requirement is necessary to protect the safety and well-being of the unaccompanied children in ORR's care and custody until the allegation is either found to be not substantiated, unfounded, or is administratively closed. Additionally, ORR notes that care provider facility actions must be consistent with 45 CFR 411.66, which requires that any ORR and care provider facility staff, contractors, and volunteers suspected of perpetrating sexual abuse or sexual harassment must be suspended from all duties that would involve or allow access to unaccompanied children pending the outcome of an investigation.

At § 412.100(e)(5), ORR is establishing minimum standards that ORR shall follow when investigating allegations of child abuse and neglect. ORR investigations under this rule are not intended to replace investigations that may be performed by other relevant authorities, including State law enforcement or other Federal agencies, or entities designated under the VCAA to receive reports of child abuse. Accordingly, to the extent possible and appropriate, ORR is requiring at § 412.100(e)(5)(i) that it coordinate with any local or State law enforcement or other Federal agencies during its investigation. ORR may pause or resume an investigation at its discretion, with input from law enforcement partners or other relevant investigatory bodies, as necessary. Such coordination and cooperation with outside investigations is consistent with similar principles described in the PSA IFR.[44]

Additionally, under § 412.100(e)(5)(ii), ORR shall establish, as necessary, a multidisciplinary team comprised of ORR staff, which may include, but is not limited to, child welfare experts, forensic interviewers, mental health practitioners, child development and disability practitioners, pediatricians and other medical experts as needed, policy advisors, Federal program analysts, Federal program management staff, and subject matter experts to collaborate with the ORR Child Welfare Investigator. Although the ORR Child Welfare Investigator is responsible for rendering a final disposition based on their investigation, the multidisciplinary team will engage a range of ORR staff who are subject matter experts to provide input and an assessment of the reported allegation of child abuse or neglect to assist the ORR Child Welfare Investigator's investigation. The multidisciplinary team will also focus on the physical and behavioral healthcare needs of unaccompanied children potentially impacted by, and during the course of, the investigation of child abuse or neglect. This team is different from, and in addition to, the ORR Child Welfare Investigator and the DCPI will have the option to consult with the separate multidisciplinary team as necessary and appropriate. ORR believes that this collaborative approach to the investigation will lead to a coordinated response, representing a variety of fields and disciplines to support unaccompanied children while also ensuring a more efficient and thorough investigation.

Under § 412.100(e)(5)(iii), the Child Welfare Investigator is required to complete certain minimum actions during an investigation. The Investigator should demonstrate that they have thoroughly investigated the allegation to obtain sufficient information for ORR to make a disposition. Under § 412.100(e)(5)(iii)(A), ORR is requiring that upon receipt of the intake report, the ORR Child Welfare Investigator must review the intake report and the care provider facility's records on the alleged victim and alleged perpetrator, conduct a background check on the alleged perpetrator, interview the person who reported the allegation if this person was not interviewed during intake, immediately request preservation of any potential video and documentary evidence, and as needed, establish a plan for thoroughly investigating the allegation. ORR already requires background checks of care provider facility staff, contractors, and volunteers prior to hiring or before such individuals may have contact with unaccompanied children;[45] but the intent of this requirement is to ensure that ORR has an updated background check regarding the alleged perpetrator. This may include an FBI fingerprint check of national and State criminal history repositories, a National Sex Offender Public website check, state child abuse and neglect registry checks, or other public records checks. Further, ORR recognizes the importance of avoiding the loss of any video and documentary evidence and therefore requires the ORR Child Welfare Investigator to immediately seek preservation of that evidence. At § 412.100(e)(5)(iii)(B), ORR is requiring the ORR Child Welfare Investigator to visit the care provider facility, as appropriate, to conduct a walkthrough of the facility and review video and documentary evidence. The intent of this requirement is to ensure the Investigator is able to review any video and documentary evidence in a timely way and record any observations that may be relevant to the investigation. Visits to the care provider facility may be unannounced, and the ORR Child Welfare Investigator may visit a care provider facility as often as necessary to complete an investigation.

Under § 412.100(e)(5)(iii)(C), ORR is requiring the ORR Child Welfare Investigator to make reasonable efforts

[44] *See, e.g.,* 79 FR 77768, 77793; 77797.

[45] *See* 45 CFR 411.16(c), (d).

to interview all individuals who have information relevant to the report of child abuse or neglect, including, but not limited to, the alleged perpetrator, care provider facility staff, the alleged victim, sponsor(s), and the parent(s) or legal guardian(s) (as appropriate) of the alleged victim, and any other potential witnesses. ORR recognizes the importance of conducting investigations in a way that minimizes the number of times individual children, including the alleged victim and those who may have relevant information, are interviewed, so as to mitigate potential trauma during the investigation process and to promote reliability of the information collected. This includes taking into consideration when law enforcement or other Federal entities are conducting an investigation of the same allegation in alignment with § 412.100(e)(5)(i). ORR recognizes that some children, however, may require multiple interviews in order to feel more comfortable discussing allegations of child abuse and neglect, remember details, or overcome feelings of shame or guilt.[46]

Care provider facility staff will not be compelled to address questions about allegations regarding either themselves or other staff, under threat of disciplinary actions. ORR will not use threat of discharge to force an employee to be interviewed.

ORR notes that there may be circumstances where the ORR Child Welfare Investigator may not be able to interview all individuals who have information relevant to the report of child abuse or neglect. For example, the ORR Child Welfare Investigator may be unable to locate the individual after making reasonable efforts or the individual is unable to be interviewed due to the individual's parent, legal guardian, sponsor, or attorney representing the individual, refusing to permit the interview. ORR also notes that there may be situations in which it would not be appropriate for the parent, legal guardian, or sponsor to be interviewed (*e.g.,* when a child 14 years old or older has not consented to disclosure). Additionally, the ORR Child Welfare Investigator may not be able to interview an alleged perpetrator if the perpetrator was arrested or is under investigation by a law enforcement agency and the interview would interfere with the investigation; or the alleged perpetrator is detained and the jail, prison, or other detention facility where the alleged perpetrator is detained will not permit the interview.

At § 412.100(e)(5)(iii)(D), ORR is requiring the ORR Child Welfare Investigator ensure that interviews conducted as part of the investigation are accessible for all unaccompanied children, including those with disabilities and those with limited English proficiency and are properly documented either in writing or by audio or video recording. In order to be accessible for unaccompanied children with disabilities, the interviews must provide effective communication consistent with section 504 of the Rehabilitation Act of 1973. In addition, ORR notes that the requirements for language access and the requirements for unaccompanied children with disabilities under the UC Program Foundational Rule must also be met, at 45 CFR 410.1306 and 45 CFR 410.1311 respectively.

At § 412.100(e)(5)(iii)(F), ORR is requiring that the ORR Child Welfare Investigator review any available evidence in DCPI's records relating to past conduct of an alleged perpetrator, except allegations that resulted in a finding of unfounded or administrative closure. ORR's intent in taking these steps is to ensure that it captures situations that reveal patterns of behavior warranting further scrutiny but protects the rights of the individual as relates to prior unfounded or administratively closed allegations.

At § 412.100(e)(5)(iii)(F), ORR is requiring the ORR Child Welfare Investigator to gather relevant information as part of the investigation, including documents and audio or video evidence.

Lastly, at § 412.100(e)(5)(iii)(G), ORR is requiring the ORR Child Welfare Investigator to assess any imminent or ongoing risk of child abuse or neglect to the unaccompanied children at the care provider facility and, as appropriate, request that the care provider facility implement a plan to mitigate the risk and ensure the safety of the children. ORR's intent, in addition to investigating the underlying allegation, is also to assess any imminent or ongoing risks to children at the care provider facility following an allegation and to ensure the care provider facility implements safeguards to mitigate any such risks and ensure the safety of the children. The ORR Child Welfare Investigator is responsible for identifying any immediate risks to child welfare during the initial care provider facility visit following an allegation. This is not the same as determining whether the allegation occurred, which is done through the described investigation process, but rather to gain additional insight on how the allegation may have occurred. As appropriate, the ORR Child Welfare Investigator may request that the care provider facility implement a plan to mitigate the risk of child abuse or neglect to ensure safety of the unaccompanied children in ORR care at the care provider facility.

ORR is establishing at § 412.100(e)(6), that once the ORR Child Welfare Investigator's investigation is complete, ORR has the authority to render a disposition based on a preponderance of the evidence for each allegation. Possible dispositions include substantiated allegation-Tier I; substantiated allegation-Tier II; not substantiated allegation; unfounded; or administrative closure. If ORR determines the allegation is not substantiated, unfounded, or administratively closed, it may nevertheless consider further future investigation of the allegation if new information becomes available. ORR based its disposition types and definitions, including the relevant factors in § 412.100(e)(7) and (8), on a variety of existing State domestic child welfare systems and established best practices that balance children's needs and safety, the nuances that can exist in each allegation, and the due process rights of alleged perpetrators.

ORR notes that the first step in determining the disposition of an investigation is establishing whether child abuse or neglect, as defined under § 412.001, occurred based on the available information. If ORR finds, based on a preponderance of the evidence, that child abuse or neglect occurred, the allegation is considered substantiated as defined in § 412.001. ORR will determine whether each substantiated allegation is considered a substantiated allegation-Tier I or substantiated allegation-Tier II as to the substantiated perpetrator, based on the circumstances described at § 412.100(e)(7) and § 412.100(e)(8). ORR will make every reasonable effort to determine the perpetrator(s) responsible for each substantiated allegation of child abuse or neglect, and what role any other individuals involved in the abuse or neglect had, even if they did not perpetrate the act. An individual against whom an allegation of child abuse or neglect has been substantiated by ORR at Tier I or Tier II is considered a substantiated perpetrator, as defined in § 412.001. Under § 412.001, a substantiated perpetrator at Tier I or Tier II may appeal ORR's disposition pursuant to the established appeals process in § 412.102(d).

[46] Child Welfare Information Gateway. (2023). *Forensic interviewing: A primer for child welfare professionals.* U.S. Department of Health and Human Services, Administration for Children and Families, Children's Bureau. Available at: *https://www.childwelfare.gov/pubs/factsheets/forensicinterviewing/.*

ORR distinguishes an ''unfounded'' disposition from a ''not substantiated'' disposition based on whether there was evidence indicating that a child was harmed or placed at risk of harm. ORR believes that distinguishing these two categories in this way allows for a more child-centric approach to conducting investigations and rendering dispositions by ensuring that any situation in which a child is harmed or placed at risk of harm is specifically documented as such. While there are other existing mechanisms, including ORR's Significant Incident Reporting and monitoring systems, that may capture this information, these mechanisms do not specifically document ORR investigation dispositions.

By distinguishing ''unfounded'' and ''not substantiated'' dispositions, ORR will be able to better monitor and track individuals, grantees, and contractors who may have repeated instances of allegations against them. Even where alleged child abuse and neglect is ultimately not substantiated, ORR believes documenting ''not substantiated'' is important for child welfare because over time such findings may reveal patterns of conduct requiring further scrutiny or action by ORR. Notably, ORR is also requiring at § 412.100(e)(5)(iii)(F) that any available evidence of past conduct in DCPI's records relating to the same alleged perpetrator be reviewed as part of the Child Welfare Investigator's investigative process, except for allegations that resulted in a finding of unfounded or administrative closure.

Under § 412.100(e)(7), a disposition of substantiated allegation-Tier I is automatically required where the allegation is (1) substantiated by a preponderance of the evidence, and (2) where certain enumerated factors are present. The factors warranting an automatic Tier I substantiated allegation are: (i) death or near death of a child as a result of child abuse or neglect; (ii) subjecting or exposing a child to sexual abuse or sexual harassment; (iii) inflicting an injury or creating a condition requiring a child to be hospitalized or to receive significant medical attention; (iv) repeated instances of physical abuse committed by the individual against any unaccompanied child in ORR care; (v) failure to take reasonable action to protect a child from sexual abuse or repeated instances of physical abuse under circumstances where the individual knew or should have known that such abuse was occurring; and (vi) depriving a child of necessary care (*e.g.,* food, shelter, healthcare, supervision) which either caused serious harm or created a substantial risk of serious harm. ORR notes that ''individual'' in this case means the care provider facility staff, contractors or sub-grantees of the care provider facility, care provider facility volunteers, or other individuals who have access to children in ORR care through contracts or grants with ORR. Under § 410.100(e)(7)(iv), when repeated instances of physical abuse are committed by the individual, the finding of substantiated allegation-Tier I could apply to the first incident reported if evidence is found which indicates a pattern of abusive behavior, injuries to a child, or harm. Additionally, under § 410.100(e)(7)(v), the condition of an individual failing to take reasonable action to protect a child from sexual abuse or repeated instances of physical abuse would be met, for example, when another individual is aware of the abuse, and fails to take any action to stop it, and thus allows the perpetrator's abusive behavior to continue. Under § 410.100(e)(7)(vi), the condition of depriving a child of necessary care which either caused serious harm or a substantial risk of harm includes cases of willful abandonment, deprivation of food, withholding of vital healthcare, forced isolation, and other acts or omissions of similar severity.

If no automatic Tier I substantiating circumstances, as described at § 412.100(e)(7), are present, § 412.100(e)(8) enumerates aggravating and mitigating factors which will be considered in determining if child abuse or neglect should be substantiated at Tier I or II. In the absence of automatic Tier I substantiating circumstances, where ORR finds under a preponderance of the evidence that child abuse or neglect occurred, ORR will make a determination as to whether the allegation should be substantiated as Tier I or Tier II by weighing aggravating and mitigating factors together. Consideration of aggravating and mitigating factors will be based on the totality of the circumstances and in the interest of protecting child welfare. ORR again notes that the ''individual'' means the care provider facility staff, contractors or sub-grantees of the care provider facility, care provider facility volunteers, or other individuals who have access to children in ORR care through contracts or grants with ORR. Aggravating factors include any of the following under § 412.100(e)(8)(i): (A) violations of ORR behavior management requirements pursuant to the UC Program Foundational Rule at 45 CFR 410.1304; (B) failure to comply with clearly established care provider facility policies, corrective action plans, or agreed-upon conditions; (C) the tender age, delayed developmental status or other vulnerability of the child; (D) any significant or lasting physical, psychological, or emotional harm to the child; (E) an attempt to inflict any significant or lasting physical, psychological, or emotional harm to the child; and (F) evidence suggesting a repetition or pattern of abuse or neglect, including multiple instances in which child abuse or neglect was substantiated at Tier I or Tier II, or not substantiated allegations if they demonstrate a pattern of abuse or neglect.

Under § 412.100(e)(8)(i)(A), violations of ORR behavior management requirements [47] include, for example, the use of prone physical restraints, chemical restraints, or peer restraints for any reason in any care provider facility setting, especially considering the age and particular vulnerability of the child. ORR notes the factor under § 412.100(e)(8)(i)(C) includes tender age as defined in ORR's Policy Guide which means children 12 years of age or younger. It also includes the alleged victim's vulnerable status (including history of trauma), particularly if the child is under the age of five; the child's developmental stage; the child's individualized needs, the child's disabilities, if any; and other vulnerabilities of the child. ORR's consideration of an attempt to inflict any significant or lasting physical, psychological, or emotional harm on the child under § 412.100(e)(8)(i)(E) will include whether there was an attempt to harm the child, even if the child does not appear to have suffered actual harm. Finally, to understand whether there is a repetition or pattern of child abuse or neglect under § 412.100(e)(8)(i)(F), ORR will consider whether there have been multiple Tier I or Tier II allegations that have been sustained pursuant to this IFR, or determined to have occurred by other relevant authorities that indicate such a pattern. ORR will also consider whether there is evidence to indicate prior occurrences or ongoing incidents of child abuse or neglect even if it is the first incident investigated by ORR.

Under § 412.100(e)(8)(ii), mitigating factors shall be weighed together with any existing aggravating factors. ORR again notes that the ''individual'' means the care provider facility staff, contractors or sub-grantees of the care provider facility, volunteers, or other individuals who have access to children in ORR care through contracts or grants with ORR. Mitigating factors include

[47] *See* 45 CFR 410.1304.

any of the following: (A) remedial actions taken by the individual before the investigation was concluded; (B) extraordinary, situational, or temporary stressors that caused the individual to act in an uncharacteristically abusive or neglectful manner; (C) the isolated or aberrational nature of the child abuse or neglect; and (D) the limited, minor, or negligible physical, psychological, or emotional impact of the abuse or neglect on the child. Under § 412.100(e)(8)(ii)(C), ORR will consider the isolated nature of the child abuse or neglect and that there is no evidence of a pattern. If a subsequent report yields additional evidence of a historical pattern or behavior, however, this mitigating factor would be eliminated.

Under § 412.100(f), records created, and information gathered or obtained during the course of an investigation are for internal purposes only, will not be shared or made public unless otherwise required or authorized by law, and may not be disclosed without prior ORR approval. All records will be maintained in an appropriate recordkeeping system with protections for the privacy and security of the individuals identified in the records. This provision refers to the entire record gathered during the course of an investigation under this part, in contrast to § 412.101(d), which states ORR will refer names and other identifying information of sustained perpetrators to relevant State and local authorities and to relevant law enforcement agencies in the State in which the child abuse and neglect occurred. This provides ORR with discretion to disclose records, for example, to Federal, State, or local government authorities, or any agents of such authorities, that have a need for such information in order to carry out their responsibilities under law to protect children from child abuse and neglect. The provision also provides ORR with discretion to share relevant information with the HHS Office of the Inspector General (OIG) for purposes of conducting investigations in accordance with the Inspector General Act (IG Act) of 1978.[48] ORR notes that § 412.100(f) applies to all records and information gathered, whether they pertain to an alleged perpetrator, an unaccompanied child who is an alleged victim or any other unaccompanied child, an individual making an allegation to ORR, or any other individual associated with an allegation, intake report, or investigation under this part. Safeguarding and maintaining the confidentiality of an unaccompanied child's case file records is critical to carrying out ORR's responsibilities under the HSA and the TVPRA.[49] Additionally, requiring confidentiality is critical for promoting compliance with the requirement to report allegations of child abuse and neglect at § 412.100(d).[50]

ORR is establishing requirements pertaining to notification of dispositions at § 412.100(g). At § 412.100(g)(1), ORR must notify the alleged perpetrator of the disposition of an investigation in writing within five days of making the disposition. ORR must also notify in writing the alleged victim and their parent(s), legal guardian(s) (as appropriate), or sponsor(s), of the disposition within five days of making a disposition.

Under § 412.100(g)(2), if the disposition is substantiated at Tier I, the notification must state: (i) the substantiated perpetrator will be considered a sustained perpetrator at Tier I and their name and other relevant information will be placed on the ORR Central Registry (unless they seek an appeal of the disposition pursuant to § 412.102) and that once identified in the Central Registry, they will be prohibited from working or volunteering in any way on ORR-funded grants or contracts, and may not have access to or contact with any unaccompanied child in ORR custody; (ii) the reasons for the Tier I substantiated perpetrator's placement on the ORR Central Registry in terms sufficient to put the perpetrator on notice of the conduct or incident(s) upon which it is based; (iii) the substantiated perpetrator may appeal ORR's disposition pursuant to § 412.102, but that if the Tier I substantiated perpetrator either fails to request such appeal in a timely manner, or upon conclusion of the appeal and subsequent review, if any, the disposition is upheld, the perpetrator will be added to the ORR Central Registry and the disposition will be reported to Federal, State, and local authorities as appropriate (such as notifying the State in which the allegation occurred when an allegation is sustained); and (iv) ORR's procedures for making the disposition. ORR believes these requirements are a key part in ensuring a Tier I substantiated perpetrator has adequate notification that they will be placed on the ORR Central Registry, the consequences of being placed on the Registry, and of the ability to request an appeal and subsequent review.

Under § 412.100(g)(3), if the disposition is a Tier II substantiated allegation, the notification must inform the Tier II substantiated perpetrator that they may appeal ORR's disposition pursuant to § 412.102, but that if the Tier II substantiated perpetrator either fails to request such appeal in a timely manner, or upon the conclusion of the appeal and subsequent review, if any, the disposition is upheld, the Tier II substantiated perpetrator will be designated as a Tier II sustained perpetrator and ORR's disposition will be retained in ORR records. ORR may use these records for determining patterns of abuse and neglect and for informing future safety planning at care provider facilities. A Tier II sustained perpetrator will not be placed on the ORR Central Registry.

Section 412.101 Interventions and Discipline

Under § 412.101, ORR is establishing mechanisms for interventions and discipline related to substantiated and sustained allegations of child abuse and neglect as determined by ORR under § 412.100. These intervention and discipline mechanisms include maintenance by ORR of a ORR Central Registry of individuals with Tier I sustained allegations of child abuse and neglect; prohibitions on hiring, employing, or permitting as volunteers individuals who are listed in the ORR Central Registry; required disciplinary sanctions by ORR care provider facilities; and provisions for ORR referrals of substantiated allegations of child abuse and neglect to other government and law enforcement agencies. ORR believes that these enforcement mechanisms and requirements are crucial to carrying out the purpose of this part, as specified and described under § 412.100(a) and (c) above.

Section 412.101(a) describes an ORR Central Registry to list Tier I sustained perpetrators under this rule. Under § 412.101(a)(1), for purposes consistent with § 412.100(a) and (c), ORR will create and maintain an ORR Central Registry of Tier I sustained perpetrators, including names and other identifying information, and details regarding the sustained allegations. Under § 412.101(a)(2), subject to legal requirements regarding disclosure of information (*e.g.,* under Freedom of Information Act (FOIA), the Privacy Act, or the IG Act), the ORR Central Registry

[48] *See* 5 U.S.C. 6(a).

[49] *See* 89 FR 34384, 34494. *See also* 81 FR 46682 (stating that ORR treats systems of records containing unaccompanied child information as subject to the provisions of the Privacy Act, 5 U.S.C. 552a).

[50] ORR further notes that it has finalized regulations relating to the confidentiality of case files of unaccompanied children in ORR care in the Unaccompanied Children Program Foundational Rule. *See id.* at 34599 (codified at 45 CFR 410.1303(h)).

will not be public-facing, nor available to persons outside of ORR, since its purpose is to inform employment decisions by ORR care provider facilities, home study providers, and post-release service providers by providing the names and other identifying information of Tier I sustained perpetrators, and for ORR to use as part of the screening process by care provider facilities as described in § 412.101(b).

Section 412.101(b) sets out certain working and volunteering prohibitions for individuals listed in the ORR Central Registry, as well as requirements for checking the ORR Central Registry. ORR is requiring at § 412.101(b)(1) that the individuals listed in the ORR Central Registry shall be prohibited from working or volunteering in any way on ORR-funded grants or contracts, and may not have access to or contact with any unaccompanied child in ORR custody, unless ORR removes such individual from the Central Registry (*e.g.,* circumstances contemplated under § 412.102(c)(2)(ii), addressing temporary removal of an individual from the Central Registry while an appeal is pending; § 412.102(e), addressing possible reversal of a DAB finding by second-level review, carried out by the Assistant Secretary for ACF). ORR-funded grants or contracts where individuals listed in the ORR Central Registry will be prohibited from working or volunteering may cover, for example, other care provider facilities, ORR home study and post-release service providers, or other ORR-funded services that may include access to unaccompanied children. At § 412.101(b)(2), ORR is requiring that, as part of the screening process for hiring decisions for staff, contractors or sub-grantees, or for screening volunteers, all care provider facilities, home study providers, and post-release service providers, whether or not located in States that investigate child abuse and neglect allegations at ORR care provider facilities, must check with ORR to confirm that an applicant is not listed in the ORR Central Registry.

At § 412.101(b)(3), ORR sets out the requirement that all care provider facilities, home study providers, and post-release service providers, whether or not located in States that investigate child abuse and neglect allegations at ORR care provider facilities, must also check all of their personnel against the ORR Central Registry at least once annually. Checking applicants and current personnel against the ORR Central Registry is an especially important child safety measure for care provider facilities located in States that do not investigate allegations of child abuse and neglect, and thus whose registries will not include individuals alleged, or found through investigation, to have perpetrated abuse or neglect at ORR care provider facilities. ORR notes that the requirements at § 412.101(b) are supplementary to those in the PSA IFR at 45 CFR 411.16 and 45 CFR 411.81.

Under § 412.101(c), care provider facilities must implement appropriate disciplinary or remedial measures where they or ORR find care provider facility staff, contractors or sub-grantees of the care provider facility, or care provider facility volunteers engaged in conduct that does not rise to the level of a Tier I substantiated allegation, as defined at § 412.001, but nevertheless raises child welfare concerns.

ORR believes that it is important to share information regarding sustained perpetrators with relevant State and local authorities such that they can take additional action as necessary to protect children in their jurisdictions in accordance with their legal obligations. This information sharing does not mean that information on the registry is public facing, such as other public criminal records databases. Rather, ORR will only share information directly with relevant entities and in accordance with applicable State and Federal information sharing, privacy, and due process protections. Accordingly, under § 412.101(d)(1), ORR will refer names and other identifying information of Tier I sustained perpetrators to relevant State and local authorities (*e.g.,* child protective services) and to relevant law enforcement agencies in the State in which the sustained allegation of child abuse and neglect occurred. This requirement comports with existing requirements in the PSA IFR that all terminations for violations of ORR or care provider facility policies and procedures regarding sexual abuse and sexual harassment, or resignations by staff who would have been terminated if not for their resignation, must be reported to law enforcement agencies and to any relevant State or local licensing bodies.[51] Additionally, if requested by a relevant State or local authority or relevant law enforcement agency, including an authority or agency outside of the State in which the Tier I sustained allegation occurred, ORR will confirm whether a particular individual is on the ORR Central Registry. Furthermore, under § 412.101(d)(2), ORR will provide the names and other identifying information of Tier I sustained perpetrators to the Federal Bureau of Investigation, and HHS Office of the Inspector General (OIG), consistent with any applicable agreements. Finally, § 412.101(d)(3) requires that neither ORR nor care provider facilities shall interfere with another State, local, or Federal authority or agency's investigation into allegations of child abuse and neglect.

[51] *See* 45 CFR 411.81(c).

Section 412.102 Appeal and Review Process

ORR is establishing guidelines and requirements regarding the availability of an appeal and review process of dispositions made by ORR at § 412.102.

Under § 412.102(a), a substantiated perpetrator, whether at Tier I or Tier II, may appeal the disposition made by ORR to an Administrative Law Judge (ALJ) in the HHS Departmental Appeals Board (DAB) pursuant to § 412.102(c).

ORR is requiring, at § 412.102(b), that ORR shall notify substantiated perpetrators at Tier I or Tier II of their opportunity for an appeal. As stated above, all alleged perpetrators receive notice of the allegations against them pursuant to § 412.100(e)(3). Under § 412.102(b)(1), after completing an investigation and upon substantiation of any relevant allegations, ORR will send a written notice to the substantiated perpetrator at Tier I or Tier II, in accordance with § 412.100(g). The notice will state that the relevant allegations have been substantiated and that the Tier I substantiated perpetrator will be placed on the ORR Central Registry unless they appeal the disposition by ORR and that the Tier II substantiated perpetrator's information will be retained as a Tier II sustained perpetrator in agency records. Under § 412.102(b)(2), the written notice shall: (i) clearly describe the basis for ORR's disposition that substantiates the relevant allegations at Tier I or Tier II and shall explain the Tier I or Tier II substantiated perpetrator's right to appeal the disposition and the steps required to initiate the appeal; (ii) inform the substantiated perpetrator that they may appeal the disposition before an ALJ; (iii) provide the substantiated perpetrator at Tier I or Tier II and their attorney, if any, with written information and instructions describing the appeal process; and (iv) inform the substantiated perpetrator at Tier I or Tier II that if they do not appeal within 30 days of receiving the notice, the DAB will consider the substantiated perpetrator to have waived their opportunity for an appeal and any subsequent review. A Tier I substantiated perpetrator will be identified on the ORR Central Registry as a Tier I sustained perpetrator. A Tier II substantiated perpetrator's

information will be retained as a Tier II sustained perpetrator in agency records.

At § 412.102(c), ORR is establishing a process for substantiated perpetrators at Tier I or Tier II to appeal of ORR's disposition. Under § 412.102(c)(1)(i), and as further elaborated at § 412.102(c)(2), if the substantiated perpetrator elects to appeal ORR's disposition that a child abuse or neglect allegation is substantiated at Tier I or Tier II, they must file a written notice of appeal with the DAB within 30 days of receipt of the written notice of ORR's disposition. Under § 412.102(c)(1)(ii), within 30 days of receiving this written notice of appeal, ORR will provide all evidence it used in making its disposition to the DAB. Under § 412.102(c)(1)(iii), within 30 days of receiving this written notice of appeal, ORR will provide to the substantiated perpetrator at Tier I or Tier II, and their attorney, if any, all information used in making its disposition, except any information that ORR determines: (A) would compromise the safety and well-being of a child, the reporter, or any other person; (B) would reveal the identity of a child who furnished information with the understanding that their identity would be held in confidence; (C) would reveal the identity of any other alleged perpetrator(s) involved in the same case who has an unfounded disposition (to protect the privacy of the alleged perpetrator with an unfounded disposition); or (D) is otherwise prohibited by State or Federal law or regulation. In the case of information being withheld, the substantiated perpetrator at Tier I or Tier II will be advised of the general nature of the information and the reasons that it is being withheld. Neither the substantiated perpetrator at Tier I or Tier II nor the care provider facility are required to provide information unless they would like the ALJ to consider such information as part of the hearing or record review, and they will not be compelled to provide it.

Dismissal of appeals is covered in § 412.102(c)(2). Under § 412.102(c)(2)(i), the ALJ may dismiss an appeal when the ALJ determines that the substantiated perpetrator waived appeal by not submitting the notice of appeal in a timely manner (*i.e.,* an appeal within 30 days of receiving written notice of ORR's disposition) and failed to demonstrate good cause for the untimely request, withdraws the appeal, abandons the appeal, or does not have a right to ALJ review (including, but not limited to, situations where the case does not involve a Tier I or Tier II substantiated allegation). If the appeal is dismissed, the Tier I substantiated perpetrator will be placed on the ORR Central Registry as a Tier I sustained perpetrator or ORR will retain the information regarding the Tier II substantiated perpetrator as a Tier II sustained perpetrator in agency records, as applicable. Notwithstanding such a dismissal, under § 412.102(c)(2)(ii) the DAB may in its discretion temporarily remove the designation of sustained perpetrator at Tier I or Tier II, which would result in ORR removing the individual who was designated as a Tier I sustained perpetrator from the ORR Central Registry, in situations where, for example, the ALJ determines that the sustained perpetrator at Tier I or Tier II has established good cause for exceeding the appeal timeframe. This rule contemplates that good cause may be established, for example, where a serious medical condition prevented timely filing of the notice of appeal.

The appeal and review processes are described in § 412.102(d) and (e). Under § 412.102(d)(1), when a substantiated perpetrator at Tier I or Tier II appeals, ORR must transmit all of the evidence upon which ORR's disposition was based to the ALJ. Under § 412.102(d)(2), the evidentiary record must contain all documents and other materials, such as video or audio recordings, that were used by ORR in making its disposition. The ALJ may remand the case to ORR if the ALJ determines that the evidentiary record is insufficiently complete to determine whether ORR's disposition is supported by a preponderance of the evidence. Under § 412.102(d)(3), the substantiated perpetrator at Tier I or Tier II may be represented by an attorney. As described in § 412.102(d)(4), the substantiated perpetrator shall have the burden to show that, considering the totality of the evidence, there is not a preponderance of the evidence to support the substantiated allegation at Tier I or Tier II, and to dispute whether any automatic Tier I substantiating circumstances described at § 412.100(e)(7) existed (if applicable) or whether aggravating factors or mitigating factors described at § 412.100(e)(8) existed (if applicable). Both ORR and the substantiated perpetrator may present the testimony of witnesses, documents, factual data, arguments, or other submissions of proof. The testimony of care provider facility staff shall be voluntary and failure to provide such testimony will not subject the care provider staff member to disciplinary action. Under § 412.102(d)(5), if the substantiated perpetrator appeals and the appeal is not dismissed by the ALJ pursuant to § 412.102(d)(7), ORR must notify the alleged victim and the alleged victim's parent(s), legal guardian(s) (as appropriate), or sponsor(s) that an appeal of ORR's disposition will be conducted by an ALJ. The alleged victim, other child witness(es), and family members of the alleged victim shall not be required to testify. Refusal to testify shall have no bearing on a determination as to whether the alleged abuse or neglect did or did not take place.

Under § 412.102(d)(6), both parties (ORR and the substantiated perpetrator) may cross examine witnesses and ask questions during a live hearing, as well as request additional information, either during a live hearing or pursuant to a record review. In order to mitigate the potential for re-traumatization of an alleged victim while still providing a substantiated perpetrator with the opportunity to respond to the allegations, a substantiated perpetrator may not personally cross examine the alleged victim. The parties will be given an opportunity to file briefs or other written statements of fact or law. Under § 412.102(d)(7), the ALJ must conduct a fair and impartial hearing under a de novo standard of review to determine whether the substantiated perpetrator met their burden of proving that, considering the totality of the evidence, there is not a preponderance of the evidence to support the substantiated allegation. The ALJ will issue a written decision upholding, modifying, or reversing the ORR's disposition. Under § 412.102(d)(8), the ALJ shall serve a copy of the decision upon the parties and the Assistant Secretary for ACF. The ALJ's decision shall provide the substantiated perpetrator at Tier I or Tier II and their attorney, if any, with instructions for filing a request for review with the Assistant Secretary for ACF. The ALJ also shall provide a copy of the decision to the alleged victim, and, as appropriate, the alleged victim's parent(s), legal guardian(s), or sponsor(s). The complete record upon which the decision is based shall be made available to the Assistant Secretary.

This rule provides another level of review under § 412.102(e). This subsection provides that the Assistant Secretary for ACF may review the ALJ's determination, either sua sponte or upon a request by the substantiated perpetrator. Under § 412.102(e)(1), a substantiated perpetrator at Tier I or Tier II may request review of the ALJ's decision within 30 days of receipt of the ALJ's decision, by filing a request for review with Office of the Assistant

Secretary for ACF. Under § 412.102(e)(2), the Assistant Secretary has discretion, within 30 days after receiving a timely request for review of an ALJ's decision under § 412.102(e)(1), to review the ALJ's decision and to dismiss a request for review based on untimeliness or other procedural defects, or to affirm, modify, or reverse the ALJ's decision with regard to dismissal or ORR's disposition of the allegation. A review by the Assistant Secretary will determine whether the ALJ's decision was based on a material error of law or fact.

Section 412.102(e)(3) provides that if the Assistant Secretary affirms the ALJ's decision, or does not modify or reverse the ALJ's decision, within 30 days after receiving a timely review request under § 412.102(e)(1), then the ALJ's decision becomes the final decision of the Assistant Secretary and is binding on both parties (ORR and the substantiated perpetrator). Likewise, under § 412.102(e)(4), if the Assistant Secretary modifies or reverses the ALJ's decision pursuant to § 412.102(e)(2), then the Assistant Secretary's decision is final and binding.

Under § 412.102(e)(5), if at the end of the 30-day period in § 412.102(e)(1), no timely request for review has been made, the Assistant Secretary has 30 days from that point to exercise discretion to review the ALJ's decision. If the Assistant Secretary does not modify or reverse the ALJ's decision, then the ALJ's decision becomes the final decision of the Assistant Secretary and is binding on both parties. The intent of § 412.102(e)(5) is to make clear that the Assistant Secretary has discretion to review the ALJ's decision regardless of whether a timely request for review is made.

Under § 412.102(e)(6), the Office of the Assistant Secretary for ACF shall notify the parties of the Assistant Secretary's final decision. The Office of the Assistant Secretary also shall provide a copy of the final decision to the alleged victim and the alleged victim's parent(s), legal guardian(s) (as appropriate), or sponsor(s), based on review of the ALJ's previous decision, under § 412.102(e).

Section 412.103 Obligations of Care Provider Facilities

To ensure that ORR can obtain sufficient information to make fair, accurate, and impartial decisions regarding allegations of child abuse and neglect, at § 412.103, ORR is establishing obligations with which care provider facilities must comply during investigations.

Under § 412.103(a)(1) through (3), during any investigation of child abuse and neglect by ORR, a care provider facility must permit ORR: (1) to have unrestricted access to the premises, any physical property on the premises, buildings, staff, and children in the physical custody of the care provider facility; (2) to conduct interviews with children residing at the care provider facility, and without care provider facility staff, contractors or sub-grantees of the care provider facility, or care provider facility volunteers, present; and (3) to observe the activities of care provider facility staff, contractors or sub-grantees of the care provider facility, care provider facility volunteers, or other individuals who have access to children in ORR care through contracts or grants with ORR. Under § 412.103(a)(4), care provider facilities must promptly preserve any potential video or documentary evidence. ORR notes that this requirement is aligned with the requirement at § 412.100(e)(5)(iii)(A), which states that upon receiving an intake report, the ORR Child Welfare Investigator must immediately request preservation of any potential video and documentary evidence. Additionally, under § 412.103(a)(5), care provider facilities must promptly provide and facilitate access to, upon request, all files, records, reports, data, video recordings, and other information, including copies of any such documents, requested by ORR either prior to or during the investigation. Care provider facilities subject to this rule must also promptly provide access to and contact information for staff, contractors, or sub-grantees of the care provider facility, its volunteers, or other individuals who have access to children in ORR care (§ 412.103(a)(6)); submit complete and accurate responses to any written questions in a timely manner (§ 412.103(a)(7)); and fully cooperate with ORR (§ 412.103(a)(8)). Finally, under § 412.103(a)(9) care provider facilities are required to fully cooperate with any investigation of the same allegation by other State, local, and Federal authorities, and relevant law enforcement agencies.

Further, in alignment with existing ORR policy and 45 CFR 411.67, ORR is requiring at § 412.103(b) that care provider facility staff, contractors or sub-grantees of the care provider facility, and care provider facility volunteers must not retaliate against any person who in good faith reports or participates in an investigation of child abuse or neglect.

Under § 412.103(c), a care provider facility's obstruction, interference, delay of, or failure to permit or cooperate with any investigation under this part, including failure to protect unaccompanied children from retaliation pursuant to § 412.103(b), may result in ORR taking monitoring and enforcement measures. Such measures may include remote monitoring of the care provider facility (*i.e.,* monitoring that does not occur on-site); on-site monitoring of the care provider facility; monitoring of the corporate offices to review internal policies and reporting structures, as well as supervisory responses to events (*e.g.,* mitigation or future preventative measures); limiting or stopping new placements of unaccompanied children at the care provider facility; removing all children in ORR care and custody from the care provider facility and placing them into other care provider facilities; issuing corrective actions; terminating the contract or cooperative agreement with the care provider facility; or imposing other such remedies for noncompliance applicable to HHS grant recipients and contractors. ORR notes that the cooperation of care provider facilities is critical in investigations of child abuse and neglect, and that enforcement measures such as those described are appropriate to help ensure that ORR can obtain the information necessary to determine whether allegations are substantiated.

Under § 412.103(d), ORR requires care provider facilities, during the course of an investigation, to provide unaccompanied children confidential access to attorneys of record and other legal service providers, as well as their families and legal guardians, in a manner consistent with requirements established at 45 CFR 411.55 (as applicable) as well as 45 CFR 410.1309. Care provider facilities must provide unaccompanied children with access to their child advocates, in a manner consistent with the requirements of the TVPRA at 8 U.S.C. 1232(c)(6) and 45 CFR 410.1308. Finally, care provider facilities must also provide unaccompanied children access to health services (including specialists and mental health practitioners), individual counseling sessions, and crisis intervention (including access to outside victim services and rape crisis centers where appropriate) to most appropriately address unaccompanied children's needs, in a manner consistent with requirements established at 45 CFR 410.1302(c)(5), 45 CFR 410.1307, 45 CFR 410.1311, and 45 CFR 411.21 (as applicable).

VI. Good Cause for Issuing This IFR

When engaging in rulemaking, ORR ordinarily publishes a notice of proposed rulemaking (NPRM) in the **Federal Register** and invites public comment on the proposed rule. However, under the Administrative Procedure Act, 5 U.S.C. 553(b), an NPRM is not required when an agency, for good cause, finds that notice and public comment is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the agency's reasons in the rule issued. With respect to this rulemaking, delaying implementation of the provisions of this regulation until a public notice and comment process is complete would risk serious and imminent harm to unaccompanied children in Texas care provider facilities (and in the future at EIFs, which ORR may need to open on short notice, before it can execute formal written agreements describing child welfare investigations of child abuse and neglect with relevant local authorities), and thus would be impracticable. As such, ORR believes that it has good cause to issue this rulemaking as an Interim Final Rule (IFR) rather than issuing an NPRM.

ORR has determined that this rulemaking is imminently necessary because ORR must have the ability to establish employment consequences at relevant care provider facilities for sustained perpetrators of abuse and neglect in order to fulfill its statutory responsibilities.[52] Critically, as mentioned earlier, ORR began taking immediate action soon after it became clear that Texas DFPS was not going to resume its historical child welfare and investigative functions when it extended its emergency declaration in 2022. Subsequently, ORR began consulting with other federal agencies, developing the necessary expertise and capacity to conduct investigations, drafting policies and procedures to inform how investigations are conducted, obtaining administrative approval for new agency positions, creating new comprehensive technical systems for recording and tracking investigations, and hiring, onboarding, and training qualified investigative staff. Most pertinently, as discussed at section IV.A, ORR's recently established Division of Unaccompanied Child Protective Investigations (DCPI) began its investigations of allegations of child abuse and neglect in ORR-funded care provider facilities in Texas as of July 2024.

In addition to investigating allegations of abuse and neglect at care provider facilities located in States that do not conduct investigations, and at EIFs, ORR needs to be able to direct its care provider facilities to prohibit individuals from working or volunteering on ORR-funded grants or contracts when there has been a sustained allegation of abuse or neglect at Tier I (as defined in this rule), and to ensure that perpetrators with such sustained allegations do not have access to or contact with children in ORR custody. To that end, this rulemaking establishes an ORR Central Registry listing Tier I sustained perpetrators, as described in this rule. Further, this rule establishes that Tier I sustained perpetrators listed on the ORR Central Registry are prohibited from working or volunteering in any way on ORR-funded grants or contracts, so as to prohibit them from having access to or contact with any unaccompanied child in ORR custody. Because such requirements potentially implicate alleged perpetrators' ability to work in their chosen profession (if the allegation is sustained at Tier I), ORR believes that substantive rulemaking is required to codify appeal and review procedures with appropriate due process protections for alleged perpetrators (*e.g.,* notice and an opportunity to be heard).

There is good cause to issue this rulemaking as an IFR because requiring notice and comment before implementing these provisions would risk serious and imminent harm to unaccompanied children. For example, even if DCPI concludes through an investigation that an individual perpetrated child abuse or neglect, without an ORR Central Registry, such a perpetrator could potentially pass a background check and be re-hired at any time at another ORR care provider facility, which would undermine the very purpose of the rule—to protect children from such perpetrators. As noted above, ORR understands that creation of the Central Registry requires rulemaking because adequate due process procedures need to be established in consideration of the employment interests at stake. In other words, ORR's DCPI can now investigate, substantiate, and sustain allegations of abuse and neglect of unaccompanied children in its custody against alleged perpetrators in accordance with existing statutory authority, but requiring notice and comment before this rule goes into effect would prevent ORR from using that critical information in the ORR Central Registry to keep children safe in the near and long term. Until ORR is able to begin operating the ORR Central Registry, unaccompanied children are at elevated risk of abuse or neglect—a risk that ORR seeks to prevent by using this IFR to prohibit the hiring of Tier I sustained perpetrators of child abuse and neglect.

As discussed above, as of July 2024, ORR began investigative activities in relation to reported child abuse and neglect at care provider facilities in Texas. As a result, there is an urgent need to have the provisions of this rule in place to protect child welfare while also providing appropriate due process protections for alleged perpetrators of child abuse and neglect. Notice and comment rulemaking would prevent ORR from taking swift and appropriate action when it identifies an imminent threat to child safety and would allow perpetrators of child abuse and neglect to evade ORR's efforts, pursuant to statutory responsibilities, to protect unaccompanied children in its custody. Notice and comment rulemaking would increase the risk of serious potential harm to unaccompanied children—which ORR seeks to address through this IFR by prohibiting employment of individuals on the ORR Central Registry.

ORR has therefore found good cause in the specific circumstances presented here—where ORR has recently established a new Division to conduct child welfare investigations at EIFs and in States that do not do so given that there is an immediate and ongoing risk to unaccompanied children in such States without the protections described in this rule. This rulemaking is urgently required now to establish required employment consequences for individuals found by ORR investigations to have perpetrated child abuse or neglect, and ORR has not delayed responding to the urgent need to establish such consequences because DCPI began initiating investigations as of July 2024.

Therefore, HHS finds good cause to waive the notice of proposed rulemaking and to issue this final rule on an interim basis. Finally, HHS is providing a 60-day public comment period and will carefully consider public comments received and may update the final rule, as appropriate. ORR plans to finalize the rule within one year of implementation.

[52] *See supra,* Sec. IV.B (referencing various provisions of the HSA, including 6 U.S.C. 279(b)(1)(G) (making the ORR Director responsible for ''overseeing the infrastructure and personnel of facilities in which unaccompanied alien children reside'') and 6 U.S.C. 279(b)(1)(L) (making the ORR Director responsible for ''conducting investigations and inspections of facilities and other entities in which [unaccompanied children] reside. . .'')).

VII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), HHS is required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a control number assigned by OMB.

This interim final rule with comment requires information collections for which HHS plans to seek OMB approval at a later date. The information collection requirements associated with this interim final rule will not take effect until approved by OMB. HHS will issue future **Federal Register** notices to seek comments on its information collections within one month following finalization, as required by the PRA,[53] and will include a system of records notice related to the requirements in this rule.

To estimate the costs associated with the information collection activities described in this interim final rule, ORR utilizes median hourly wage rates in accordance with the Bureau of Labor Statistics' (BLS) most recent update in April 2024 for Education and Childcare Administrators.[54] The median hourly wage rate is calculated to be $26.10 with fringe benefits at 100 percent, for a total hourly wage rate of $52.20 ($26.10 + $26.10).

Section 412.100(d) requires that care provider facility staff, contractors, sub-grantees, volunteers, and all ORR staff must report allegations of child abuse and neglect by care provider facility staff, contractors or sub-grantees of the care provider facility, care provider facility volunteers, or other individuals who have access to children in ORR care through contracts or grants with ORR in accordance with ORR policies and procedures to ORR, and to Federal, State, and local authorities in accordance with any applicable Federal, State, and local reporting and licensing laws. Because this reporting requirement would not require additional reporting above and beyond existing ORR policy, this requirement will not result in additional burden for care provider facilities.

[53] See 44 U.S.C. 3506(c)(2)(A).

[54] *https://www.bls.gov/oes/current/oes119031.htm.* Accessed July 31, 2024.

VIII. Regulatory Impact Analysis

A. Economic Analysis

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866, as amended by Executive Order 14094, defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $200 million or more (adjusted every 3 years for changes in gross domestic product), or adversely affecting in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impact of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in the Executive Order. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. While there are some costs associated with these regulations, they do not exceed the monetary threshold for significance as defined under section 3(f)(1) of E.O. 12866, as amended. However, the regulation is significant and has been reviewed by OMB.

As previously discussed, ORR has developed the child abuse and neglect investigation requirements for ORR care provider facilities with the intention of keeping the best interests of unaccompanied children at the forefront. Because the requirements in this IFR are in line with existing ORR policy, ORR anticipates that care provider facilities will need to make only minimal updates to their staffing, training, and/or policy in order to meet the requirements. Specifically, ORR anticipates that care provider facilities will need to make updates to meet requirements under § 412.101(c) and § 412.103. Typically, ORR care provider facilities spend up to approximately 5 hours to cooperate with a State-led investigation of alleged child abuse or neglect, which can vary widely depending on the circumstances of the specific allegation. ORR expects that its Texas care provider facilities will spend the same amount of time cooperating with investigations conducted by ORR. Because ACF lacks the ability to account for the specific details of every care provider facility and their ability to meet the requirements, ORR is only able to estimate costs associated with other remedies in general, rather than specific to each care provider facility.

To estimate the economic impacts associated with the policies promulgated in this interim final rule, ACF uses wage rate and annual salary data provided by BLS for Childcare Workers and First-Line Supervisors working in the Child Care Services industry.[55] [56] The median hourly wage rate for childcare workers is calculated to be $14.60. Assuming benefits and indirect costs of labor equal 100 percent of the hourly wage, the corresponding fully loaded cost of labor for childcare workers is $29.20 per hour. Additionally, the mean hourly wage rate for First-Line Supervisors working in the Child Care Services industry is calculated to be $22.45. Note that we do not use the median wage rate because BLS only provides mean wage rates for specific industries. Assuming benefits and indirect costs of labor equal 100 percent of the hourly wage, the corresponding fully loaded cost of labor for childcare supervisors is $44.90 per hour. ORR assumes that it will take between 0.25 and 0.5 hours at a cost between $7.30 ($29.20 × 0.25 hours) and $14.60 ($29.20 × 0.5 hours) for each childcare worker to receive the relevant policy update training and between $11.23 ($44.90 × 0.25 hours) and $22.45 ($44.90 × 0.5 hours) for each childcare supervisor to administer the training. This training would include administrative guidance related to how investigations will be conducted and due process under the interim final rule. ORR also assumes that it will take approximately 1 hour at a cost of $44.90 ($44.90 × 1 hour) for each childcare supervisor to update relevant policies.

In § 412.100(a) through (g) ORR discusses the establishment and operation of its investigations into alleged child abuse and neglect. Currently, based on FY 2024 levels of wages, benefits, and indirect labor costs, ORR estimates 24 full-time staff will be required at a cost of approximately $209,000 per staff member for a total of approximately $5 million ($209,000 ×

[55] *https://www.bls.gov/oes/current/oes399011.htm.* Accessed July 31, 2024.

[56] *https://www.bls.gov/oes/current/oes391022.htm.* Accessed July 31, 2024.

24 staff) per year. The ORR Child Welfare Investigators will receive allegations of child abuse and neglect as intake reports, assess the allegation to determine whether it meets applicable requirements and definitions, conduct all necessary interviews, review and preserve all relevant evidence, implement any necessary safety plans, coordinate with the multidisciplinary team as needed, and render a disposition. ORR expects no new costs or burdens on care provider facilities to cooperate with ORR's investigations.

ORR also notes that all care provider facilities discussed in this interim final rule are ACF grantees and the costs of maintaining compliance with the requirements are allowable costs to grant awards under the Basic Considerations for cost provisions at 45 CFR 403 through 405, in that the costs are reasonable, necessary, ordinary, treated consistently, and are allocable to the award. Additional costs associated with the policies discussed in this interim final rule that were not budgeted, and cannot be absorbed within existing budgets, would be allowable for the grant recipient to submit a request for supplemental funds to cover the costs.

B. Regulatory Flexibility Analysis

The Secretary certifies under 5 U.S.C. 605(b), as enacted by the Regulatory Flexibility Act (Pub. L. 96–354), that this rule will not result in a significant impact on a substantial number of small entities. This rule primarily affects the operations of the Federal Government and requires that ORR care provider facilities within the scope of this rule cooperate with Federal investigations of child abuse and neglect. As of publication of this rule, 66 of 284 (23 percent) ORR care provider facilities are located in Texas and would be impacted by the requirements in this interim final rule. While the affected percentage of small entities exceeds the threshold of 5 percent for this subcategory of care provider facilities within the U.S., ORR believes the burden associated with the requirements in this interim final rule are equal to or negligibly greater than the burden imposed by any State-based requirements to which the affected care provider facilities would otherwise be subjected. While this rule primarily affects the Federal Government, ORR assumes all of these care provider facilities qualify as small businesses as defined by the Small Business Administration (SBA), and ORR has therefore attempted to ensure the economic impact on individual care provider facilities is kept to a minimum.

C. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires ORR to prepare a written statement, which includes estimates of anticipated impacts, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $177 million, using the most current (2022) Implicit Price Deflator for the Gross Domestic Product. This interim final rule would not likely result in unfunded expenditures that meet or exceed this amount.

D. Executive Order 13132: Federalism

This interim final rule would not have substantial direct effects on the States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government. This interim final rule would implement ORR's explicit statutory authority to investigate child abuse and neglect allegations in ORR care provider facilities, and would enable it to make findings relevant to its responsibility for the care of unaccompanied children. In codifying these practices, ORR was mindful of its obligations to meet the requirements of Federal statutes while also minimizing conflicts between State law and Federal interests. At the same time, ORR is also mindful that its fundamental obligations are to ensure that it implements its statutory responsibilities pursuant to both the HSA and TVPRA, to protect the safety of unaccompanied children while in ORR care.

Typically, ORR enters into cooperative agreements or contracts with non-profit and private organizations to provide shelter and care for unaccompanied children in a care provider facility licensed by the appropriate State or local licensing authority if the State licensing agency provides for licensing of care provider facilities that provide services to unaccompanied children. This regulation allows ORR to investigate allegations of child abuse and neglect only in instances where a State will not investigate allegations of child abuse and neglect in ORR care provider facilities, and at EIFs. ORR has designed its policies and regulations, as well as the terms of its cooperative agreements and contracts with the unaccompanied children care provider facilities, to complement applicable State and local licensing rules, not to supplant or replace the requirements. Because the applicability of this regulation is limited precisely to circumstances where a State does not investigate child abuse and neglect at ORR care provider facilities, and EIFs, it does not implicate federalism concerns or impose substantial direct compliance costs on State or local governments. Further, this regulation does not preempt State laws and regulations because it applies specifically where States have explicitly abdicated their investigatory responsibility in ORR care provider facilities housing unaccompanied children, and at EIFs where States may not have authority to conduct investigations. Where State or local authorities enter into formal written agreements with ORR to conduct investigations, ORR may still, pursuant to its statutory authority, carry out its own investigations, but any potential ORR investigation under this rule would not interfere with the State or local authority's investigation.

Therefore, in accordance with section 6 of Executive Order 13132, it is determined that this interim final rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

Notwithstanding the determination that the formal consultation process described in Executive Order 13132 is not required for this rule, ORR welcomes any comments from representatives of State and local juvenile or family residential facilities—among other individuals and groups—during this rulemaking.

E. Executive Order 12988: Civil Justice Reform

This interim final rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

IX. Assessment of Federal Regulation and Policies on Families

Section 654 of the Treasury and General Government Appropriations Act of 1999 requires Federal agencies to determine whether a policy or regulation may affect family well-being. If the agency's determination is affirmative, then the agency must prepare an impact assessment addressing criteria specified in the law. This regulation will not have an impact on family well-being as defined in this legislation, which asks agencies to assess policies with respect to whether the policy: strengthens or erodes family

stability and the authority and rights of parents in the education, nurture, and supervision of their children; helps the family perform its functions; and increases or decreases disposable income.

Dated: November 20, 2024.

Xavier Becerra,

Secretary, Department of Health and Human Services.

List of Subjects in 45 CFR Part 412

For the reasons set forth in the preamble, the ORR adds 45 CFR part 412 to read as follows:

PART 412—INVESTIGATIONS OF ALLEGATIONS OF CHILD ABUSE AND NEGLECT

Sec.

412.001 Definitions
412.100 Investigations of allegations of child abuse and neglect
412.101 Interventions and discipline
412.102 Appeal and review process
412.103 Obligations of care provider facilities

PART 412—INVESTIGATIONS OF ALLEGATIONS OF CHILD ABUSE AND NEGLECT

§ 412.001 Definitions.

ACF means the Administration for Children and Families, Department of Health and Human Services.

Administrative closure means that ORR has determined that it will not make a finding regarding an allegation of child abuse or neglect. ORR may make a determination of administrative closure both before and after an investigation begins. Reasons for administrative closure of an intake report before investigation may include, but are not limited to, lack of jurisdiction to conduct an investigation of the allegation, transfer of the report to another jurisdiction or agency, duplication of an already existing report, an allegation not rising to the level of child abuse or neglect, or an allegation is otherwise outside the scope of this rule, as described at § 412.100(c). Reasons for a disposition of administrative closure after investigation may include, but are not limited to, inability to contact the child, insufficient information to proceed with the investigation, or transfer of the report to another jurisdiction or agency.

Allegation means a written or oral report to ORR of suspected child abuse or neglect.

Alleged perpetrator means a person who is alleged to have abused or neglected a child within the scope of this part as described at § 412.100(a) and (c).

Appeal and review process means the appeal to an Administrative Law Judge (ALJ) of the HHS Departmental Appeal Board (DAB), and review by the Assistant Secretary for ACF of the disposition that an allegation of child abuse or neglect was substantiated at Tier I or Tier II.

Attorney of record has the same definition as provided under 45 CFR 410.1001.

Care provider facility has the same definition as provided under 45 CFR 410.1001.

Child abuse and neglect means any act or failure to act which results in death, serious physical or emotional harm, sexual abuse, or exploitation of a child; or an act or failure to act which presents an imminent risk of serious harm to a child including but not limited to physical abuse, verbal or emotional abuse, sexual harassment, sexual abuse, inappropriate sexual behavior, neglect, and medical neglect.

Child advocates has the same definition as provided under 45 CFR 410.1001.

Contractor means an entity that receives a contract as provided under 45 CFR 75.2.

Days means calendar days, unless otherwise stated.

Disposition means a finding by ORR at the conclusion of an investigation that an allegation of abuse or neglect is substantiated at Tier I, substantiated at Tier II, not substantiated, unfounded, or administratively closed.

Emergency or influx facility (EIF) has the same definition as provided under 45 CFR 410.1001.

HHS means the U.S. Department of Health and Human Services.

Inappropriate sexual behavior refers to inappropriate sexual, derogatory, or offensive conduct that does not rise to the level of sexual abuse or sexual harassment.

Intake report means an allegation of child abuse or neglect identified by ORR as describing child abuse or neglect of an unaccompanied child by an alleged perpetrator.

Legal service provider (LSP) has the same definition as provided under 45 CFR 410.1001.

Medical neglect means any failure to provide medical care or access to medical services that endangers the health of the child.

Multidisciplinary team is a group of individuals comprised of ORR staff that includes subject matter experts that provides input to ORR's Child Welfare Investigators by assessing reported allegations of child abuse and neglect at care provider facilities and making recommendations regarding the physical and behavioral healthcare needs of unaccompanied children potentially impacted by child abuse and neglect at these facilities.

Neglect refers to any failure to provide adequate food, water, clothing, shelter, or other necessities; punitive, careless, or unnecessary denial of access to other basic services such as education, legal aid, exercise, recreation, bathroom usage, and communication or correspondence with families, sponsors, or attorneys.

Not substantiated allegation means a disposition that there is not a preponderance of the evidence establishing that the alleged perpetrator committed child abuse or neglect, but there is at least some evidence that the unaccompanied child was harmed or placed at risk of harm, whether or not by the alleged perpetrator.

ORR means the Office of Refugee Resettlement, Administration for Children and Families, U.S. Department of Health and Human Services.

ORR Central Registry means a database maintained by ORR consisting of ORR findings of sustained perpetrators of child abuse and neglect at Tier I.

ORR Child Welfare Investigator means an ORR staff member who investigates reports of alleged abuse or neglect of children, renders the investigative disposition, and issues corrective action on behalf of ORR and performs other related work for ORR.

Physical abuse means physical harm to a child that includes, but is not limited to, bruises, cuts, sprains, welts, fractures, burns, lacerations, missing or broken teeth, muscle strains, or internal injuries; in addition to physical mistreatment such as whipping, punching, shoving, kicking, hitting, biting, shaking, dragging, throwing, stabbing, or choking a child, as well as the inappropriate use of restraints.

Preponderance of the evidence means proof, after assessing the totality of available information, that leads to the conclusion that the fact at issue is more probably true than not.

Sexual abuse has the same definition as provided under 45 CFR part 411.6.

Sexual harassment has the same definition as provided under 45 CFR part 411.6.

Sub-grantee means a person or entity that receives a subaward from a care provider facility to carry out activities and programs of ORR or the care provider facility pursuant to a grant or agreement with ORR or with a care provider facility (but does not include an individual that is a beneficiary of such program).

Substantiated allegation—Tier I means a disposition that there is a preponderance of the evidence establishing that the alleged perpetrator committed child abuse or neglect, and the investigation indicates one or more Automatic Tier I substantiating circumstances are found pursuant to § 412.100(e)(7), or substantiation is warranted based on consideration of aggravating and mitigating factors pursuant to § 412.100(e)(8).

Substantiated allegation—Tier II means a disposition that there is a preponderance of the evidence establishing that the alleged perpetrator committed child abuse or neglect, and that based on consideration of aggravating and mitigating factors pursuant to § 412.100(e)(8), the evidence does not warrant a finding of Substantiated Allegation—Tier I.

Substantiated perpetrator means a person against whom an allegation of child abuse or neglect has been substantiated by ORR at Tier I or Tier II, but who has not exhausted all applicable appeal and review processes for such allegations.

Sustained allegation means an allegation that was substantiated by ORR at Tier I or Tier II and:

(1) That was upheld pursuant to appeal and review processes, as described at § 412.102; or

(2) For which the appeal was dismissed, including when the substantiated perpetrator waives their right to appeal by not making a timely request to the DAB ALJ or by waiving those rights as specified in § 412.102(c).

Sustained perpetrator means a substantiated perpetrator at Tier I or Tier II:

(1) Whose child abuse or neglect finding was upheld in the appeal and review process; or

(2) Whose appeal and review process was dismissed, including due to waiving their right to appeal by not timely requesting an appeal to the DAB ALJ or by waiving those rights as specified in § 412.102(c).

Unaccompanied child/children has the same definition as provided under 45 CFR 410.1001.

Unfounded allegation means a disposition that there is not a preponderance of the evidence establishing that the alleged perpetrator committed child abuse or neglect, and the evidence indicates that the unaccompanied child was not harmed or placed at risk of harm.

Verbal or emotional abuse means any criticisms, comments, behaviors, or threats that cause harm to a child's psychological, intellectual, or emotional functioning or self-esteem, which may be exhibited by a child's anxiety, loneliness, fear, sadness, withdrawal, aggression, or loss of trust with staff.

Volunteer has the same definition as provided under 45 CFR 411.

§ 412.100 Investigations into allegations of child abuse and neglect.

(a) *Purpose.* This part establishes standards, requirements and procedures for investigations by ORR of allegations of child abuse and neglect of an unaccompanied child in ORR custody alleged to have been committed by care provider facility staff, contractors or sub-grantees of the care provider facility, care provider facility volunteers, or other individuals who have access to children in ORR care through contracts or grants with ORR, subject to § 412.100(c).

(b) *Severability.* The provisions of this part are separate and severable from one another. If any provision is stayed or determined to be invalid by a court of law, the remaining provisions shall continue in effect.

(c) *Applicability.* This part applies to:

(1) Care provider facilities housing unaccompanied children in States where the State agency responsible for investigating child abuse and neglect allegations will not investigate such allegations in ORR-funded care provider facilities; and

(2) Emergency or influx facilities (EIFs).

(d) *Reporting.* Care provider facilities to whom this part applies must have written policies and procedures that allow unaccompanied children, care provider facility staff, contractors or sub-grantees of the care provider facility, care provider facility volunteers, families of unaccompanied children, legal service providers, child advocates, attorneys of record, and any other persons, to report allegations of child abuse and neglect to ORR directly, to the care provider facility, or to a designated entity or office that is not part of the care provider facility. The care provider facility written policies and procedures must:

(1) Provide unaccompanied children and other individuals with methods for reporting and inform them of how they can report an allegation of child abuse and neglect to a designated entity or office that is not part of the care provider facility. Such entity or office must be able to receive allegations of child abuse and neglect and must immediately forward such allegations to ORR. The method for reporting must allow unaccompanied children to remain anonymous upon request.

(2) Ensure all the methods of reporting described at § 412.100(d)(1) are accessible for unaccompanied children with disabilities and with limited English proficiency.

(3) Ensure that unaccompanied children, staff, or others who report allegations of child abuse and neglect are protected against retaliation.

(e) *Investigations.* When receiving reports of allegations of child abuse and neglect and conducting investigations, ORR must ensure the health and safety of unaccompanied children while making every effort to reduce further trauma to the alleged victim(s).

(1) If ORR receives a report of an allegation of child abuse or neglect, it must generate an intake report and determine whether the report includes an allegation that, if found to be true, would meet the definition of child abuse and neglect in this part and is consistent with § 412.100(a) and (c). If so, ORR will assign the intake report for investigation. If not, ORR will administratively close the report.

(2) If ORR determines that an intake report is appropriate for investigation, ORR shall assign an ORR Child Welfare Investigator to make a prompt and thorough investigation of the report to obtain sufficient information to determine whether the allegation of child abuse or neglect is substantiated, either at Tier I or II, based on a preponderance of the evidence.

(3) ORR shall provide notification that an allegation of child abuse and neglect will be investigated by ORR to the alleged perpetrator; care provider facility; alleged victim; alleged victim's attorney of record (if the child has an attorney of record); and the alleged victim's parent(s), legal guardian(s), or sponsor(s) (as appropriate), unless ORR has evidence showing the parents, legal guardians, or sponsors should not be notified or the victim is 14 years old or older. If the alleged victim is 14 years old or older and ORR has determined that the alleged victim is able to make an independent decision, the alleged victim can affirmatively consent to disclosure.

(4) Upon notification that an investigation has been initiated, the care provider facility must take immediate responsive measures, for the protection of child welfare, and notify the alleged perpetrator, as appropriate, and ORR of such measures. These measures may extend throughout the pendency of an investigation, and during the pendency of the appeal and review process, as necessary and applicable.

(5) *Investigations process.* (i) ORR shall coordinate with any local or State law enforcement agencies, or other Federal agencies, as appropriate, during its investigation. ORR may pause or

resume an investigation at its discretion, with input from law enforcement partners or other relevant investigatory bodies, as necessary.

(ii) A multidisciplinary team of ORR staff that includes subject matter experts, shall be established, as necessary, to provide input and an assessment of the reported allegation of child abuse or neglect to assist the ORR Child Welfare Investigator.

(iii) During the investigation, the ORR Child Welfare Investigator must complete, at a minimum, the following actions:

(A) Upon receiving an intake report, review the intake report and the care provider facility's records on the alleged victim and alleged perpetrator, conduct background checks on the alleged perpetrator, interview the person who reported the allegation if this person was not interviewed during intake, immediately request preservation of any potential video and documentary evidence, and as needed, establish a plan for thoroughly investigating the allegation;

(B) Visit the care provider facility, as appropriate, to conduct a walkthrough of the facility and review video and documentary evidence;

(C) Make reasonable efforts to interview all individuals who have information relevant to the allegation of child abuse or neglect, including, but not limited to, the alleged perpetrator (as appropriate), care provider facility staff, the alleged victim, sponsor(s), and the parent(s) or legal guardian(s) (as appropriate) of the alleged victim, and any other potential witnesses;

(D) Ensure that interviews conducted as part of the investigation are accessible for individuals with disabilities and with limited English proficiency and are properly documented either in writing or by audio or video recording;

(E) Gather all relevant information, including documents and audio or video evidence;

(F) Review any available evidence of past conduct contained in DCPI's records relating to the same alleged perpetrator, except for allegations that resulted in a finding of unfounded or administrative closure; and

(G) Assess the ongoing risk of child abuse or neglect to the unaccompanied children at the care provider facility and, as appropriate, request that the care provider facility implement a plan to mitigate the risk and ensure the safety of the children.

(6) After the investigation is complete, ORR may make any of the following dispositions based on the preponderance of the evidence for each reported allegation:

(i) Substantiated allegation—Tier I;

(ii) Substantiated allegation—Tier II;

(iii) Not substantiated allegation;

(iv) Unfounded allegation; or

(v) Administrative closure.

(7) *Automatic Tier I substantiating circumstances.* The existence of any one of the following circumstances in connection to a substantiated finding, by a preponderance of the evidence, of child abuse or neglect shall result in an automatic finding of Substantiated allegation—Tier I:

(i) The death or near death of a child as a result of child abuse or neglect;

(ii) Subjecting or exposing a child to sexual abuse or sexual harassment;

(iii) The infliction of injury or creation of a condition requiring a child to be hospitalized or to receive significant medical attention;

(iv) Repeated instances of physical abuse committed by the individual against any unaccompanied child in ORR care;

(v) Failure to take reasonable action to protect a child from sexual abuse or repeated instances of physical abuse under circumstances where the individual knew or should have known that such abuse was occurring; and

(vi) Depriving a child of necessary care (food, shelter, healthcare, supervision) which either caused serious harm or created a substantial risk of serious harm.

(8) *Aggravating factors and mitigating factors.* If ORR determines that there are no automatic Tier I substantiating circumstances under § 412.100(e)(7), ORR shall consider the following aggravating and mitigating factors together in determining if child abuse or neglect should be substantiated at Tier I or II. Consideration of aggravating and mitigating factors will be based on the totality of the circumstances and the interest of protecting child welfare:

(i) *Aggravating factors.* Aggravating factors shall be weighed together with any existing mitigating factors. Aggravating factors include any of the following:

(A) Violations of ORR behavior management requirements pursuant to § 410.1304;

(B) The individual's failure to comply with clearly established care provider facility policies, corrective action plans, or agreed-upon conditions;

(C) The tender age, delayed developmental status or other vulnerability of the child;

(D) Any significant or lasting physical, psychological, or emotional harm to the child;

(E) An attempt to inflict any significant or lasting physical, psychological, or emotional harm to the child;

(F) Evidence suggesting a repetition or pattern of abuse or neglect, including multiple instances in which child abuse or neglect was substantiated at Tier I or Tier II and not substantiated allegations if they demonstrate a pattern of abuse or neglect or harm.

(ii) *Mitigating factors.* Mitigating factors shall be weighed together with any existing aggravating factors. Mitigating factors include any of the following:

(A) Remedial actions taken by the individual before the investigation was concluded;

(B) Extraordinary, situational, or temporary stressors that caused the individual to act in an uncharacteristically abusive or neglectful manner;

(C) The isolated or aberrational nature of the child abuse or neglect; and

(D) The limited, minor, or negligible physical, psychological, or emotional impact of the abuse or neglect on the child.

(f) *Confidentiality.* Records created and information gathered or obtained during an investigation are for internal purposes only, will not be shared or made public unless otherwise required or authorized by law, and may not be disclosed without prior ORR approval. All records must be maintained in an appropriate recordkeeping system with protections for the privacy and security of the individuals identified in the records.

(g) *Notifications of a Disposition.* (1) ORR must notify the alleged perpetrator of the disposition in writing within five days of making a disposition. ORR must also notify in writing the alleged victim, their parent(s) or legal guardian(s) (as appropriate), or sponsor(s), of the disposition within five days of making a disposition.

(2) If the disposition is substantiated at Tier I, the notification must state:

(i) The substantiated perpetrator will be considered a Tier 1 sustained perpetrator and their name and other details related to the relevant abuse or neglect findings will be placed on the ORR Central Registry, unless they seek an appeal of the disposition pursuant to § 412.102, and that once identified in the ORR Central Registry they will be prohibited from working or volunteering in any way on ORR-funded grants or contracts, and may not have access to or contact with any unaccompanied child in ORR custody;

(ii) The reasons for the Tier I substantiated perpetrator's placement on the ORR Central Registry in terms sufficient to put the perpetrator on

notice of the conduct or incident(s) upon which it is based;

(iii) The Tier I substantiated perpetrator may appeal ORR's disposition pursuant to § 412.102, but that if the Tier I substantiated perpetrator either fails to timely submit a notice of appeal, or upon conclusion of the appeal and subsequent review, if any, the disposition is upheld, the Tier I substantiated perpetrator will be added to the ORR Central Registry as a Tier I sustained perpetrator and the disposition will be reported to Federal, State, and local authorities, as appropriate; and

(iv) ORR's procedures for making the disposition.

(3) If the disposition is substantiated at Tier II, the notification must inform the Tier II substantiated perpetrator that they may appeal ORR's disposition pursuant to § 412.102, but that if they either fail to timely submit a notice of appeal, or upon the conclusion of the appeal and subsequent review, if any, the disposition is upheld, the Tier II substantiated perpetrator will be designated as a Tier II sustained perpetrator and ORR's disposition will be retained in ORR records. ORR may use these records to determine patterns of child abuse and neglect and to inform future safety planning at care provider facilities. A Tier II sustained perpetrator will not be placed on the ORR Central Registry.

§ 412.101 Interventions and discipline.

(a) *ORR Central Registry.* (1) ORR will maintain an ORR Central Registry consisting of the names of Tier I sustained perpetrators for purposes consistent with § 412.100(a) and (c). The ORR Central Registry will contain names and other identifying information for such persons, and details regarding any sustained allegations of child abuse and neglect against those persons.

(2) Subject to legal requirements regarding disclosure of information, as well as information sharing obligations with relevant State, local, or Federal authorities, the ORR Central Registry will not be public-facing, nor available to persons outside of ORR. The ORR Central Registry will only be used by ORR to identify Tier I sustained perpetrators, as defined in this part, and for ORR to use as part of the screening process by care provider facilities as described in § 412.101(b).

(b) *Working and Volunteering Prohibitions and Mandatory ORR Central Registry Checks.* (1) The individuals listed in the ORR Central Registry shall be prohibited from working or volunteering in any way on ORR-funded grants or contracts and may not have access to or contact with any unaccompanied child in ORR custody unless ORR removes such individual from the ORR Central Registry.

(2) As part of the screening process for hiring decisions for staff, contractors or sub-grantees, or for screening volunteers, all care provider facilities, home study providers, and post-release service providers, whether or not located in States that investigate child abuse and neglect allegations at ORR care provider facilities, must check with ORR to confirm that an applicant is not listed in the ORR Central Registry.

(3) All care provider facilities, home study providers, and post-release service providers, whether or not located in States that investigate child abuse and neglect allegations at ORR care provider facilities, must also check all of their personnel against the ORR Central Registry at least once annually.

(c) *Disciplinary Sanctions.* Care provider facilities must implement appropriate disciplinary or remedial measures where they or ORR find that care provider facility staff, contractors or sub-grantees of the care provider facility, or care provider facility volunteers whose conduct does not rise to the level of a Tier I substantiated allegation, as defined at § 412.001, but nevertheless raises child welfare concerns.

(d) *Referrals to State, Local, and Other Federal Agencies.* (1) ORR shall refer the names and other identifying information of Tier I sustained perpetrators to relevant State and local authorities and to relevant law enforcement agencies in the State in which the sustained allegation of child abuse or neglect occurred. Additionally, if a State or local authority or relevant local law enforcement agency outside of the State in which the Tier I sustained allegation occurred requests information about the sustained perpetrator, ORR will confirm whether a particular individual is on the ORR Central Registry.

(2) ORR will provide the names and other identifying information of Tier I sustained perpetrators to the Federal Bureau of Investigation and HHS Office of the Inspector General (OIG), consistent with any applicable agreements.

(3) ORR and care provider facilities shall not interfere with another State, local, or Federal authority or agency's investigation into allegations of child abuse and neglect.

§ 412.102 Appeal and review process.

(a) A substantiated perpetrator at Tier I or Tier II may appeal the disposition made by ORR to an Administrative Law Judge (ALJ) of the HHS Departmental Appeals Board (DAB) pursuant to § 412.102(c).

(b) *Notice of Opportunity for an Appeal.* (1) After ORR substantiates an allegation of child abuse and neglect at Tier I or Tier II, it will send a written notice to the substantiated perpetrator at Tier I or Tier II, in accordance with § 412.100(g), with notification that the allegation has been substantiated and that, unless they appeal the disposition by ORR, a Tier I substantiated perpetrator will be placed on the ORR Central Registry as a Tier I sustained perpetrator and a Tier II substantiated perpetrator's information will be retained as a Tier II sustained perpetrator in agency records.

(2) The written notice shall:

(i) Clearly describe the basis for ORR's disposition that substantiates the relevant allegations at Tier I or Tier II and shall explain the Tier I or Tier II substantiated perpetrator's right to appeal the disposition and the steps required to initiate the appeal.

(ii) Inform the substantiated perpetrator that they may appeal the ORR disposition before an ALJ.

(iii) Provide the substantiated perpetrator at Tier I or Tier II and their attorney, if any, with written information and instructions describing the appeal process.

(iv) Inform the substantiated perpetrator at Tier I or Tier II that if they do not submit a notice of appeal within 30 days of receiving the notice of disposition, the DAB will consider the substantiated perpetrator to have waived their opportunity to appeal and any subsequent review. If the appeal is determined to be waived, a Tier I substantiated perpetrator will be identified as a Tier I sustained perpetrator on the ORR Central Registry and a Tier II substantiated perpetrator's information will be retained as a Tier II sustained perpetrator in agency records.

(c) *Notice of Appeal and Dismissal of an Appeal*—(1) *Notice of Appeal.* (i) If the substantiated perpetrator at Tier I or Tier II elects to appeal ORR's disposition that an allegation is substantiated at Tier I or Tier II, they must file a written notice of appeal with the DAB within 30 days of receipt of the written notice of ORR's disposition.

(ii) Within 30 days of receipt of the notice of appeal, ORR shall provide all evidence it used in making its disposition to the DAB.

(iii) ORR shall provide the substantiated perpetrator at Tier I or Tier II and their attorney, if any, all information used in making its disposition except any portion that ORR determines:

(A) Would compromise the safety and well-being of a child, the reporter, or any other person;

(B) Would reveal the identity of a child who furnished information with the understanding that their identity would be held in confidence;

(C) Would reveal the identity of any alleged perpetrator(s) involved in the same case who has an unfounded disposition; or,

(D) Is otherwise prohibited by State or Federal law or regulation. In the case of information being withheld, the substantiated perpetrator at Tier I or Tier II shall be advised of the general nature of the information and the reasons that it is being withheld.

(2) *Dismissal of appeal.* (i) The ALJ shall dismiss an appeal when the substantiated perpetrator waives appeal by not submitting a notice of appeal within 30 days of receiving written notice of ORR's disposition, pursuant to § 410.102(b)(2)(iv), and does not demonstrate good cause for the untimely submission; or when the substantiated perpetrator withdraws the appeal, abandons the appeal, or does not have a right to ALJ review. If the appeal of a Tier I substantiated perpetrator is dismissed, they will be placed on the ORR Central Registry as a Tier I sustained perpetrator. If the appeal of a Tier II substantiated perpetrator is dismissed, ORR will retain the information regarding the Tier II substantiated perpetrator as a Tier II sustained perpetrator in agency records.

(ii) Notwithstanding such dismissal, the DAB may in its discretion temporarily remove the designation of sustained perpetrator at Tier I or Tier II, which would result in ORR removing the individual who was designated as a sustained perpetrator at Tier I from the ORR Central Registry, for situations including, for example, where the ALJ determines that the sustained perpetrator at Tier I or Tier II has established good cause for exceeding the appeal timeframe.

(d) *Appeal of ORR's disposition.* (1) When a substantiated perpetrator at Tier I or Tier II appeals the ORR's disposition to an ALJ pursuant to § 412.102(c)(1)(i), ORR must transmit to the ALJ all of the evidence upon which the disposition was based.

(2) The evidentiary record must contain all documents and other materials, such as video or audio recordings, that were used by ORR in making its disposition. The ALJ may remand the case to ORR if the ALJ determines that the evidentiary record is insufficiently complete to decide whether ORR's disposition is supported by a preponderance of the evidence.

(3) The substantiated perpetrator at Tier I or Tier II may be represented by an attorney and may present the testimony of witnesses, documents, factual data, arguments, or other submissions of proof.

(4) The substantiated perpetrator shall have the burden to show that, considering the totality of the evidence, there is not a preponderance of the evidence to support the substantiated allegation at Tier I or Tier II, and to dispute whether any automatic Tier I substantiating circumstances existed (if applicable) or whether any aggravating factors or mitigating factors existed (if applicable). Both ORR and the substantiated perpetrator may present the testimony of witnesses, documents, factual data, arguments, or other submissions of proof. The testimony of care provider facility staff shall be voluntary and failure to offer such testimony will not be subject to disciplinary action.

(5) If the substantiated perpetrator submits a notice of appeal and the appeal is not dismissed by the ALJ pursuant to § 412.102(d)(7), ORR must notify the alleged victim and the alleged victim's parent(s), legal guardian(s) (as appropriate), or sponsor(s) that that an appeal of ORR's disposition will be conducted by an ALJ. The alleged victim, other child witness(es), and family members of the alleged victim shall not be required to testify. Refusal to testify shall have no bearing on the determination as to whether abuse did or did not take place.

(6) The parties may direct and cross examine witnesses either during a live hearing or pursuant to a record review. The parties will be given an opportunity to file briefs or other written statements as to fact or law.

(7) The ALJ shall conduct a fair and impartial hearing and de novo review to determine whether the substantiated perpetrator proved their burden of showing that, considering the totality of the evidence, there is not a preponderance of the evidence to support the substantiated allegation. The ALJ may either dismiss the case for untimeliness, withdrawal of the appeal, abandonment of the appeal, or because the individual does not have the right to appeal or because of other procedural defects, or will issue a written decision to uphold, modify, or reverse ORR's disposition.

(8) The ALJ shall serve a copy of the decision upon the parties and the Assistant Secretary for ACF. The ALJ's decision shall provide the sustained perpetrator at Tier I or Tier II and their attorney, if any, with instructions for requesting review by the Assistant Secretary for ACF. The ALJ also shall provide a copy of the decision to alleged victim and the alleged victim's parent(s), legal guardian(s) (as appropriate), or sponsor(s). The complete record upon which the decision is based shall be made available to the Assistant Secretary.

(e) *Review of the ALJ's Decision.* (1) A substantiated perpetrator at Tier I or Tier II may request a review of the ALJ's decision within 30 days of receipt of the ALJ's decision, by filing a request for review with Office of the Assistant Secretary for ACF.

(2) The Assistant Secretary for ACF has discretion, within 30 days after receiving a timely submission by a substantiated perpetrator of a request for review of an ALJ's decision under § 412.102(e)(1) to review the ALJ's decision to dismiss a case for untimeliness or other procedural defects, and to affirm, modify, or reverse the ALJ's decision with regard to dismissal or ORR's disposition of the allegation. A review by the Assistant Secretary will determine whether the ALJ's decision was based on a material error of law or fact.

(3) If the Assistant Secretary affirms the ALJ's decision or does not modify or reverse the ALJ's decision within 30 days after receiving a timely review request pursuant to § 412.102(e)(1), the ALJ's decision becomes the final decision of the Assistant Secretary and is binding on the parties.

(4) If the Assistant Secretary modifies or reverses the ALJ's decision pursuant to § 412.102(e)(2), the Assistant Secretary's decision is final and binding.

(5) If at the end of the 30-day period in § 412.102(e)(1), no timely request for review has been made, the Assistant Secretary has 30 days from that point to exercise discretion to review the ALJ's decision. If the Assistant Secretary does not modify or reverse the ALJ's decision, then the ALJ's decision becomes the final decision of the Assistant Secretary and is binding on both parties.

(6) The Office of the Assistant Secretary for ACF shall serve a copy of the final decision upon the parties involved. The Office of the Assistant Secretary for ACF also shall provide a copy of the final decision issued by the Assistant Secretary, based on review on the ALJ's decision under § 412.102(e), to the alleged victim and the alleged victim's parent(s), legal guardian(s) (as appropriate), or sponsor(s).

§ 412.103 Obligations of care provider facilities.

(a) *General requirements.* During any investigation by ORR, a care provider facility must:

(1) Permit ORR unrestricted access to the premises, any physical property on the premises, buildings, staff, and children in the physical custody of the care provider facility;

(2) Permit ORR to conduct interviews with children residing at the care provider facility, and without care provider facility staff, contractors, or sub-grantees of the care provider facility, or care provider facility volunteers present;

(3) Permit ORR to observe the activities of care provider facility staff, contractors, or sub-grantees of the care provider facility, care provider facility volunteers, or other individuals who have access to children in ORR care through contracts or grants with ORR;

(4) Promptly preserve any potential video or documentary evidence;

(5) Promptly provide access to and, upon request, copies of all files, records, reports, data, video recordings, and other information to ORR, either prior to or during the investigation;

(6) Promptly provide access to and contact information for care provider facility staff, contractors, or sub-grantees of the care provider facility, care provider facility volunteers, or other individuals who have access to children in ORR care through other contracts or grants with ORR;

(7) Submit complete and accurate responses to any written questions in a timely manner;

(8) Fully cooperate with ORR;

(9) Fully cooperate with any investigation of the same allegation by State, local, and Federal authorities and relevant law enforcement agencies.

(b) *Protection against retaliation.* Care provider facility staff, contractors, or sub-grantees of the care provider facility, and care provider facility volunteers must not retaliate against any person who in good faith reports or participates in an investigation of child abuse or neglect.

(c) *Obstruction, interference, delay of, or failure to permit an investigation.* Obstruction, interference, delay of, or failure of a care provider facility to permit or cooperate with any investigation under this part, including failure to protect unaccompanied children from retaliation pursuant to § 412.103(b), may result in ORR taking monitoring and enforcement measures including, but not limited to: remote monitoring of the care provider facility; on-site monitoring of the care provider facility; monitoring of the corporate offices to review internal policies and reporting structures, as well as supervisory response to events; limiting or stopping new placements of unaccompanied children at the care provider facility; removing all unaccompanied children from the care provider facility and placing them into other care provider facilities; issuing corrective actions; terminating the cooperative agreement or contract with the care provider facility; or imposing other such remedies for noncompliance applicable to HHS grant recipients and contractors.

(d) *Rights to legal representation, familial supports, and other supports.* During the course of an investigation, care provider facilities must provide unaccompanied children confidential access to attorneys of record and other legal service providers, in a manner consistent with requirements established at 45 CFR 411.55 (as applicable) and 45 CFR 410.1309. Care provider facilities must provide unaccompanied children access to their families, including legal guardians, in a manner consistent with requirements established at 45 CFR 411.55 (as applicable) and 45 CFR 410.1309. Care provider facilities must provide unaccompanied children with access to their child advocates, in a manner consistent with the requirements at 8 U.S.C. 1232(c)(6) and 45 CFR 410.1308. Care provider facilities must also provide unaccompanied children access to health services (including specialists and mental health practitioners), individual counseling sessions, and crisis intervention (including access to outside victim services and rape crisis centers where appropriate) to most appropriately address unaccompanied children's needs, in a manner consistent with requirements established at 45 CFR 410.1307, 45 CFR 410.1311, 45 CFR 410.1302(c)(5), and 45 CFR 411.21 (as applicable).

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 241120–0297]

RTID 0648–XD848

Fisheries Off West Coast States; Coastal Pelagic Species Fisheries; Annual Specifications; 2024–2025 Annual Specifications and Management Measures for Pacific Sardine

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

ACTION: Final rule.

SUMMARY: NMFS is implementing annual harvest specifications and management measures for the northern subpopulation of Pacific sardine (hereafter, Pacific sardine), for the fishing year from July 1, 2024, through June 30, 2025. This rule prohibits most directed commercial fishing for Pacific sardine off the coasts of Washington, Oregon, and California. Pacific sardine harvest is allowed only for use as live bait, in minor directed fisheries, as incidental catch in other fisheries, or as authorized under exempted fishing permits. The incidental harvest of Pacific sardine will be limited to 30 percent by weight of all fish per trip when caught with other stocks managed under the Coastal Pelagic Species (CPS) Fishery Management Plan (FMP), or up to 2 metric tons (mt) per trip when caught with non-coastal pelagic species stocks. The harvest specifications for 2024–2025 include an overfishing limit (OFL) of 8,312 mt, an acceptable biological catch (ABC) and annual catch limit (ACL) of 6,005 mt, and an annual catch target (ACT) of 5,500 mt. This final rule is intended to conserve, manage, and rebuild the Pacific sardine stock off the coasts of Washington, Oregon, and California.

DATES: Effective December 27, 2024.

FOR FURTHER INFORMATION CONTACT: Katie Davis, West Coast Region, NMFS, (323) 372–2126, *Katie.Davis@noaa.gov.*

SUPPLEMENTARY INFORMATION: NMFS manages the Pacific sardine fishery in the U.S. exclusive economic zone (EEZ) off the Pacific coast (*i.e.,* off the U.S. West Coast states of California, Oregon, and Washington) in accordance with the CPS FMP. The CPS FMP and its implementing regulations require NMFS to set annual reference points and management measures for the Pacific

sardine fishery based on the annual specification framework and control rules in the FMP. These control rules include the harvest guideline (HG) control rule, which, in conjunction with the OFL and ABC control rules in the FMP, are used to set required reference points, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (MSA) (16 U.S.C. 1801 *et seq.*). Additionally, the CPS FMP requires additional management measures, intended to restrict harvest, for the Pacific sardine fishery, such as catch restrictions.

NMFS publishes annual specifications in the **Federal Register** to establish these annual reference points (*e.g.,* the OFL, ABC, and ACL) and management measures for each Pacific sardine fishing year. NMFS published proposed specifications and management measures on June 21, 2024 (89 FR 52005). Additionally, in response to a court order, and to avoid a lapse in regulations, NMFS published an interim final rule (89 FR 62668; August 1, 2024) that was effective July 29, 2024, and is in place until replaced by these 2024–2025 final specifications.

Final Reference Points and Management Measures

Based on the 2024 benchmark stock assessment for Pacific sardine, the associated estimated age 1+ biomass of 58,614 mt, the control rule formulas in the FMP, and recent related Court orders, NMFS is implementing, as proposed, an OFL of 8,312 mt, an ABC of 6,005 mt, an ACL of 6,005 mt, and an ACT of 5,500 mt.

The CPS FMP includes a prohibition of the primary directed fishery when the biomass is at or below 150,000 mt. The Pacific sardine primary directed fishery is therefore closed, and Pacific sardine catch during the 2024–2025 fishing season is prohibited unless it is harvested as part of the live bait, tribal, or minor directed fisheries, as incidental catch in other fisheries, or as part of exempted fishing permit (EFP) activities.

The 2024–2025 fishing year specifications can be found in table 1, and management measures are listed after table 1.

TABLE 1—HARVEST SPECIFICATIONS FOR THE 2024–2025 SARDINE FISHING YEAR, IN METRIC TONS

[mt]

Biomass estimate	OFL	ABC	HG	ACL	ACT
58,614	8,312	6,005	0	6,005	5,500

The following are the additional management measures and in-season accountability measures for the 2024–2025 Pacific sardine fishing year:

(1) If landings in the live bait fishery reach 3,000 mt of Pacific sardine, then a per-trip limit of 1 mt of Pacific sardine applies to the live bait fishery;

(2) An incidental per-landing limit of 30 percent (by weight) of Pacific sardine applies to other CPS primary directed fisheries (*e.g.,* Pacific mackerel);

(3) If the ACT of 5,500 mt is attained, then a per-trip limit of 1 mt of Pacific sardine applies to all CPS fisheries (*i.e.,* (1) and (2) will no longer apply); and

(4) An incidental per-landing allowance of 2 mt of Pacific sardine applies to non-CPS fisheries until the ACL is reached.

In addition to the management measures and in-season accountability measures listed in the previous paragraphs, Pacific sardine catch in the minor directed fishery for finfish remains limited to 1 mt per trip per day, and 1 trip per day by any vessel, per regulations at 50 CFR 660.511(d)(2).

Background

At the April 2024 Pacific Fisheries Management Council (Council) meeting, the Council's Scientific and Statistical Committee (SSC) reviewed a Stock Assessment Review (STAR) panel report on the Southwest Fisheries Science Center's 2024 benchmark stock assessment, and also reviewed the benchmark stock assessment itself, titled ''Assessment of the Pacific sardine resource (*Sardinops sagax*) in 2024 for U.S. management in 2024–2025.'' The SSC concluded that the 2024 benchmark assessment for Pacific sardine is the best scientific information available for the management of Pacific sardine. During their review, the SSC noted major improvements in methodology from the 2020 benchmark assessment, including an updated habitat model for assigning fishery catch and survey biomass to the northern and southern subpopulations of Pacific sardine. However, the SSC applied a category 2d sigma uncertainty buffer which, compared to a category 1, equates to a larger allowance for scientific uncertainty, and therefore a lower ABC and a decreased risk of overfishing. During the discussion of the appropriate category, the SSC discussed potential uncertainty in the relationship between sardine productivity and ocean temperatures recently used to calculate the E_{MSY} parameter of the OFL and ABC control rules, as well as uncertainty in the strength of the 2023 year-class represented in the stock assessment, along with other uncertainties in the data used in the assessment.

The CPS FMP control rules, as they apply to annual reference points, use the following formulas:

OFL = Biomass * E_{MSY} * DISTRIBUTION

ABC = Biomass * BUFFER * E_{MSY} * DISTRIBUTION

Biomass. The estimated stock biomass of Pacific sardine ages 1 and older, in metric tons.

E_{MSY}. The exploitation rate for deterministic equilibrium maximum sustainable yield. Since 2014, based on annual recommendations by the Pacific Fishery Management Council's SSC, the E_{MSY} for Pacific sardine has most recently been based on a temperature-recruitment relationship based on a running 3-year average of the California Cooperative Oceanic Fisheries Investigations (CalCOFI) temperature index.

DISTRIBUTION. The average portion of the Pacific sardine biomass estimated to be in the U.S. EEZ off the Pacific coast. DISTRIBUTION is currently defined in the CPS FMP as 87 percent and is based on the average historical larval distribution obtained from scientific cruises and the distribution of the resource according to the logbooks of aerial fish-spotters.

BUFFER. The percentage reduction of the OFL as determined by the SSC's evaluation of scientific uncertainty (sigma) and the Council's risk policy (P*).

Rebuilding Plan and Oceana, Inc., v. Raimondo, et al.

During the 2019–2020 fishing year, the estimated biomass of sardine dropped below its minimum stock size threshold of 50,000 mt, which triggered an overfished determination process. NMFS accordingly declared the stock overfished on June 26, 2019 and notified the Council on July 9, 2019. NMFS worked with the Council to develop a rebuilding plan for Pacific sardine to

implement within two years and finalized it on June 24, 2021 (86 FR 33142). The rebuilding plan maintained the status quo management for Pacific sardine, which includes a complete closure of the primary sardine fishery. Oceana, an environmental non-governmental organization, challenged this rebuilding plan and later included a challenge to the 2023–2024 annual specifications (''2023 Final Rule''; 88 FR 41040), in an action filed in the United States District Court for the Northern District of California: *Oceana, Inc.,* v. *Raimondo, et al.,* No. 5:21–cv–05407–VKD (N.D. Cal., filed July 14, 2021). In its rulings on the challenges, the Court partially vacated the rebuilding plan and held that NMFS failed to demonstrate that it relied on best available science to set the overfishing limits in using the CalCOFI temperature index to determine E_{MSY} for the 2023 Final Rule.

Partially-Vacated Rebuilding Plan

The Court partially vacated the rebuilding plan on June 28, 2024. Accordingly, NMFS cannot rely on the vacated components of the rebuilding plan to guide these annual specifications. The harvest control rules in place before Amendment 18 to the CPS FMP implemented the now partially-vacated rebuilding plan are still applicable. None of the provisions of Amendment 18, whether vacated or not, changed the previously applicable harvest control rules.

E_{MSY}

NMFS considered the recent order from the Court in making a determination that the harvest specifications and management measures in this action would prevent overfishing, rebuild the stock, and are supported by the best scientific information available. As they have in previous years, the SSC recommended an OFL and ABC for the 2024–2025 fishing year that were calculated, in part, by using an E_{MSY} based on a relationship with CalCOFI temperatures as best scientific information available for preventing overfishing. The CPS FMP does not mandate that E_{MSY} be based on this relationship. Under the MSA, the SSC provides scientific advice for NMFS' consideration in fishery management decisions, including ABC and preventing overfishing. Per National Standard 2 at 50 CFR 600.315(a)(2), scientific information that is used to inform decision making should include an evaluation of its uncertainty and management decisions should recognize the risks, such as those to overfishing, associated with the sources of uncertainty. The SSC discussed the potential uncertainty surrounding the use of the CalCOFI-based E_{MSY} when considering their choice of the appropriate sigma for the ABC. NMFS has determined that the use of a Category 2 sigma, as recommended by the SSC, appropriately accounts for any scientific uncertainty and gaps in scientific information that may exist, including any surrounding E_{MSY}, in the information used to calculate the recommended reference points.

In making the determination to approve the OFL and ABC recommended by the Council, NMFS took into account the fact that the SSC recommended that the analysis and assumptions surrounding a CalCOFI based E_{MSY} be revisited. This was one of several scientific recommendations made by the SSC in April 2024. Other recommendations included a potential reconsideration of the need for the precaution provided by the DISTRIBUTION term, noting that a substantial proportion of the U.S. catch in recent years is inferred to be from the southern subpopulation of Pacific sardine and that there has been a decline in the assumed catch of northern subpopulation by Mexico, as well as endorsement of the eight high-priority research recommendations for future sardine stock assessments in the 2024 sardine STAR panel report. All of these recommendations are typical of the scientific process to inform fishery management decisions such as determining an appropriate OFL and ABC to prevent overfishing and achieve optimum yield in the fishery.

NMFS also examined recent and past years' CalCOFI temperatures in relation to this year's calculated CalCOFI-based E_{MSY}. The calculated value for this year is 0.163 and represents the lowest E_{MSY} in 10 years, and falls in the lower range of expected values. The decline in E_{MSY} this year compared to the last 3 years is the result of a high temperature record year in 2020 falling out of the running 3-year average temperature used to calculate E_{MSY}. This effect was also observed between 2014 and 2017 when a very large marine heatwave off the Pacific coast caused unprecedented disruptions in the ocean environment, resulting in high CalCOFI temperatures. The highest CalCOFI temperature in 40 years was recorded in 2015. Such events increase the running 3-year average temperature used to calculate E_{MSY}. To reduce the risk of potentially excessive E_{MSY} values, the SSC recommended in 2014 that a CalCOFI-based E_{MSY} be restricted to a maximum of 0.25 (for reference, this equated to a temperature of 16.16 °C when the median temperature was 15.90 °C). This cap on E_{MSY} was applied to calculations of the reference points for the 2016–2017 and 2018–2019 fishing years.

Although the Court found that NMFS' rationale for exclusively using CalCOFI data to determine E_{MSY} in order to set the 2023–2024 specifications was inadequate, it explicitly declined to prohibit NMFS from employing the CalCOFI-based E_{MSY} in setting catch limits, and stated that the agency must reassess the rebuilding plan and determine how to meet the requirements of the MSA in view of the Court's order. In light of the Court's finding prior to the issuance of the 2024–2025 harvest specifications, and as part of a robust decision-making process, NMFS considered whether there was alternative scientific information, per 50 CFR 600.315(a)(2), that would warrant disapproving the Council's recommendation.

Although E_{MSY} is lower this year than any E_{MSY} used in the last 10 years, NMFS acknowledges there is still scientific uncertainty surrounding the predictive efficacy of the CalCOFI temperature index. However, as explained in both the proposed rule and this final rule, this uncertainty was considered by the SSC and the Council when recommending a 2,307 mt reduction from the OFL to the ABC (*i.e.,* OFL is 8,312 mt but ABC and ACL are both 6,005 mt). Importantly, as discussed in the proposed rule and in the paragraphs that follow, in addition to accounting for any scientific uncertainty surrounding CalCOFI, NMFS also considered the only available alternative to its use, which resulted in a higher value than the CalCOFI-based E_{MSY}, and determined the lower value was appropriate to use in setting this year's specifications.

Currently, there are no other formulaic relationships between Pacific sardine recruitment and an environmental variable on which to base E_{MSY}. However, past analyses have calculated a stochastic (referenced as ''static'' in proposed rule) E_{MSY} of 0.18 when the effects of temperature on productivity are ignored.[1] This value for E_{MSY} was recommended by the SSC and utilized by NMFS as best scientific information available for management in 2012–2014 as an alternative to the default option of applying the temperature-stock relationship due to uncertainty surrounding the

[1] Hurtado-Ferro, F., and Punt, A.E. 2013. Revised analyses related to Pacific sardine harvest parameters. PFMC June 2013 Briefing Book. Agenda Item I.4.b Attachment 1.

relationship at that time.[2] During the Council's April 2023 Pacific sardine harvest specification process, the SSC specifically compared this stochastic value to the CalCOFI-based 2023–2024 E_{MSY} of 0.22 in its discussion of an appropriate OFL buffer: ''There was no support among SSC members for a category 1 designation, but there was some discussion of the merits of a category 2 versus a category 3 assessment. Although uncertainty in E_{MSY} would argue for increased uncertainty in the OFL, it was noted that the 'nondynamic' harvest rate (estimated to maximize long-term yield in stochastic simulations), of 0.18, is not very different from 0.22 based on current SSTs, and that other CPS stocks have rates that are higher still (Pacific mackerel E_{MSY} is ~0.3).'' [3]

NMFS considers this modeled stochastic E_{MSY} of 0.18 as the only available alternative that could have been considered in making OFL determinations for Pacific sardine without the use of the CalCOFI temperature index. However, the Council's SSC recommended to the Council an OFL that utilized the CalCOFI-based E_{MSY} as the best scientific information available. In making the decision to approve the OFL and ABC in this action, NMFS considered the stochastic E_{MSY} of 0.18. NMFS concluded that, at this time, it cannot make a determination that the stochastic E_{MSY} of 0.18 represents a better alternative to the CalCOFI-based E_{MSY} value the SSC recommended as the best scientific information available for determining this year's OFL. Since 2000, when the CPS FMP was adopted and harvest control rules were established for Pacific sardine, it has been determined that making efforts to include environmental information into the management of Pacific sardine is the preferred approach. And although the relatively recent running 3-year average CalCOFI temperatures have resulted in higher values than in previous years, likely as a result of anomalous, although becoming more frequent, oceanographic events, that may appear to contradict the original concept of the environmental E_{MSY}, this year's temperature and resulting E_{MSY} align with the concept as they are both in the lower range of values during a time of relatively low sardine recruitment. NMFS will continue, as it has each year, to evaluate whether the use of the CalCOFI-based E_{MSY} is the best scientific information available for future annual specifications.

As noted in the proposed rule, the Council's recommended OFL, calculated using an E_{MSY} of 0.163, is a lower OFL and therefore more precautionary than an OFL would have been based on the stochastic E_{MSY} of 0.18. Additionally, it has been previously suggested that one approach to set a precautionary proxy fishing mortality rate for small pelagic fish such as Pacific sardine is to use a value that equates to one half of the species natural mortality rate.[4] Based on the estimates of natural mortality from the 2024 Pacific sardine stock assessment, this formula would produce an E_{MSY} in the range of 0.25–0.30. By contrast, the E_{MSY} utilized to calculate the OFL implemented through this action is only 0.163. For these reasons, NMFS has determined that the reference points recommended by the Council are based on the best scientific information available and, therefore, NMFS has determined to implement them through this action.

Annual Catch Limit

Although this action implements an ACL equal to the ABC at 6,005 mt, as envisioned by the FMP, NMFS has determined that as a result of the closure of the directed fishery and additional management measures, landings of the northern subpopulation of Pacific sardine will remain very low and total U.S. sardine landings are highly unlikely to exceed 2,200 mt, similar to what has occurred since the 2015–2016 fishing year, when the directed fishery was closed (see table 2).

TABLE 2—LANDINGS ATTRIBUTED IN THE 2024 PACIFIC SARDINE STOCK ASSESSMENT TO NORTHERN AND SOUTHERN SUBPOPULATIONS OF PACIFIC SARDINE (2014–2023), IN METRIC TONS

Fishing year	ACL	Total landings of Pacific sardine (combined catch of northern and southern subpopulations)	Assumed landings of northern subpopulation of Pacific sardine
2014–2015	23,293	23,113	19,969
2015–2016	7,000	1,919	75
2016–2017	8,000	1,885	602
2017–2018	8,000	1,775	351
2018–2019	7,000	2,278	525
2019–2020	4,000	2,062	627
2020–2021	4,000	2,276	657
2021–2022	3,000	1,772	298
2022–2023	3,800	1,619	517

All sources of catch, including any EFP set-asides, the live bait fishery, and other minimal sources of harvest, such as incidental catch in CPS and non-CPS fisheries and minor directed fishing, will be accounted for against the ACT and ACL. Any Pacific sardine harvested between July 1, 2024, and the effective date of this final rule will count toward the 2024–2025 ACT and ACL.

At the April 2024 Council meeting, the Council recommended apportioning 670 mt of the ACL for two EFP proposals to support stock assessments for Pacific sardine. NMFS published a notice of receipt of EFP applications on June 26, 2024 (89 FR 53396). The comment period closed on July 26,

[2] Prior to 2012, E_{MSY} was based on a relationship with sea surface temperature measured at the Scripps Institution of Oceanography (SIO) pier, in La Jolla, CA. A scientific paper was published calling into question this relationship, so while that was reviewed, 18 percent was used for E_{MSY}. The subsequent review of the SIO pier temperature and E_{MSY} relationship determined it was actually still correlated.

[3] Scientific and Statistical Committee Minutes. April 2023. PFMC. *https://www.pcouncil.org/documents/2023/06/scientific-and-statistical-committee-draft-april-1-2-2023-minutes.pdf/.*

[4] Pikitch, E. et al. 2012. Little Fish, Big Impact: Managing a Crucial Link in Ocean Food Webs. Lenfest Ocean Program. Washington, DC. 108 pp.

2024, and NMFS received no comments. NMFS is deciding whether to issue the EFPs during the promulgation of this final rule. The NMFS West Coast Regional Administrator will publish a notice in the **Federal Register** to announce when catch reaches the incidental limits, as well as any changes to allowable incidental catch percentages or trip limits. Additionally, to ensure that the regulated community is informed of any closure, NMFS will make announcements through other means available, including emails to fishermen, processors, and state fishery management agencies.

Comments and Responses

On June 21, 2024, NMFS published a proposed rule for this action and solicited public comments through July 8, 2024 (89 FR 52005). NMFS received two public comment letters relevant to this action, one from the California Wetfish Producer's Association (CWPA) and one from the non-governmental conservation organization Oceana. After considering the public comments, NMFS made no changes from the proposed rule. The comment from CWPA supported this action. The comment letter from Oceana included multiple comments, some of which are beyond the scope of this action. Additionally, some of the comments and requests provided by Oceana were the subject of recent litigation. The U.S. District Court (N.D. Cal.) has ruled in this case, and NMFS notes that it must complete the remand of the Pacific sardine rebuilding plan by June 1, 2025 (*Oceana, Inc.,* v. *Raimondo, et al.*). NMFS summarizes and responds to those comments from Oceana below.

Comment 1: Oceana states that the E_{MSY} used to set the OFL, ABC, and ACL fails to prevent overfishing and is inconsistent with the best available science on sardine productivity. Oceana states that in NMFS' rationale for continuing to use the CalCOFI index for E_{MSY}, NMFS incorrectly asserts that the identified flaws in the CalCOFI index are due to uncertainty.

Response: NMFS has determined that the OFL and ABC implemented through this action will prevent overfishing and are supported by the best scientific information available. NMFS notes that this issue was the subject of recent court orders: on April 22, 2024, the Court issued an order stating that NMFS failed to demonstrate that it had relied on the best available science in setting the 2023–2024 OFL for Pacific sardine using an exclusively CalCOFI-derived E_{MSY}. As stated in this rule, NMFS took into account the Court's finding on this matter and has determined that reference points established by this action, specifically the OFL and ABC, will prevent overfishing, support the rebuilding of the stock, and are supported by the best scientific information available. In an attempt to address the Court's concern for these 2024–2025 harvest specifications, NMFS expressly considered what available information exists that would necessitate that NMFS disapprove the Council's recommended OFL. As stated above, NMFS considered the only alternative E_{MSY} value previously analyzed and used by the Council's SSC and NMFS, which was 18 percent. The use of the 18 percent E_{MSY} was previously supported by analyses conducted by Hurtado-Ferro and Punt (2013) developed to evaluate the performance of alternative candidate OFL and HG control rule variants. That analysis used a Pacific sardine specific model to calculate an E_{MSY} to examine constant exploitation rate harvest control rules (*i.e.,* an E_{MSY} that does not account for an environmental effect), and is also the E_{MSY} value that was used to project the population in the rebuilding analysis for Pacific sardine.

For this year, the alternative of an 18 percent E_{MSY} would be higher than the CalCOFI-based E_{MSY} value, and would therefore result in a higher OFL than the OFL recommended by the SSC. As described in this rule, the CalCOFI-based E_{MSY} is among the lowest values produced by the CalCOFI (sea surface) temperature index in the past 10 years. The literature cited by the commenter (Zwolinski and Demer, 2019) re-evaluated the correlation between the sea surface temperature E_{MSY} values and recruitment success of the northern subpopulation of Pacific sardine over a specific period of years and suggested that the relationship was no longer statistically valid. However, the same journal article that called into question the validity of the CalCOFI temperature index in predicting the productivity of Pacific sardine stated that ''. . . even a marginally statistically significant environment-dependent recruitment model may be useful. For example, if required by the HCR, it could be used to predict recruitment in the management year and forecast the stock biomass into the following year more precisely than a model without environmental influence.'' [5] While NMFS will continue to evaluate E_{MSY}, it has determined that use of the CalCOFI temperature index is the best scientific information available in setting the 2024–2025 Pacific sardine harvest specifications.

Comment 2: Oceana argues that the stochastic E_{MSY} value of 18 percent is outdated and incorrect and that NMFS fails to analyze other available alternatives for setting the E_{MSY} value for the 2024–2025 specifications. Oceana suggests using an E_{MSY} value of 5 percent from Alternative 3 in Amendment 18 to the CPS FMP to set the OFL. Oceana states that NMFS could alternatively also readily produce an E_{MSY} from the 2024 stock assessment, as it did in the 2022 northern anchovy stock assessment, and use it to calculate the 2024–2025 annual catch specifications.

Response: As stated previously in this rule, in light of the Court's finding that NMFS' rationale for using the CalCOFI based E_{MSY} in the 2023–2024 specifications was inadequate, NMFS re-examined and reviewed the relevant information available to make a determination on approving the OFL and ABC implemented through this action. While Oceana states that the CalCOFI-based E_{MSY} and the stochastic 18 percent E_{MSY} are not consistent with the best scientific information available on sardine productivity, the comment did not offer alternative best scientific information available and NMFS has determined that none exists. Oceana suggests that NMFS consider a 5 percent E_{MSY}; however, NMFS could not, through this action, implement an OFL utilizing a 5 percent E_{MSY} and additionally has no evidence that this would represent best scientific information available. NMFS recognizes that a harvest rate of 5 percent was considered as part of alternative 3 for Amendment 18, and this could remain a potential alternative under any future rebuilding plan; however, NMFS has determined it does not represent the best scientific information available for use as an E_{MSY} to calculate this year's OFL. NMFS has no basis to consider a 5 percent E_{MSY} as alternative best scientific information available. Unlike the stochastic 18 percent described above, 5 percent is not a result of modeling work explicitly designed to calculate E_{MSY}. The 5 percent value under alternative 3 represented a harvest level between status quo management and zero U.S. harvest, which was analyzed as a policy option to explore the differences in potential rebuilding timelines as a result of reduced harvest levels. Absent any support for an E_{MSY} of 5 percent as a basis for calculating the OFL, NMFS could not determine that it was the best scientific information available.

[5] Zwolinski, JP & Demer, DA. 2019. Re-evaluation of the environmental dependence of Pacific sardine recruitment. Fisheries Research, 216, 120–125. *https://doi.org/10.1016/j.fishres.2019.03.022.*

In addition, Oceana's suggestion that NMFS could ''readily'' produce an updated E_{MSY} from the 2024 stock assessment as was done for the central subpopulation of northern anchovy (CSNA) is misleading, because the 2024 sardine stock assessment did not produce an E_{MSY} that could be considered in this rulemaking. The management of Pacific sardine has never utilized an E_{MSY} derived from a stock assessment model. No such E_{MSY} is available because it has not been produced by scientists and peer reviewed, and thus an E_{MSY} derived from a stock assessment model would not be the best scientific information available as required under the MSA. Calculating E_{MSY} for CPS stocks from a stock assessment requires scientists to run multiple data analyses, including reassessments to address potential issues, and these results would then need to be packaged and written up. This is not a straightforward process that could be accomplished and appropriately reviewed in the time available to complete this rulemaking.

The complications of this process are highlighted by the CSNA E_{MSY} development. The most appropriate way to calculate the CSNA E_{MSY} was discussed at multiple meetings, including the STAR panel meeting for the 2022 CSNA assessment as well as a full SSC meeting. These discussions included scientifically technical deliberations on the parameters of the stock assessment that influence the E_{MSY} calculation. Ultimately the SSC recommended an E_{MSY} value resulting from the stock assessment model; however, at the time the SSC noted that uncertainty in that value remained: ''The SSC endorses the E_{MSY} value (labeled F_{MSY} in the assessment) of 0.493 estimated within the assessment, where E is expressed as annual total catch divided by summary age-1+ biomass, while noting that the value of E_{MSY} remains a major uncertainty.'' During the 2024 Pacific sardine stock assessment process an E_{MSY} was not developed. Furthermore, any sort of E_{MSY} from the assessment model for Pacific sardine would likely carry similar uncertainties as those associated with the CSNA value that would require a thorough review and would not be reliable for the 2024–25 specifications.

Comment 3: Oceana states that the proposed ACL would not allow rebuilding within the legally required timeline because it represents a harvest rate and overall catch level that NMFS's rebuilding analysis showed will not rebuild the Pacific sardine population. Oceana states that in contrast, NMFS's rebuilding analysis showed that a constant catch of 2,200 metric tons or a 5 percent harvest rate would rebuild the population.

Response: NMFS acknowledges that the Court's order vacated parts of the rebuilding plan that must be addressed by June 1, 2025, including that the plan failed to rebuild the stock within the statutory timeframe under the MSA. The Court has provided NMFS until June 1, 2025 to develop a new rebuilding plan that will specify a time period for rebuilding Pacific sardine that will be as short as possible, taking into account the status and biology of any overfished stocks of fish, the needs of fishing communities, recommendations by international organizations in which the United States participates, and the interaction of the overfished stock of fish within the marine ecosystem. The rebuilding plan will also include conservation and management measures consistent with achieving rebuilding within the specified time period. It is not required by the Court's order to implement this rebuilding plan in this rule.

Comment 4: Oceana states that given the uncertainties, evidence of previous overfishing, and the need to rebuild, Oceana recommended NMFS use a lower P-star parameter than the 0.4 recommended by the Council. Noting that P-star represents the risk of overfishing.

Response: The choice of P-star is only one factor in creating a buffer between the OFL and ABC to help ensure overfishing is prevented. The other factor used for Pacific sardine is the sigma value recommended by the SSC. This sigma value is intended to capture scientific uncertainty in the OFL estimate. The Council's P-star choice is then intended to capture other factors, such as management uncertainty, in preventing overfishing. There is extremely limited management uncertainty associated with tracking catch levels against the applicable catch reference points for Pacific sardine. NMFS is readily able to track fishing mortality across the various sectors in season to ensure landings do not exceed the ACL or ABC. NMFS therefore has determined that the ABC has been appropriately reduced from the OFL to prevent overfishing.

Comment 5: Oceana states that given the stock remains near the 50,000 mt minimum stock size threshold, the proposed incidental harvest rate of 30 percent is excessive.

Response: The CPS FMP dictates that if the estimated biomass is below 50,000 mt, then the incidental harvest rate is restricted to 20 percent landing by weight. The 2024 estimated biomass is 58,614 mt. Under the CPS FMP, at this value, the incidental rate could be up to 45 percent; therefore, 30 percent is in line with the allowances of the CPS FMP. Additionally, during the 2018–2019 fishing year, the last year that the stock's biomass was more than 50,000 mt, the incidental harvest allowance was 40 percent, and the incidental fishery harvested 272 mt. The following year, the incidental harvest allowance was restricted to 20 percent, and the incidental fishery harvested 249 mt. Increasing the incidental harvest allowance doesn't necessarily change the amount of Pacific sardine catch, but allows more flexibility for vessels to reduce unwanted discards when the catch ratio of sardine to other CPS is greater than 20 percent.

Classification

Pursuant to section 304(b)(1)(A) of the MSA, the NMFS Assistant Administrator has determined that this final rule is consistent with the CPS FMP, other provisions of the MSA, and other applicable law.

This final rule is exempt from review under Executive Order 12866 because it is a routine rule that would implement regulations for less than 1 year.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration during the proposed rule stage that this action would not have a significant economic impact on a substantial number of small entities for the purposes of the Regulatory Flexibility Act. The factual basis for the certification was published in the proposed rule (89 FR 52005, June 21, 2024) and is not repeated here. As a result, a final regulatory flexibility analysis was not required and none was prepared.

Pursuant to Executive Order 13175, this proposed rule was developed after meaningful consultation and collaboration with the Council's tribal representative, who has agreed with the provisions that apply to tribal vessels.

This action does not contain a collection-of-information requirement for purposes of the Paperwork Reduction Act. There are no relevant Federal rules that may duplicate, overlap, or conflict with the proposed action.

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

Dated: November 20, 2024.

Samuel D. Rauch III,

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

[FR Doc. 2024–27685 Filed 11–26–24; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 89, No. 229
Wednesday, November 27, 2024

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–2543; Project Identifier MCAI–2024–00342–T]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc., Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all Bombardier, Inc., Model BD–700–2A12 airplanes. This proposed AD was prompted by the discovery that a partial loss of thrust after an engine failure during a required navigation performance authorization required (RNP–AR) approach under certain weight, altitude and temperature (WAT) conditions, may lead to a descent below the specified path guidance. This proposed AD would require a revision to the existing airplane flight manual (AFM), to incorporate updated WAT tables for RNP–AR approach operations. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by January 13, 2025.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *regulations.gov*. Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2024–2543; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For Bombardier material identified in this proposed AD, contact Bombardier Business Aircraft Customer Response Center, 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–2999; email *ac.yul@aero.bombardier.com;* website *bombardier.com*.
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

FOR FURTHER INFORMATION CONTACT: Joseph Catanzaro, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: 516–228–7300; email: *9-avs-nyaco-cos@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2024–2543; Project Identifier MCAI–2024–00342–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend the proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *regulations.gov*, including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this NPRM.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Joseph Catanzaro, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: 516–228–7300; email: *9-avs-nyaco-cos@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

Transport Canada, which is the aviation authority for Canada, has issued Transport Canada AD CF–2024–22, dated June 13, 2024 (Transport Canada AD CF–2024–22) (also referred to after this as the MCAI), to correct an unsafe condition on all Bombardier, Inc., Model BD–700–2A12 airplanes. The MCAI states that it was discovered that a partial loss of thrust after an engine failure during an RNP–AR approach under certain WAT conditions, may lead to a descent below 75 foot of the path guidance, requiring a go-around. The resultant vertical deviation may exceed allowable approach containment for obstacle clearance and may largely reduce the safety margins in the missed approach.

The FAA is proposing this AD to address the unsafe condition on these products.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA____.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed (Bombardier) Global 7500 Airplane Flight Manual Temporary Revision TR–58, dated March 21, 2024. This material specifies procedures to update WAT tables for RNP–AR approach operations to contain possible vertical deviations within the 75 foot requirement.

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

FAA's Determination

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI and material referenced above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would require a revision to the existing AFM to incorporate updated WAT tables for RNP–AR approach operations that contain possible vertical deviations within the 75 foot requirement.

Compliance With AFM Revisions

Transport Canada AD CF–2024–22 requires operators to ''advise all flight crews'' of revisions to the AFM, and thereafter to ''operate the aeroplane accordingly.'' However, this proposed AD would not specifically require those actions as those actions are already required by FAA regulations.

FAA regulations require operators furnish to pilots any changes to the AFM (for example, 14 CFR 121.137), and to ensure the pilots are familiar with the AFM (for example, 14 CFR 91.505). As with any other flightcrew training requirement, training on the updated AFM content is tracked by the operators and recorded in each pilot's training record, which is available for the FAA to review. FAA regulations also require pilots to follow the procedures in the existing AFM including all updates. 14 CFR 91.9 requires that any person operating a civil aircraft must comply with the operating limitations specified in the AFM. Therefore, including a requirement in this proposed AD to operate the airplane according to the revised AFM would be redundant and unnecessary.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 70 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
1 work-hour × $85 per hour = $85	$0	$85	$5,950

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Bombardier, Inc.: Docket No. FAA–2024–2543; Project Identifier MCAI–2024–00342–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by January 13, 2025.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Bombardier, Inc., Model BD–700–2A12 airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 34, Navigation.

(e) Unsafe Condition

This AD was prompted by the discovery that a partial loss of thrust after an engine failure during a required navigation performance authorization required (RNP–AR) approach under certain weight, altitude, and temperature (WAT) conditions, may lead to a descent below 75 feet of the path guidance, requiring a go-around. The resultant vertical deviation may exceed allowable approach containment for obstacle clearance and may reduce the safety margins in the missed approach.

(f) Compliance

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

(g) Revision of Existing Airplane Flight Manual (AFM)

Within 30 days after the effective date of this AD, revise the existing AFM to include the information specified in (Bombardier) Global 7500 Airplane Flight Manual Temporary Revision TR–58, dated March 21, 2024.

(h) Additional AD Provisions

The following provisions also apply to this AD:

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

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

(i) Additional Information

For more information about this AD, contact Joseph Catanzaro, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: 516–228–7300; email: *9-avs-nyaco-cos@faa.gov.*

(j) Material Incorporated by Reference

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

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

(i) (Bombardier) Global 7500 Airplane Flight Manual Temporary Revision TR–58, dated March 21, 2024.

(ii) Reserved

(3) For material identified in this AD, contact Bombardier Business Aircraft Customer Response Center, 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–2999; email *ac.yul@aero.bombardier.com;* website *bombardier.com.*

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

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

Issued on November 21, 2024.

Victor Wicklund,

Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2024–27784 Filed 11–26–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2024–2530; Airspace Docket No. 24–ASO–33]

RIN 2120–AA66

Amendment of Class E Airspace; Ahoskie, NC

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Class E airspace extending upward from 700 feet above the surface for Ahoskie, NC, by adding airspace for ECU Health Roanoke Chowan Heliport, Ahoskie, NC. This action also proposes to amend the airport information for Tri-County at Henry Joyner Field Airport by updating the airport name and coordinates. Additionally, this action would bring the Ahoskie Class E airspace into compliance with FAA orders. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations at this airport.

DATES: Comments must be received on or before January 13, 2025.

ADDRESSES: Send comments identified by FAA Docket No. FAA–2024–2530 and Airspace Docket No. 24–ASO–33 using any of the following methods:

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

* *Mail:* Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.

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

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

Docket: Background documents or comments received may be read at *www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except for Federal holidays.

FAA Order JO 7400.11J Airspace Designations and Reporting Points and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/.* You may also contact the Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Marc Ellerbee, Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Avenue, College Park, GA 30337; Telephone: (404) 305–5589.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority, as it would amend Class E airspace in Ahoskie, NC.

Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should submit only one time if comments are filed electronically, or commenters should

send only one copy of written comments if comments are filed in writing.

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments it receives on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this proposal in light of the comments it receives.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edits, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

Availability of Rulemaking Documents

An electronic copy of this document may be downloaded through the internet at *www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Operations office (see **ADDRESSES** section for address, phone number, and hours of operations). An informal docket may also be examined during regular business hours at the office of the Eastern Service Center, Federal Aviation Administration, Room 210, 1701 Columbia Ave., College Park, GA 30337.

Incorporation by Reference

Class E airspace designations are published in Paragraph 6005 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document proposes to amend the current version of that order, FAA Order JO 7400.11J, Airspace Designations and Reporting Points, dated July 31, 2024, and effective September 15, 2024. These updates will be published in the next update to FAA Order JO 7400.11. FAA Order JO 7400.11J is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11J lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA proposes an amendment to 14 CFR part 71 to amend Class E airspace by adding airspace extending upward from 700 feet above the surface within a 6-mile radius of ECU Health Roanoke Chowan Heliport, Ahoskie, NC. This action also proposes to correct the coordinates and airport name for Tri-County at Henry Joyner Field Airport. Additionally, this action would remove the city associated with the airport in the airspace legal description to comply with changes to FAA Order JO 7400.2P, Procedures for Handling Airspace Matters. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations in the area.

Regulatory Notices and Analyses

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

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' prior to any final regulatory action by the FAA.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11J, Airspace Designations and Reporting Points, dated July 31, 2024, and effective September 15, 2024, is amended as follows: Paragraph 6005. Class E Airspace Areas Extending Upward from 700 feet or More Above the Surface of the Earth.

* * * * *

ASO NC E5 Ahoskie, NC

Tri-County at Henry Joyner Field Airport, NC
(Lat. 36°17′51″ N, long. 77°10′15″ W)
ECU Health Roanoke Chowan Heliport, NC
(Lat. 36°17′5″ N, long. 76°59′44″ W)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Tri-County at Henry Joyner Field Airport and within a 6-mile radius of ECU Health Roanoke Chowan Heliport.

* * * * *

Issued in College Park, Georgia, on November 21, 2024.

Patrick Young,

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

[FR Doc. 2024–27697 Filed 11–26–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE INTERIOR

National Park Service

36 CFR Parts 7 and 21

[NPS–HOSP–DTS38124; XXXP1039C6, PPMWHOSPM0, PRCRURUC6.U00000]

RIN 1024–AE86

Hot Springs National Park; Use of Thermal Water and Commercial Passenger-Carrying Vehicles

AGENCY: National Park Service, Interior.

ACTION: Proposed rule.

SUMMARY: The National Park Service (NPS) proposes to amend the special regulations for Hot Springs National Park to update regulations about the use of thermal water. The NPS also proposes to remove outdated regulations concerning commercial passenger-carrying motor vehicles.

DATES: Comments on the proposed rule must be received by 11:59 p.m. ET on January 27, 2025.

ADDRESSES: You may submit comments, identified by Regulation Identifier Number (RIN) 1024–AE86, by either of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *https://www.regulations.gov/.* Follow the instructions for submitting comments.

(2) *By hard copy:* Mail to: Superintendent, Hot Springs National Park, 101 Reserve Street, Hot Springs, Arkansas 71901.

Instructions: Comments will not be accepted by fax, email, or in any way other than those specified above. All submissions received must include the words ''National Park Service'' or ''NPS'' and must include the docket number or RIN (1024–AE86) for this rulemaking. Comments received may be posted without change to *https://www.regulations.gov/,* including any personal information provided.

Docket: For access to the docket to read comments received, go to *https://www.regulations.gov/* and search for ''1024–AE86''

FOR FURTHER INFORMATION CONTACT: Laura Miller, Superintendent, Hot Springs National Park; (501)–620–6735; *laura_a_miller@nps.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States. In compliance with the Providing Accountability Through Transparency Act of 2023, the plain language summary of the proposal is available on *Regulations.gov* in the docket for this rulemaking.

SUPPLEMENTARY INFORMATION:

Background

Purpose and Significance of Hot Springs National Park

Hot Springs National Park is a 5,500-acre park in Hot Springs, Arkansas, located approximately 55 miles southwest of Little Rock, Arkansas. The U.S. Congress created the park in 1832 when it designated the land as Hot Springs Reservation. In 1921, the reservation name was changed to Hot Springs National Park. Today, the NPS administers the park as one of more than 400 units of the National Park System.

The purpose of the park is to protect its unique geothermal spring water and associated lands for public health, wellness, and enjoyment. The park encompasses mostly forested mountains but includes a developed urban edge formed by Bathhouse Row, which was designated a national historic landmark in 1987. The NPS preserves and manages natural and cultural resources in the park for over 1.5 million annual visitors. Geothermal spring water originating within the park provides ample opportunities for public recreation, health, and wellness activities, including therapeutic bathing. The NPS collects and distributes thermal water to public fountains and to various entities (referred to collectively as bathhouses), including spas, a hotel, and a brewery, within and outside the park. The public uses and enjoys thermal water in bathhouses, by viewing display springs, and by collecting and drinking water free of charge from public fountains.

Legal Framework for the Use of Thermal Water

Under the NPS Organic Act of 1916, the NPS has broad authority to regulate the use of the lands and waters within National Park System units. See 54 U.S.C. 100101; 100751(a). The enabling act that established Hot Springs National Park, now codified at 16 U.S.C. Subchapter XL, specifically authorizes the NPS to make all needful rules and regulations regarding the use of thermal water, including the use of thermal water by bathhouses. 16 U.S.C. 363. The park's enabling act authorizes specific uses and establishes conditions for the use of thermal water. 16 U.S.C. 361–363. In 1959, the NPS promulgated regulations, now codified at 36 CFR 7.18(b), prohibiting the removal of water from any source of supply within the park for the purpose of sale, or for any use other than personal drinking. In 1979, the NPS promulgated regulations, now codified at 36 CFR part 21, governing bathhouses that receive thermal water originating in the park and use it for purposes authorized by the superintendent. These regulations primarily address bathing in thermal water for medical treatment. They contain specific provisions about registration of prescribing physicians, health examinations for infectious or communicable diseases, and the control of persons with acute or infectious diseases and other maladies.

Since 1979, the use of thermal water in bathhouses has evolved. Historical use of thermal water for medicinal purposes has been largely replaced by bathing for recreation or general health and wellness. The NPS receives requests for new uses of thermal water within and outside the park and the existing regulations do not clearly define procedures and standards for evaluating such requests. In particular, the existing regulations do not provide adequate notice about specific provisions in the park's enabling act about written instruments, priority users, surplus water, and rates and costs, none of which are addressed in the existing regulations.

Proposed Rule

Summary of the Proposed Rule

The NPS proposes to update park regulations about the use of thermal water to reflect contemporary uses of water and provisions in the park's enabling act about the use of thermal water. For easier reference and improved transparency, all regulations addressing the use of thermal water would be located in paragraph (b) of § 7.18, rather than split between paragraph (b) of § 7.18 and part 21. This rule would remove part 21 in its entirety. This rule also would remove existing regulations in part 21 about registration of physicians (§ 21.4), requirements to have medical prescriptions before bathing (§ 21.5), control of persons with diseases and other maladies (§ 21.6), health examinations and infectious diseases (§ 21.7), solicitation by bathhouse employees for tips (§ 21.9), loss of personal valuables (§ 21.10), and the redemption and loss of bath tickets (§§ 21.11–21.12) as outdated and unnecessary because of changes in how the public uses thermal water and changes in how bathhouses operate.

In addition to updating regulations about the use of thermal water, this rule would revise existing paragraph (a) in § 7.18. This paragraph contains outdated permit and fee requirements for commercial passenger-carrying motor vehicles operating in the park. The NPS has a statutory authority to manage these services through commercial use authorizations (CUAs) that it did not have when paragraph (a) was promulgated. 54 U.S.C. 101925. Consistent with this authority, the NPS manages commercial passenger-carrying motor vehicles in the park through CUAs and applicable policy. In order to provide notice to the public, including affected service providers, this rule would replace the existing language in paragraph (a) with a statement that CUAs and fees for the operation of commercial passenger-carrying vehicles will be required in accordance with 54 U.S.C. 101925.

Below is a paragraph-by-paragraph analysis of the proposed rule that explains changes to existing similar regulations, if any.

Section-by-Section Analysis

Paragraph (b)(1)—Definitions

Proposed regulation	Existing regulations
§ 7.18(b)(1) Definitions.	• § 7.18(b) Use of water. • § 21.1 Definitions.

Existing regulations in § 21.1 define the terms ''physician,'' ''registered physician,'' ''employee,'' and ''bathhouse''. The proposed rule would remove definitions for ''physician'' and ''registered physician'' because those terms would no longer be used in the regulations due to changes in how thermal water is used by the public. The existing definition of ''employee'' is any person licensed or certified by a State or territory in his or her specialty, or certified by the superintendent to perform special services in a bathhouse. The rule would remove the definition of ''employee'' as redundant with a provision in new paragraph (b)(3)(v) that would require bathhouses to ensure and maintain employee licenses and certifications where required by Federal or State law. The remainder of the existing definition of ''employee'' is outdated and unnecessary because the superintendent no longer issues such certifications.

The proposed rule would simplify the definition of ''bathhouse'' by removing unnecessary references to individuals, trustees, partnerships, corporations, and business entities as potential operators, which is not relevant to the issue of authorized use of thermal water. Instead, the definition would simply state that bathhouse is a facility authorized to use thermal water for any purpose pursuant to a written instrument signed by the superintendent.

The proposed rule would add a new definition of ''bathing'' to mean soaking in thermal water for health benefits. This definition is necessary to implement a distinction in the park's enabling act about rates charged to bathhouses for use of thermal water, explained below. The proposed rule would add a new definition of ''thermal water'' to mean water that emerges from springs, fountains, or other natural sources within the park. This language is similar to language in existing paragraph (b) of § 7.18 and serves to distinguish water that is subject to NPS administration, and water that is not. The rule would add a new definition of ''use of thermal water'' to mean heating, cooling, storing, removing from the park, combining with other substances, or otherwise altering thermal water in any manner. This definition is intentionally broad to include any possible use so that the NPS can effectively protect this resource through restrictions and conditions on the use of thermal water that appear elsewhere in the regulations. Finally, the rule would add a definition of ''water treatment'' to mean the introduction of any substance into thermal water, including chemicals, solutions, or other water. This type of use would be further defined because it requires specific approval by the NPS Office of Public Health (OPH), as explained below.

Paragraph (b)(2)—Use of Thermal Water

Proposed regulation	Existing regulations
§ 7.18(b)(2) Use of thermal water.	• § 7.18(b) Use of water. • § 21.3 Use of thermal water.

Existing regulations in § 7.18(b) prohibit the carrying away of water, hot or cold, from any of the springs, fountains, or other sources of supply in the park for the purpose of sale, or for any use other than personal drinking. Existing regulations in § 21.3 prohibit the use of thermal waters for purposes other than those authorized by the superintendent. They further prohibit the heating, reheating, or otherwise increasing the temperature of thermal water, and the introduction of any substance, chemical, or other material or solution into thermal waters, except as may be prescribed by a physician for a bather or as may be directed by the superintendent.

This rule would replace these existing regulations with new paragraph (b)(2) of § 7.18. In order to continue to protect the integrity of thermal water, new paragraph (b)(2)(i) would prohibit the use of thermal water except by individuals for personal consumption or as authorized in writing by the superintendent. As explained above, the new definition of ''use of thermal water'' would be broad enough to include any of the specific uses of water prohibited by the existing regulations.

Under the rule, the superintendent's authority to allow use of thermal water would be limited to use that is consistent with the purposes of the park, including the protection of natural resource values. The park's Foundation Document (2022) states that the purpose of the park is to protect its geothermal spring water and associated lands for public health, wellness, and enjoyment. This regulatory provision, then, would allow the superintendent to authorize the use of thermal water for the general public welfare, to include, for example, use of thermal water for bathing, drinking, and relaxation, but not in a manner that is inconsistent with the mandate to protect the resource. The rule would more specifically prevent the superintendent from authorizing the removal of thermal water from the park for direct sale or use in products for sale. This would not prevent the superintendent from authorizing the use of thermal water by bathhouses that are commercial operations. Historic and contemporary bathhouses have and continue to operate as commercial businesses, such as spas, hotels, and (most recently) a brewery. This provision, similar to existing § 7.18(b), would prohibit the commercial exploitation of thermal water as a product that is created, packaged, and sold outside of the park or any bathhouse. These types of uses are too far removed from the establishment of the park as an in-situ reserve where the public can visit and benefit from thermal water originating in the park.

The last sentence of new paragraph (b)(2)(i) would state that the superintendent, in addition to any other appropriate written instrument, may use lease agreements to authorize the use of thermal water, but only those lease agreements specifically authorized by the park's enabling legislation. The NPS intends this specific reference to the park's enabling legislation to clarify that lease agreements entered into by the NPS under its general leasing authority in 54 U.S.C. 102102, as implemented by NPS regulations in 36 CFR part 18, should not be used to authorize the use of thermal water.

New paragraph (b)(2)(ii) would require all water treatment to be approved by the OPH, and be limited to the minimum amount and type necessary for the maintenance of public health and safety, as determined by the OPH.[1] This provision would codify an additional level of protection for thermal water in NPS regulations. This is consistent with existing practice, as NPS staff at the park work closely with OPH officers to maintain the health and safety of thermal water. The rule would not include the allowance in existing § 7.18(b) that physicians can prescribe the introduction of substances into thermal water for a bather. Bathing for medicinal purposes is not a

[1] Water treatment also may be subject to approvals from local, county or State officials that have been delegated authority to enforce Federal statutes such as the Safe Drinking Water Act.

contemporary use of thermal water and the employees of the OPH are more appropriate subject matter experts than personal physicians to determine the potential impacts of water treatment on public health.

New paragraphs (b)(2)(iii)–(v) would codify in NPS regulations, for the first time, provisions in the park's enabling act that establish priority uses of thermal water by bathhouses located within and outside of the park. Restating these provisions in a more accessible format would benefit the NPS and existing and prospective bathhouses. Bathhouses would better understand how the park's enabling act prioritizes the use of thermal water among authorized users. Bathhouses also would better understand the requirement that there be a surplus of thermal water before the superintendent can authorize bathhouses located outside of the park, except for the Arlington Hotel, to use thermal water. New paragraph (b)(2)(iii) would restate the order of priority for using thermal water, consistent with 16 U.S.C. 362:

1. Bathhouses located within the park, in the order in which they were authorized to use thermal water.
2. Arlington Hotel.
3. Bathhouses located outside of the park, in the order in which they were authorized to use thermal water, and only when the Superintendent has determined that there is a surplus of thermal water.

The park's enabling act refers to the ''Army and Navy hospital bathhouse'' and the ''public bathhouse'' as having priority use before any of the bathhouses identified in the rule. These entities are not listed in the rule, however, because the Army and Navy hospital bathhouse ceased operation in 1959 and the public bathhouse, which referred to the Libbey Physical Medicine Center, ceased operation in 2005. In the future, if new bathhouses are established in either location, they would be categorized as bathhouses located within the park, and have priority use relative to other bathhouses within the park in the order in which they were authorized to use thermal water, but always before the Arlington Hotel and other bathhouses located outside of the park. The Arlington Hotel is located outside of the park and is specifically named in the park's enabling act as having priority use of thermal water in the order identified in the rule. Although it is located outside of the park, the superintendent is not required to determine there is a surplus of thermal water before authorizing the Arlington Hotel to use thermal water pursuant to a written instrument due to its specific mention in the enabling act. Currently, Levi Hospital is the only other bathhouse located outside of the park that is authorized to use thermal water. Levi Hospital is not named in the enabling act and its use of thermal water is conditioned upon the superintendent determining there is a surplus of thermal water. As long as it remains in continuous operation, its use of thermal water will have priority over other bathhouses located outside of the park that may be authorized to use thermal water in the future.

New paragraph (b)(2)(iv) would explain that a surplus of thermal water exists when, after accounting for all of the thermal water that bathhouses located within the park and the Arlington Hotel are authorized to use, the superintendent determines that additional thermal water may be used by other bathhouses located outside of the park in a manner that would not conflict with the requirements of applicable Federal laws and policies, including those that require the NPS to preserve the resources of the park. When the superintendent evaluates whether there is a surplus, the relevant value is the full amount of thermal water that may be used by bathhouses within the park and the Arlington Hotel, not the amount of thermal water actually used by those bathhouses at any time. The superintendent then must evaluate whether there is any remaining thermal water that could be used by other bathhouses, and whether such use would violate any applicable Federal laws (*e.g.,* the park's enabling act and the NPS Organic Act) or any applicable Federal policies (*e.g.,* NPS Management Policies 2006). This includes an evaluation of whether additional use of thermal water will cause impairment of park resources, including wildlife and other natural features in the park that use or depend on the water. The superintendent must determine there is a surplus of water before signing a written instrument authorizing the use of thermal water by a bathhouse located outside of the park.

New paragraph (b)(2)(v) would require the NPS to provide adequate notice to bathhouses that have lower priority use authorizations before it authorizes a bathhouse higher in the order of priority to use thermal water. This paragraph would further require the NPS to provide adequate notice to bathhouses located outside of the park, other than the Arlington Hotel, if the superintendent's determination that there is a surplus of thermal water changes in a manner that will impact their authorizations to use thermal water. These provisions would help ensure that bathhouses have reasonable notice about potential decreases in the amount of thermal water they are authorized to use. This would allow them to adjust operations and notify customers about impacts to offered products and services. The superintendent may change the amount of thermal water bathhouses are authorized to use based upon determinations of surplus or determinations that use would be inconsistent with the purposes of the park, notwithstanding the terms and conditions of any written instrument authorizing use of thermal water.

New paragraph (b)(2)(vi) would require bathhouses to have a thermal water management plan approved by the superintendent and the OPH, with an additional requirement that thermal water management plans for bathhouses located outside of the park also must be approved by the Arkansas Department of Health, as required by State law. Thermal water management plans are already required as a term and condition of all written instruments authorizing bathhouses to use thermal water. Including this requirement in the regulations would provide additional notice and transparency for bathhouses.

The park's enabling act vests full power to the Secretary, acting through the NPS, to promulgate regulations that authorize the superintendent to examine and inspect at any time the manner of using thermal water in any bathtub. 16 U.S.C. 363. Consistent with this authority, new paragraph (b)(2)(vii) would give the superintendent (or someone with delegated authority) the right to examine and inspect the use of thermal water by a bathhouse at reasonable times to determine whether the bathhouse is being operated in accordance with the terms and conditions of the written instrument authorizing the use of thermal water, the approved thermal water management plan, and with the provisions of the regulations.

Paragraph (b)(3)—Prohibited Acts

Proposed regulation	Existing regulations
§ 7.18(b)(3) Prohibited acts.	• § 21.1 Definitions. • § 21.2 Penalties • § 21.8 Employee certification.

The park's enabling act authorizes the Secretary, acting through the NPS, to provide penalties for the violation of any regulation as to the use of thermal water, including the cancellation of any lease for the use of such water. 16 U.S.C. 363. Consistent with this authorization,

new paragraphs (b)(3)(i)–(v) would identify prohibited acts and state that they may result in the revocation or suspension of a written authorization to use thermal water. Prohibited acts would be failures to:

- comply with a written instrument authorizing the use of thermal water;
- comply with a provision of an approved water management plan;
- make a required payment;
- operate a pool or spa without appropriate certification, as determined by the OPH;
- ensure and maintain employee licenses and certifications where required by Federal or State law; and
- comply with any regulations addressing the use of thermal water.

This list of prohibited acts would provide notice and transparency to bathhouses about the repercussions of certain actions. Existing regulations in § 21.1 and § 21.8 require persons performing special services in bathhouses, such as physical therapy, massage, and attending to baths, to be licensed or certified by a State or U.S. territory, or by the superintendent upon completion of examinations and (for bath attendants) an apprenticeship. Individuals who provide special services in bathhouses are already subject to licensing and certification requirements under applicable law. Rather than imposing those requirements again in NPS regulations, new paragraph (b)(3)(v) would instead hold bathhouses accountable for the services they offer their customers by requiring bathhouses to ensure and maintain employee licenses and certifications where required by Federal or State law. The superintendent no longer examines or certifies bathhouse employees. As a result, those provisions also would be removed.

Existing regulations in § 21.2 state that any person convicted of violating any regulation in part 21 shall be punished by a fine not exceeding $100 and be adjudged to pay all costs of the proceedings. Existing regulations in 36 CFR 1.3 state that a person convicted of violating any regulation in parts 1 through 7, part 9 subpart B, and parts 12 and 13, shall be subject to the criminal penalties provided under 18 U.S.C. 1865. As a result of moving all regulations about the use of thermal water to § 7.18, a violation of any provision of the rule would result in criminal penalties under § 1.3. New paragraph (b)(3)(vi) would state this explicitly for additional notice and transparency.

Paragraph (b)(4)—Rates and Cost Recovery

Proposed regulation	Existing regulation
§ 7.18(b)(4) Rates and cost recovery.	N/A.

The park's enabling act requires the NPS to charge bathhouses the same rates for thermal water that will be used for bathing, but allows the superintendent to charge bathhouses individual rates for thermal water that will not be used for bathing. 16 U.S.C. 362. The park's enabling act requires bathhouses located outside of the park that are authorized to use thermal water if there is a surplus, to pay all costs associated with connections for obtaining such thermal water. 16 U.S.C. 362. The park's enabling act requires the superintendent to readjust the terms and amounts of payment required under a written instrument authorizing the use of thermal water every five years during the term of the instrument. 16 U.S.C. 362. As stated above, the park's enabling act authorizes the NPS to make all needful rules and regulations regarding the use of thermal water, including the use of thermal water by bathhouses, and specifically states that such regulations can be made to prevent waste and be what the NPS deems best for the public interest. 16 U.S.C. 363.

In order to provide additional notice and transparency to bathhouses, this rule would include regulations that address rates and cost recovery for the use of thermal water that are consistent with the statutory authorities discussed above. All of these proposed provisions reflect current practice by the NPS. New paragraph (b)(4)(i) would state that rates charged for thermal water will be specified in the written instrument authorizing the use of thermal water. New paragraph (b)(4)(ii) would state that rates for thermal water that will be used for bathing will be the same for all bathhouses, and that rates for thermal water that will not be used for bathing will be determined by the superintendent for each bathhouse. New paragraph (b)(4)(iii) would state that bathhouses located outside of the park that may be authorized to use thermal water if there is a surplus must pay all costs incurred by the NPS associated with connections for obtaining such thermal water. Connection costs include all costs incurred from activities that cause the connections to be made. These may include, but are not limited to, design and construction costs, and costs incurred to comply with applicable laws and policies, such as the National Environmental Policy Act and the National Historic Preservation Act. New paragraph (b)(4)(iv) would state that written instruments authorizing the use of thermal water may require bathhouses to reimburse the NPS for costs incurred from the distribution of thermal water and maintenance of the distribution system. The ability of the NPS to recover these costs, when appropriate, will help ensure that thermal water is distributed safely, efficiently, and without waste. Finally, new paragraph (b)(5)(v) would state that the NPS will readjust the terms and amounts of payments required under a written instrument authorizing the use of thermal water at least every five years during its term and upon the renewal of a written instrument at the end of its term.

Compliance With Other Laws, Executive Orders and Department Policy

Regulatory Planning and Review (Executive Orders 12866 and 13563 and 14094)

Executive Order 12866, as amended by Executive Order 14094, provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget will review all significant rules. OIRA has determined that the proposed rule is not significant.

Executive Order 14094 amends Executive Order 12866 and reaffirms the principles of Executive Order 12866 and Executive Order 13563 and states that regulatory analysis should facilitate agency efforts to develop regulations that serve the public interest, advance statutory objectives, and be consistent with Executive Order 12866, Executive Order 13563, and the Presidential Memorandum of January 20, 2021 (Modernizing Regulatory Review). Regulatory analysis, as practicable and appropriate, shall recognize distributive impacts and equity, to the extent permitted by law.

Executive Order 13563 reaffirms the principles of Executive Order 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. Executive Order 13563 directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. Executive Order 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process

must allow for public participation and an open exchange of ideas. The NPS has developed this proposed rule in a manner consistent with these requirements.

Regulatory Flexibility Act

This proposed rule would not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). This certification is based on information contained in the economic analyses found in the report entitled '' Regulatory Analysis of the Use of Thermal Water and Commercial Passenger-Carrying Vehicles at Hot Springs National Park Proposed Rule.'' The report may be viewed in the docket for this rulemaking action by visiting *https://www.regulations.gov/* and searching for ''RIN 1024–AE86''.

Congressional Review Act

This proposed rule is not a major rule under 5 U.S.C. 804(2). This proposed rule:

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

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

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

Unfunded Mandates Reform Act

This proposed rule does not impose an unfunded mandate on State, local, or Tribal governments or the private sector of more than $100 million per year. The proposed rule does not have a significant or unique effect on State, local or Tribal governments or the private sector. It addresses public use of national park lands and imposes no requirements on other agencies or governments. A statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

Takings (Executive Order 12630)

This proposed rule does not effect a taking of private property or otherwise have takings implications under Executive Order 12630. A takings implication assessment is not required.

Federalism (Executive Order 13132)

Under the criteria in section 1 of Executive Order 13132, the proposed rule does not have sufficient federalism implications to warrant the preparation of a Federalism summary impact statement. This proposed rule only affects use of federally administered lands and waters. It has no direct effects on other areas. A Federalism summary impact statement is not required.

Civil Justice Reform (Executive Order 12988)

This proposed rule complies with the requirements of Executive Order 12988. This proposed rule:

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

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

Consultation With Indian Tribes (Executive Order 13175 and Department Policy)

The Department of the Interior strives to strengthen its government-to-government relationship with Indian Tribes through a commitment to consultation with Indian Tribes and recognition of their right to self-governance and Tribal sovereignty. The NPS has evaluated this proposed rule under the criteria in Executive Order 13175 and under the Department's Tribal consultation policy and has determined that Tribal consultation is not required because the proposed rule will have no substantial direct effect on federally recognized Indian Tribes. Nevertheless, in support of the Department of the Interior's and the NPS's commitment to government-to-government consultation, the NPS intends to coordinate with Indian Tribes that are traditionally associated with the land that is now part of the park, including the Caddo Nation, Quapaw Nation, Osage Nation, Shawnee Tribe, and Absentee Shawnee.

Paperwork Reduction Act

This proposed rule contains existing information collections. All information collections require approval under the Paperwork Reduction Act of 1995 (PRA; 44 U.S.C. 3501 *et seq.*). The NPS may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB has reviewed and approved the information collection requirements associated with NPS Form 10–550 ''Commercial Use Authorization Application'' and assigned OMB control number 1024–0268 (currently under review for renewal; the Information Collection Request was submitted to OMB on 3/29/2023).

National Environmental Policy Act

This proposed rule does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the National Environmental Policy Act of 1969 (NEPA) is not required because the rule is covered by a categorical exclusion. NPS NEPA Handbook (2015) Section 3.3.A.8 allows for the following to be categorically excluded: Modifications or revisions to existing regulations or the promulgation of new regulations for NPS-administered areas, provided the modifications, revisions, or new regulations do not:

a. Increase public use to the extent of compromising the nature and character of the area or causing physical damage to it,

b. Introduce noncompatible uses that might compromise the nature and characteristics of the area or cause physical damage to it,

c. Conflict with adjacent ownerships or land uses, or

d. Cause a nuisance to adjacent owners or occupants.

The NPS has also determined that the proposed rule does not involve any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under NEPA.

Effects on the Energy Supply (Executive Order 13211)

This proposed rule is not a significant energy action under the definition in Executive Order 13211; the proposed rule is not likely to have a significant adverse effect on the supply, distribution, or use of energy, and the rule has not otherwise been designated by the Administrator of OIRA as a significant energy action. A Statement of Energy Effects in not required.

Clarity of This Rule

The NPS is required by Executive Orders 12866 (section 1(b)(12)) and 12988 (section 3(b)(1)(B)), and 13563 (section 1(a)), and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule the NPS publishes must:

(a) Be logically organized;

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

(c) Use common, everyday words and clear language rather than jargon;

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

(e) Use lists and tables wherever possible.

If you feel that the NPS has not met these requirements, send us comments by one of the methods listed in the

ADDRESSES section. To better help the NPS revise the rule, your comments should be as specific as possible. For example, you should identify the numbers of the sections or paragraphs that you find unclear, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

Public Participation

It is the policy of the Department of the Interior, whenever practicable, to afford the public an opportunity to participate in the rulemaking process. Accordingly, interested persons may submit written comments regarding this proposed rule by one of the methods listed in the **ADDRESSES** section of this document.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time.

List of Subjects

36 CFR Part 7

National parks, Reporting and Recordkeeping requirements.

36 CFR Part 21

National parks.

For the reasons stated in the preamble, and under the authority of 16 U.S.C. 363 and 54 U.S.C. 100751, the National Park Service proposes to amend 36 CFR chapter I, as set forth below:

PART 7—SPECIAL REGULATIONS, AREAS OF THE NATIONAL PARK SYSTEM

■ 1. The authority citation for part 7 continues to read as follows:

Authority: 54 U.S.C. 100101, 100751, 320102; Sec. 7.96 also issued under DC Code 10–137 and DC Code 50–2201.07.

■ 2. Amend § 7.18 by revising paragraphs (a) and (b) to read as follows:

§ 7.18 Hot Springs National Park.

(a) *Commercial passenger-carrying vehicles.* Commercial use authorizations and fees for the operation of commercial passenger-carrying vehicles carrying passengers for hire over park roads will be required in accordance with 54 U.S.C. 101925.

(b) *Thermal water.* The regulations contained in this paragraph (b) apply to the use of thermal water.

(1) *Definitions.* The following definitions apply to this paragraph (b):

Bathhouse means a facility authorized to use thermal water for any purpose pursuant to a written instrument signed by the Superintendent of Hot Springs National Park.

Bathing means soaking in thermal water for health benefits.

Thermal water means water that emerges from springs, fountains or other natural sources within Hot Springs National Park.

Use of thermal water means heating, cooling, storing, removing from Hot Springs National Park, combining with other substances, or otherwise altering thermal water in any manner.

Water treatment means the introduction of any substance into thermal water, including chemicals, solutions, or other water.

(2) *Use of thermal water.* (i) The use of thermal water is prohibited except by individuals for personal consumption or as authorized in writing by the Superintendent provided that such use is consistent with the purposes of Hot Springs National Park, and provided further that under no circumstances may thermal water be removed from Hot Springs National Park for direct sale or use in products for sale. A written instrument authorizing the use of thermal water may be in the form of a lease agreement entered into under the specific authority of 16 U.S.C. 361 *et seq.,* in addition to any other types of written instruments authorized by applicable law and policy.

(ii) Water treatment must be approved by the NPS Office of Public Health and is limited to the minimum amount and type necessary for the maintenance of public health and safety, as determined by the NPS Office of Public Health.

(iii) Bathhouses may use thermal water in the order of priority identified below, consistent with 16 U.S.C. 362:

(A) Bathhouses located within Hot Springs National Park, in the order in which they were authorized to use thermal water.

(B) Arlington Hotel.

(C) Bathhouses located outside of Hot Springs National Park, in the order in which they were authorized to use thermal water, and only when the Superintendent has determined that there is a surplus of thermal water.

(iv) For purposes of paragraph (b)(2)(iii)(C), a surplus may exist when, after accounting for all of the thermal water that bathhouses referred to in paragraphs (b)(2)(iii)(A) and (b)(2)(iii)(B) are authorized to use, the Superintendent determines that additional thermal water may be used by other bathhouses located outside of Hot Springs National Park in a manner that would not conflict with the requirements of applicable Federal laws and policies, including those that require the NPS to preserve the resources of Hot Springs National Park.

(v) The NPS will provide adequate notice to bathhouses that have lower priority use authorizations before it authorizes a bathhouse higher in the order of priority to use thermal water. The NPS will provide adequate notice to bathhouses referred to in paragraph (b)(2)(iii)(C) if the Superintendent's determination that there is a surplus of thermal water changes in a manner that will impact their authorizations to use thermal water.

(vi) Bathhouses must have a thermal water management plan approved by the Superintendent and the NPS Office of Public Health. Thermal water management plans for bathhouses located outside of Hot Springs National Park also must be approved by the Arkansas Department of Health.

(vii) The Superintendent has the right to examine and inspect the use of thermal water by a bathhouse at reasonable times to determine whether the bathhouse is being operated in accordance with the terms and conditions of the written instrument authorizing the use of thermal water, an approved thermal water management plan, and with the provisions of this section.

(3) *Prohibited acts.* The following acts are prohibited and may result in the revocation or suspension of a written authorization to use thermal water:

(i) Failure to comply with terms and conditions of a written instrument authorizing the use of thermal water.

(ii) Failure to comply with any provision of an approved thermal water management plan.

(iii) Failure to make any payment required under this section.

(iv) Failure to operate a pool or spa without appropriate certification, as determined by the NPS Office of Public Health.

(v) Failure by bathhouses to ensure and maintain employee licenses and certifications where required by Federal or State law.

(vi) Failure to comply with any provision of this paragraph (b) of § 7.18, which also may result in applicable penalties under § 1.3 of this chapter.

(4) *Rates and cost recovery.* (i) Rates charged for thermal water will be specified in the written instrument authorizing the use of thermal water.

(ii) Rates charged for thermal water that will be used for bathing will be the same for all bathhouses. Rates charged for thermal water that will not be used for bathing will be determined by the Superintendent for each bathhouse.

(iii) Bathhouses referred to in paragraph (b)(2)(iii)(C) must pay all costs associated with connections for obtaining such thermal water.

(iv) Written instruments authorizing the use of the thermal water may require bathhouses to reimburse the NPS for costs incurred from the distribution of thermal water and maintenance of the distribution system.

(v) The NPS will readjust the terms and amounts of payments required under a written instrument authorizing the use of thermal water at least every five years during its term and upon the renewal of a written instrument at end of its term.

* * * * *

Part 21 [Removed]

■ 3. Remove part 21, consisting of §§ 21.1 through 21.12.

Shannon Estenoz,

Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2024–27571 Filed 11–26–24; 8:45 am]

BILLING CODE 4312–52–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 147

[EPA–HQ–OW–2024–0357; FRL 12000–01–OW]

West Virginia Underground Injection Control (UIC) Program; Class VI Primacy

AGENCY: U.S. Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The U.S. Environmental Protection Agency (EPA or the Agency) has received a complete Underground Injection Control (UIC) program revision package from the State of West Virginia (State), requesting approval of a revision to the State's Safe Drinking Water Act (SDWA) section 1422 UIC program to include Class VI injection well primary enforcement responsibility (primacy). The proposed revision would allow the West Virginia Department of Environmental Protection (WVDEP) to issue UIC permits for geologic carbon sequestration facilities as Class VI wells and ensure compliance of Class VI wells under the UIC program. The EPA proposes to issue a final rule approving West Virginia's application to implement the UIC program for Class VI injection wells located within the State, except those on Indian lands. The EPA proposes amendments to reflect this proposed approval of West Virginia's Class VI primacy application.

DATES: Comments must be received on or before December 30, 2024. *Public hearing:* The EPA will hold a public hearing on December 30, 2024. Please refer to the **SUPPLEMENTARY INFORMATION** section for additional information on the public hearing.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–HQ–OW–2024–0357 by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov/* (our preferred method). Follow the online instructions for submitting comments.
- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center, Water Docket, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.
- *Hand Delivery or Courier:* EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operations are 8:30 a.m. to 4:30 p.m., Monday–Friday (except Federal Holidays).

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received may be posted without change to *https://www.regulations.gov/,* including personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Colin Dyroff, Drinking Water Infrastructure Development Division, Office of Ground Water and Drinking Water (4606M), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–3149; or Himanshu Vyas, Water Division, Source Water & UIC Section (3WD22), Environmental Protection Agency, Region 3, Four Penn Center, 1600 JFK Boulevard, Philadelphia, PA 19103; telephone number: (215) 814–2112. Both can be reached by emailing *WVClassVI@epa.gov.*

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I. Public Participation

A. Written Comments

Submit your comments, identified by Docket ID No. EPA–HQ–OW–2024–0357, at *https://www.regulations.gov* (our preferred method), or the other methods identified in the **ADDRESSES** section. Once submitted, comments cannot be edited or removed from the docket. The EPA may publish any comment received to its public docket. Do not submit to the EPA's docket at *https://www.regulations.gov* any information you consider to be Confidential Business Information (CBI), Proprietary Business Information (PBI), or other information whose disclosure is restricted by statute. If you need to submit CBI, contact Himanshu Vyas with the contact information available in the **FOR FURTHER INFORMATION CONTACT** section. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary

submission (*i.e.,* on the web, cloud, or other file sharing system). Please visit *https://www.epa.gov/dockets/commenting-epa-dockets* for additional submission methods; the full EPA public comment policy; information about CBI, PBI, or multimedia submissions; and general guidance on making effective comments.

B. Participation in Public Hearing

A public hearing is anticipated to be held on December 30, 2024. The EPA expects to announce the location, time of the hearing, as well as any updates made to any aspect of the hearing online at *https://www.epa.gov/aboutepa/epa-region-3-mid-atlantic#pn.* The hearing can also be attended virtually at *https://www.zoomgov.com/j/1600637199.* While the EPA expects the hearing to go forward as set forth above, please monitor our website or contact Himanshu Vyas at (215) 814–2112 or *WVClassVI@epa.gov* to determine if there are any updates or for additional information regarding the public hearing. The EPA does not intend to publish a document in the **Federal Register** announcing updates.

The EPA will begin pre-registering speakers for the hearing upon publication of this document in the **Federal Register**. To register to speak at the hearing, please contact Himanshu Vyas at (215) 814–2112 or *WVClassVI@epa.gov* and indicate whether you will be attending in-person or virtually. The last day to pre-register to speak at the hearing will be December 23, 2024. Prior to the hearing, the EPA will post a general agenda for the hearing that will list pre-registered speakers in approximate order at: *https://www.epa.gov/aboutepa/epa-region-3-mid-atlantic#pn.*

The EPA will make every effort to follow the schedule as closely as possible on the day of the hearing; however, please plan for the hearings to run either ahead of schedule or behind schedule. Additionally, requests to speak will be taken the day of the hearing at the hearing registration desk. The EPA will make every effort to accommodate all speakers who arrive and register, although preferences on speaking times may not be able to be fulfilled.

The EPA encourages commenters to provide the EPA with a copy of their oral testimony electronically by emailing it to *WVClassVI@epa.gov.* The EPA also recommends submitting the text of your oral comments as written comments to the rulemaking docket.

The EPA may ask clarifying questions during the oral presentations but will not respond to the presentations at that time. Written statements and supporting information submitted during the comment period will be considered with the same weight as oral comments and supporting information presented at the public hearing.

The EPA will not provide audiovisual equipment for presentations unless we receive special requests in advance. Commenters should notify Himanshu Vyas when they pre-register to speak that they will need specific equipment. If you require the services of an interpreter or special accommodations such as audio description, please pre-register for the hearing with Himanshu Vyas and describe your needs by December 23, 2024. The EPA may not be able to arrange accommodations without advance notice.

C. Public Participation Activities Conducted by West Virginia

On June 23, 2021, the WVDEP posted a notice of public comment period on their website for an action to revise West Virginia Code of State Rules 47CSR13 to add new regulations for Class VI wells and to update the State's existing Class I–V regulations. The WVDEP held a public comment period from June 23, 2021 to July 23, 2021 and held a virtual public hearing on July 23, 2021. The WVDEP received 55 comments, 19 of which commented on Class VI wells. These comments did not result in changes to the proposed regulatory revisions. The effective date for this rule revision was March 9, 2022.

Then, on June 12, 2023, the WVDEP posted a notice of public comment period on their website for another action to make additional updates to the State's Class I–VI regulations in 47CSR13 of the West Virginia Code of State Rules. The WVDEP held a public comment period from June 12, 2023 to July 18, 2023 and held a public hearing on July 18, 2023 in Charleston, WV. The WVDEP received five comments, all of which related to Class VI wells. These comments did not result in changes to the proposed updates to the regulations. The effective date for this rule revision was April 5, 2024.

Commenters on the WVDEP's proposed rulemakings shared concerns on various topics including applicant financial burden, fees, the area of review radius, post-injection site care, and seismic activity reviews. Commenters also expressed concern about whether the WVDEP has adequate staffing and technical expertise to properly manage a UIC Class VI program. Environmental justice (EJ) also appeared to be a major concern, with commenters asking about how EJ protections will be integrated into the program. The WVDEP responded to all public comments, provided various clarifications, and confirmed to commenters that EJ will be an important part of the agency's Class VI program. The WVDEP also added that the agency's Class VI team would be composed of technical specialists with expertise in geology, well construction, and UIC inspections. Additionally, the WVDEP stated that the rule revisions were adopted to be consistent with Federal requirements and that the agency's primary objective is to protect underground sources of drinking water, groundwater, and surface water. Documentation of West Virginia's public participation activities, including comments received and responses by the WVDEP, can be found in the EPA's Docket ID No. EPA–HQ–OW–2024–0357.

II. Introduction

A. UIC Program and Primary Enforcement Authority (Primacy)

The SDWA protects public health by regulating the nation's public drinking water supply, including both surface and groundwater sources. The SDWA requires the EPA to develop minimum requirements for effective State and Tribal UIC programs to prevent underground injection of fluids (such as water, wastewater, brines from oil and gas production, and carbon dioxide) from endangering underground sources of drinking water (USDWs). In general, USDWs are aquifers or parts of aquifers that supply a public water system or contain enough groundwater to supply a public water system. See 40 CFR 144.3.

The UIC program regulates various aspects of an injection well project. These include technical aspects throughout the lifetime of the project from site characterization, construction, operation, and testing and monitoring through site closure, as well as permitting, site inspections, and reporting to ensure well owners and operators comply with UIC regulations.

SDWA section 1421 directs the EPA to establish requirements that States, territories, and federally recognized Tribes (hereafter referred to as applicants) must meet to be granted primary enforcement responsibility or ''primacy'' for implementing a UIC program, including a Class VI program. An applicant seeking primacy under SDWA section 1422 for a Class VI program must demonstrate to the EPA that the applicant's Class VI program meets the Federal requirements and is protective of USDWs. An applicant agency must also demonstrate jurisdiction over underground injection

and the administrative, civil, and criminal enforcement authorities required by EPA regulation. After the EPA approves a State for UIC primacy, the State's UIC program may be revised with EPA approval. See 40 CFR 145.32. When a State that already has primacy under SDWA section 1422 seeks to add Class VI primacy to its existing program, a subsequent primacy application and review process takes the form of a program revision.

The EPA conducts a comprehensive technical and legal evaluation of each primacy application to assess and confirm that the proposed program meets Federal regulations and to evaluate the effectiveness of the State's proposed program. The EPA likewise conducts a comprehensive evaluation of a proposed revision to an existing UIC program, particularly a revision as substantial as adding Class VI primacy.

B. Class VI Wells Under the UIC Program

Class VI wells are used to inject carbon dioxide into deep rock formations for the purpose of long-term underground storage, also known as geologic sequestration. The geologic sequestration of carbon dioxide in UIC Class VI wells is used in carbon capture and storage to prevent carbon dioxide emissions from industrial sources from reaching the atmosphere. Class VI injection wells are regulated under an existing, rigorous SDWA permitting framework that protects USDWs.

The UIC Class VI program provides multiple safeguards that work together to protect USDWs and human health. Owners or operators that wish to inject carbon dioxide underground for the purpose of geologic sequestration must demonstrate that their injection well and injection activities will meet all regulatory requirements and receive a Class VI permit for each well. The UIC Class VI program requires applicants to meet strict technical, financial, and managerial requirements to obtain a Class VI permit, including:

- Site characterization to ensure the geology in the project area will contain the carbon dioxide within the zone where it will be injected.
- Modeling to delineate the predicted area influenced by injection activities through the lifetime of operation.
- Evaluation of the delineated area to ensure all potential pathways for fluid movement have been identified and addressed through corrective action.
- Well construction requirements that ensure the Class VI injection well will not leak carbon dioxide.
- Testing and monitoring throughout the life of the project, including after carbon dioxide injection has ended. Requirements include, for example, testing to ensure physical integrity of the well, monitoring for seismic activity near the injection site, monitoring of injection pressure and flow, chemical analysis of the carbon dioxide stream that is being injected, and monitoring the extent of the injected carbon dioxide plume and the surrounding area (*e.g.,* ground water) to ensure the carbon dioxide is contained as predicted.
- Operating requirements (for example, injection pressure limitations) to ensure the injection activity will not endanger USDWs or human health.
- Financial assurance mechanisms sufficient to cover the costs for all phases of the geologic sequestration project including the post-injection site care period and until site closure has been approved by the permitting authority.
- Emergency and remedial response plans.
- Reporting of all testing and monitoring results to the permitting authority to ensure the well is operating in compliance with all permit and regulatory requirements.

The permitting authority ensures that these protective requirements are included in each Class VI permit. A draft of each Class VI permit is made available to the public for comment before the decision is made whether to issue a final permit.

C. West Virginia UIC Program

The State of West Virginia received primacy for Class I, III, IV, and V injection wells under SDWA section 1422 and Class II injection wells under SDWA section 1425 on December 9, 1983 (48 FR 55127). On May 1, 2024, West Virginia applied to the EPA under section 1422 of SDWA, 42 U.S.C. 300h–1, for primacy for Class VI injection wells located within the State, except those located on Indian lands.

III. Legal Authorities

This regulation is proposed under authority of SDWA sections 1422 and 1450, 42 U.S.C. 300h–1 and 300j–9.

Section 1421 of SDWA requires the Administrator of the EPA to promulgate Federal requirements for effective State UIC programs to prevent underground injection activities that endanger USDWs. Section 1422 of SDWA establishes requirements for States and Tribes seeking EPA approval of their UIC programs. It also requires that States and Tribes seeking approval demonstrate how the applicant (after public notice) will implement a UIC program which meets the requirements that the EPA promulgated under section 1421.

For States and Tribes that seek approval for UIC programs under section 1422 of SDWA and those seeking EPA approval of revisions to existing State and Tribal UIC programs, the EPA has promulgated regulations setting forth the applicable procedures and substantive requirements codified in 40 CFR parts 144, 145 and 146. 40 CFR part 144 outlines general program requirements that each State must meet to obtain primary enforcement authority. 40 CFR part 145 specifies the procedures the EPA will follow in approving, revising, and withdrawing State programs and outlines the elements and provisions that a State must include in its application for primacy. 40 CFR part 145 also includes requirements for State permitting programs (by reference to certain provisions of 40 CFR parts 124 and 144), compliance evaluation programs, enforcement authority, and sharing of information between the EPA and the State. 40 CFR part 146 contains the technical criteria and standards applicable to each well class, including Class VI wells.

IV. The EPA's Evaluation of West Virginia's Program Revision Application

A. Background

On May 1, 2024, West Virginia submitted to the EPA a program revision application to add Class VI wells to the State's SDWA section 1422 UIC program. The UIC program revision package from West Virginia includes a description of the State's UIC Class VI program, copies of all applicable rules and forms, a statement of legal authority, a summary and results of West Virginia's public participation activities, an amended addendum to the existing Memorandum of Agreement (MOA) between West Virginia and the EPA's Region 3 office, an interagency MOA between the WVDEP and the West Virginia Geologic and Economic Survey (WVGES), and an interagency MOA between the WVDEP and the West Virginia Department of Health. The EPA reviewed the application for completeness and performed a technical evaluation of the application materials.

B. Environmental Justice in Class VI Permitting

People across the country have shared with the EPA concerns that already environmentally overburdened communities may bear a disproportionate environmental burden associated with geologic sequestration.

Executive Order 12898 (59 FR 7629, February 16, 1994) and Executive Order 14096 (88 FR 25251, April 21, 2023) direct Federal agencies, to the greatest extent practicable and permitted by law, to identify and address, as appropriate, disproportionate and adverse human health or environmental impacts on communities with EJ concerns. On August 17, 2023, the EPA released a guidance document titled *Environmental Justice Guidance for UIC Class VI Permitting and Primacy.* This guidance outlines expectations for the EPA to incorporate EJ considerations into Class VI activities. It is organized into five themes that address various aspects of EJ in UIC Class VI permitting, and strongly encourages States, Tribes, and Territories to implement their Class VI programs in a similar fashion.

As part of developing this proposal, the EPA worked with the State of West Virginia to adopt the EJ approaches encouraged in the August 17, 2023 guidance document, which West Virginia has incorporated in its primacy application. The EPA reviewed West Virginia's EJ approach as described in the State's Class VI program description and amended MOA addendum and compared it to the EJ themes and actions in the guidance document. The EJ approach in the amended MOA addendum corresponds to the five themes in the EPA's August 17, 2023 guidance document, which include identifying communities with potential EJ concerns, implementing an augmented public participation process, conducting additional assessments for projects identified as having EJ concerns, ensuring the permitting process is transparent, and minimizing adverse effects to underground sources of drinking water and the communities they may serve. Furthermore, West Virginia's Class VI program description specifies that the WVDEP will require well owners or operators to conduct an EJ review as part of the Class VI permit application process. The EPA supports the WVDEP's agreement in its Class VI program description to evaluate project sites using the EPA's EJ Screen and to take additional steps if this initial screening identifies the presence of an EJ community or other risk factors in the area of review (AOR). West Virginia's Class VI program, as described in the WVDEP's primacy application, includes approaches to ensure equity and EJ will be appropriately considered in permit reviews, and in the WVDEP's UIC Class VI program as a whole.

C. Summary of the EPA's Comprehensive Evaluation

The EPA conducted a comprehensive technical and legal evaluation of West Virginia's Class VI primacy application to assess and confirm that the State's UIC Class VI program is as stringent as the Federal regulations and evaluated the effectiveness of the State's Class VI program. To be approved for Class VI primacy under SDWA section 1422, a State or Tribe must have a UIC program that meets Federal requirements (40 CFR parts 124, 144, 145, and 146). The EPA evaluated West Virginia's Class VI UIC statutes and regulations against these Federal requirements. The EPA worked with West Virginia to address any stringency issues with their Class VI statutes and regulations prior to submittal of the Class VI primacy application. The Agency also evaluated for stringency and effectiveness West Virginia's Class VI program description, the Class VI Attorney General's statement, the amended Class VI addendum to the MOA between the EPA and West Virginia, the interagency MOA between the WVDEP and the West Virginia Geologic and Economic Survey, and the interagency MOA between the WVDEP and the West Virginia Department of Health.

The EPA evaluated West Virginia's Class VI program description against 40 CFR 145.23, which lists all the information to be submitted as part of the program description. The EPA's evaluation of the Class VI program description included reviewing the scope, structure, coverage, processes, and organizational structure of the permitting authority. The EPA evaluated the WVDEP's permitting, administrative, and judicial review procedures, as well as the State's permit application, reporting, and manifest forms. The EPA also reviewed the State's compliance evaluation and enforcement mechanisms. The EPA evaluated the WVDEP's proposed schedule for issuing Class VI permits within the first two years after program approval. The EPA required West Virginia to demonstrate that the State's Class VI program will have adequate in-house staff or access to contractor support for technical areas including site characterization, modeling, well construction and testing, financial responsibility, and regulatory and risk analysis.

The EPA evaluated West Virginia's Class VI Attorney General's statement against 40 CFR 145.24 to ensure it met Federal requirements. The Attorney General's statement is required to ensure that a State's top legal officer affirms that State statutes, regulations, and judicial decisions demonstrate adequate authority to administer the UIC program as described in the Class VI program description and consistent with the EPA's regulatory requirements for UIC programs. The EPA independently evaluates and confirms that the Attorney General's statement certifies that the State either does not have environmental audit privilege and/or immunity laws, or, if there are environmental audit privilege and/or immunity laws, that they will not affect the ability of the State to meet the enforcement and information gathering requirements under the SDWA.

The EPA evaluated West Virginia's amended Class VI MOA addendum against 40 CFR 145.25 to ensure it met Federal requirements. The MOA is the central agreement setting the provisions and arrangements between the State and the EPA concerning the administration, implementation, and enforcement of the State UIC program. The EPA's evaluation includes ensuring that the MOA contains the necessary provisions pertaining to agreements on coordination, permitting, compliance monitoring, enforcement, and EPA oversight. For example, the amended MOA addendum specifies that the WVDEP and the EPA agree to maintain a high level of cooperation and coordination to assure successful and efficient administration of the UIC Class VI program.

The EPA reviewed the WVDEP's interagency MOA with the West Virginia Geological and Economic Survey. The WVGES is a West Virginia agency with expertise to provide information to the WVDEP on local geologic characteristics in relation to proposed underground injection operations. The interagency MOA between the WVDEP and the WVGES establishes a coordinated relationship between the two state agencies to properly assess geological characteristics in a proposed work area to support permit determinations. The EPA also reviewed the WVDEP's interagency MOA with the West Virginia Department of Health (WVDOH). Under this interagency MOA, the WVDOH will conduct a review of the proposed area of work and permit application details and provide input to assist in permit determinations, among other provisions.

The EPA is aware that stakeholders have raised concern about geologic sequestration long term liability transfer provisions enacted in West Virginia and other States. The EPA reviewed the West Virginia statutory provision relating to long-term liability transfer

(W. Va. Code § 22–11B–12) and determined that it does not undermine any protections under the Safe Drinking Water Act. Under the West Virginia long-term liability transfer provision, all Class VI regulatory and permit requirements must be met before liability transfer may occur.[1] Consistent with EPA regulations, West Virginia imposes extensive post-injection monitoring—a default of 50 years—and site closure requirements at the end of a Class VI well's life cycle to ensure that there will be no danger to USDWs. Only after all those requirements are met does West Virginia's long-term liability transfer provision allow a limited transfer of any future liability to a state-administered and industry-funded trust fund. Among other additional limitations, the provision is explicit that it does not: relieve any owner or operator from any liability that arises from noncompliance with UIC laws, regulations or permits; apply if the WVDEP determines that there is fluid migration for which the operator is responsible that threatens imminent and substantial endangerment to a USDW; or interfere with the EPA's emergency authority under SDWA section 1431.

West Virginia has demonstrated that it has the legal authority to implement all permit requirements found in 40 CFR 145.11 for Class VI permits. West Virginia's UIC Class VI permitting provisions are as stringent as the EPA's regulations in 40 CFR parts 124 and 144. The State has incorporated necessary procedures, pursuant to 40 CFR 145.12 to support a robust Class VI compliance evaluation program. Additionally, West Virginia has the necessary administrative, civil, and criminal enforcement authorities pursuant to 40 CFR 145.13. West Virginia's Class VI regulations regarding permitting, inspection, operation, and monitoring meet Federal requirements found in 40 CFR parts 145 and 146. West Virginia's reporting and recordkeeping requirements meet Federal requirements found in 40 CFR 144.54 and 146.91 for Class VI wells.

As a result of this comprehensive review, the EPA is proposing to approve West Virginia's application because the EPA has determined that the application meets all applicable requirements for approval under SDWA section 1422 and the State is capable of administering a UIC Class VI program in a manner consistent with the terms and purposes of SDWA and all applicable UIC regulations.

V. The EPA's Proposed Action

A. Incorporation by Reference

The EPA is proposing to approve a revision to the State of West Virginia's UIC program for primacy for regulating Class VI injection wells in the State, except for those located on Indian lands. West Virginia's statutes and regulations that are proposed to be incorporated by reference are publicly available in the EPA's Docket No. EPA–HQ–OW–2024–0357. If finalized, this action would amend 40 CFR 147.2450 and incorporate by reference EPA-approved State statutes and regulations that contain standards, requirements, and procedures applicable to Class VI owners or operators. Any provisions incorporated by reference, as well as all permit conditions or permit denials issued pursuant to such provisions, are enforceable by the EPA pursuant to section 1423 of SDWA and 40 CFR 147.1(e). The EPA will continue to administer the UIC program for Class I, II, III, IV, V, and VI injection wells on Indian lands.

The EPA proposes to incorporate by reference the West Virginia statutes and regulations applicable to owners or operators of Class VI wells as a compilation titled ''EPA-approved West Virginia SDWA section 1422 Underground Injection Control Program Statutes and Regulations for Well Class VI,'' dated [date when the EPA compiles the notebook]. This compilation would be incorporated by reference into 40 CFR 147.2450 and is available at *www.regulations.gov* in the docket for this proposed rulemaking. The EPA also proposes to codify a table in 40 CFR 147.2450 listing the EPA-approved West Virginia Statutes and Regulations for Well Class VI included in the compilation that EPA would incorporate by reference. While the regulations in 47CSR13 contain requirements for all UIC well classes (*i.e.,* Class I–VI), only the requirements applicable to owners or operators of Class VI wells would be incorporated by reference as part of this action.

Upon approval, the EPA would oversee West Virginia's administration of its Class VI program and will continue to oversee West Virginia's administration of its programs for Class I, II, III, IV, and V wells. The EPA will require quarterly reports on non-compliance and annual UIC performance reports pursuant to 40 CFR 144.8. The amended MOA addendum between the EPA and West Virginia, signed by the Regional Administrator on October 9, 2024, articulates that the EPA will oversee the State's administration of the UIC Class VI program on a continuing basis to assure that such administration is consistent with the program MOAs, UIC grant agreements, and all applicable requirements embodied in current regulations and Federal law. In addition, the amended MOA addendum provides that the EPA may request specific information including permits and the accompanying EJ reviews.

B. Class I–V Codification—No Action

As referenced in section II.C of this preamble, the EPA approved West Virginia for Class I–V primacy in 1983. After notice and public comment, the EPA determined that West Virginia's UIC program met Federal requirements and published its decision to approve West Virginia's UIC program in the **Federal Register** (48 FR 55127, December 9, 1983). The Code of Federal Regulations (CFR) sets forth the applicable UIC program for each State (40 CFR 147.1) and, upon approving a State for UIC primacy, the EPA typically updates the CFR to reflect its approval. However, for reasons that current EPA staff were unable to ascertain, when the EPA approved West Virginia's UIC program in 1983, the CFR was not revised to reflect the EPA's approval, and the CFR currently does not reflect West Virginia's Class I–V primacy. While the EPA is not addressing this CFR discrepancy as part of this proposed action, the EPA expects to address it later as part of a separate action. The current proposal is confined to approving a revision to West Virginia's existing UIC primacy program to grant the State primacy over Class VI wells; it is not addressing other well classes.[2] Separately, the EPA is working with West Virginia to assess the State's current Class I–V program elements and expects to codify in the CFR the State's Class I–V program in 2025 as part of a separate action. An email from the WVDEP affirming the State's intention to submit a Class I–V program revision package in 2025 following the Class VI process can be found in the docket for this proposed rulemaking.

VI. Statutory and Executive Orders Reviews

Additional information about these statutes and Executive orders can be found at: *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

[1] Such requirements include the post closure deed notation and record retention requirements at 40 CFR 146.93 and 47CSR13.13.9, as specifically mentioned in the Class VI MOA amended addendum.

[2] Even if this proposed action were not a revision to an existing UIC program, the UIC regulations at 40 CFR 145.1(i) allow States to apply for primary enforcement responsibility for Class VI wells independently of other injection well classes.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 14094: Modernizing Regulatory Review

This proposed action is exempt from review under Executive Order 12866, as amended by Executive Order 14094, because the Office of Management and Budget (OMB) has exempted, as a category, the approval of State UIC programs.

B. Paperwork Reduction Act (PRA)

This proposed action will not impose any new information collection burden under the PRA. OMB has previously approved the information collection activities contained in the existing regulations and has assigned OMB control number 2040–0042. Reporting or recordkeeping requirements will be based on West Virginia's Class VI UIC Regulations, and the State of West Virginia is not subject to the PRA.

C. Regulatory Flexibility Act (RFA)

I certify that this proposed action will not have a significant economic impact on a substantial number of small entities under the RFA. This proposed action would not impose any new requirements on small entities. It simply approves and codifies West Virginia's UIC Class VI program, which meets the same standard under SDWA section 1422 as is required for the EPA's regulations governing its direct implementation of a UIC Class VI program.

D. Unfunded Mandates Reform Act (UMRA)

This proposed action does not contain an unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The proposed action imposes no enforceable duty on any state, local, or Tribal governments or the private sector. The EPA's proposed approval of West Virginia's Class VI program will not constitute a Federal mandate because there is no requirement that a state establish UIC regulatory programs and because the program is a state, rather than a Federal program.

E. Executive Order 13132: Federalism

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

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

This proposed action does not have Tribal implications as specified in Executive Order 13175. This proposed action contains no Federal mandates for Tribal governments and does not impose any enforceable duties on Tribal governments. Thus, Executive Order 13175 does not apply to this proposed action.

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

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This proposed action is not subject to Executive Order 13045 because it approves a state program.

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

This proposed action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

This proposed rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14096: Revitalizing Our Nation's Commitment to Environmental Justice for All

The EPA believes that it is not practicable to assess whether the human health or environmental conditions that exist prior to this proposed action result in disproportionate and adverse effects on communities with environmental justice concerns. There currently are no Class VI wells permitted in West Virginia and this proposed action would be a procedural action. The EPA has reviewed West Virginia's proposed approach to environmental justice, as outlined in the Class VI Program Description and Class VI MOA amended addendum, and described in section IV.B of this preamble. The EPA considers West Virginia's Class VI primacy application to integrate environmental justice and equity considerations into the State's UIC Class VI program, while ensuring protection of USDWs. This proposed action would provide West Virginia with primacy under SDWA section 1422 for a UIC Class VI program, pursuant to which West Virginia would implement a program that meets the EPA's requirements for UIC Class VI programs.

VII. References

Attorney General's Statement ''Attorney General's Statement to Accompany West Virginia's Underground Injection Program Class VI Primacy Application,'' signed by the General Counsel of the West Virginia Department of Environmental Protection, April 29, 2024.

Class VI Underground Injection Control Program Description ''WV Class 6 Program Description'', June 2024.

Email from West Virginia to EPA related to Class I–V program revision, April 22, 2024.

Letter from Governor of West Virginia to Regional Administrator, EPA Region III, April 25, 2024.

Memorandum of Agreement Amended Addendum 1 between the State of West Virginia and the EPA, Region III for the UIC Class VI Program, signed by the EPA Regional Administrator on October 9, 2024.

Federal Register notice ''West Virginia Department of Natural Resources; Underground Injection Control Program Approval'', EPA, 48 FR 55127–55128 (December 9, 1983).

Memorandum of Agreement between the State of West Virginia and the EPA, Region III, signed by the EPA Regional Administrator on August 31, 1983.

Memorandum of Agreement Between The West Virginia Department of Environmental Protection and The West Virginia Department of Health, signed April 26, 2024.

Memorandum of Agreement Between The West Virginia Department of Environmental Protection and The West Virginia Geological and Economic Survey, signed April 29, 2024.

Program Description ''Program Description for the West Virginia Underground Injection Control Program'', December 1983.

State of West Virginia. Notice of Action Taken by Legislative Rule-Making Review Committee, December 9, 2021.

State of West Virginia. Notice of Action Taken by Legislative Rule-Making Review Committee, September 13, 2023.

State of West Virginia. Notice of Public Comment Period and Hearing, June 12, 2023.

State of West Virginia. Notice of Public Comment Period and Hearing, June 23, 2021.

State of West Virginia. Public Comments and Responses, July 24, 2023.

State of West Virginia. Public Comments and Responses, July 30, 2021.

State of West Virginia. Public Hearing Transcript (Public Hearing Date: July 23, 2021), July 31, 2021.

State of West Virginia. Public Hearing Transcript (Public Hearing Date: July 18, 2023), August 12, 2023.
USEPA. 2023b. U.S. Environmental Protection Agency. Memorandum to Water Division Directors, Regions I–X, from Radhika Fox, Office of Water. Environmental Justice Guidance for UIC Class VI Permitting and Primacy (August 17, 2023).
West Virginia Code § 22–11. Water Pollution Control Act. May 13, 2024.
West Virginia Code § 22–11A. Carbon Dioxide Sequestration Pilot Program. May 20, 2022.
West Virginia Code § 22–11B. Underground Carbon Dioxide Sequestration and Storage. May 13, 2024.
West Virginia Code of State Rules § 47–13. Underground Injection Control. April 5, 2024.

List of Subjects in 40 CFR Part 147

Environmental protection, Incorporation by reference, Indian lands, Intergovernmental relations, Reporting and recordkeeping requirements, Water supply.

Michael S. Regan,
Administrator.

For the reasons set forth in the preamble, the EPA proposes to amend 40 CFR part 147 as follows:

PART 147—STATE, TRIBAL, AND EPA–ADMINISTERED UNDERGROUND INJECTION CONTROL PROGRAMS

■ 1. The authority citation for part 147 continues to read as follows:

Authority: 42 U.S.C. 300f *et seq.;* and 42 U.S.C. 6901 *et seq.*

■ 2. Add § 147.2450 to read as follows:

§ 147.2450 State-administered program—Class VI Wells

The UIC program for Class VI wells in the State of West Virginia, except those on Indian lands, is the program administered by the West Virginia Department of Environmental Protection, approved by the EPA pursuant to SDWA section 1422. The effective date of this program is [DATE 30 DAYS AFTER FINAL RULE PUBLICATION IN THE **FEDERAL REGISTER**]. The UIC program for Class VI wells in the State of West Virginia, except those located on Indian lands, consists of the following elements, as submitted to the EPA in the State's program revision application.

(a) *Incorporation by reference.* The requirements applicable to owners or operators of Class VI wells set forth in the State statutes and regulations approved by the EPA for including in ''EPA-approved West Virginia SDWA § 1422 Underground Injection Control Program Statutes and Regulations for Well Class VI,'' dated [date when the EPA compiles the notebook], and listed in table 1 to this paragraph (a), are hereby incorporated by reference and made a part of the applicable UIC program under the SDWA for the State of West Virginia. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the State of West Virginia's statutes and regulations that are incorporated by reference may be inspected at the U.S. Environmental Protection Agency, Region 3, Four Penn Center, 1600 JFK Blvd., Philadelphia, PA 19103 and the U.S. Environmental Protection Agency, Water Docket, EPA Docket Center (EPA/DC), EPA WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC 20004. If you wish to obtain materials from the EPA Regional Office, please call (215) 814–2816, or from the EPA Headquarters Library, please call the Water Docket at (202) 566–2426. You may also view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations.html* or email *fr.inspections@nara.gov.* You may also obtain the State of West Virginia's statutes and regulations that are incorporated by reference from: Room MB–27, Building 1, State Capitol Complex, Charleston, West Virginia 25305; phone: (304) 347–4836; website: *www.wvlegislature.gov.*

TABLE 1 TO PARAGRAPH (a)—EPA-APPROVED WEST VIRGINIA SDWA SEC. 1422 UNDERGROUND INJECTION CONTROL PROGRAM STATUTES AND REGULATIONS FOR WELL CLASS VI

State citation	Title/subject	State effective date	EPA approval date
West Virginia Code § 22–11	Water Pollution Control Act	May 13, 2024	[DATE OF FINAL RULE PUBLICATION IN THE **FEDERAL REGISTER**.]
West Virginia Code § 22–11A ...	Carbon Dioxide Sequestration Pilot Program.	May 30, 2022	[DATE OF FINAL RULE PUBLICATION IN THE **FEDERAL REGISTER**.]
West Virginia Code § 22–11B ...	Underground Carbon Dioxide Sequestration and Storage.	May 13, 2024	[DATE OF FINAL RULE PUBLICATION IN THE **FEDERAL REGISTER**.]
West Virginia Code of State Rules § 47–13.	Underground Injection Control ..	April 5, 2024	[DATE OF FINAL RULE PUBLICATION IN THE **FEDERAL REGISTER**.]

(b) *Memorandum of Agreement (MOA).* (1) The Memorandum of Agreement between the State of West Virginia and the EPA, Region III, signed by the EPA Regional Administrator on August 31, 1983.

(2) Memorandum of Agreement Amended Addendum 1 between the State of West Virginia and the EPA, Region III for the UIC Class VI Program, signed by the EPA Regional Administrator on October 9, 2024.

(c) *Letter from Governor.* Letter from Governor of West Virginia to Regional Administrator, EPA Region III, April 25, 2024.

(d) *West Virginia Memorandums of Agreement.* (1) Memorandum of Agreement Between The West Virginia Department of Environmental Protection and The West Virginia Geological and Economic Survey, effective April 1, 2024.

(2) Memorandum of Agreement Between The West Virginia Department of Environmental Protection and The West Virginia Department of Health, signed April 26, 2024.

(e) *Statement of legal authority.* Attorney General's Statement, ''Attorney General's Statement to Accompany West Virginia's Underground Injection Program Class VI Primacy Application'', signed by the Attorney General of West Virginia on April 29, 2024.

(f) *Program Description.* The Program Description, ''Program Description for the West Virginia Underground Injection Control Program'', and any other materials submitted as part of the application or amendment thereto, and the Class VI Underground Injection Control Program Description, ''WV Class

6 Program Description'', and any other materials submitted as part of the program revision application or as amendment thereto.

[FR Doc. 2024–27638 Filed 11–25–24; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1001

Solicitation of Proposals for New and Modified Safe Harbors and Special Fraud Alerts

AGENCY: Office of Inspector General (OIG), Department of Health and Human Services (HHS or the Department).

ACTION: Notification of intent to develop regulations.

SUMMARY: In accordance with section 205 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), this annual notification solicits proposals and recommendations for developing new, or modifying existing, safe harbor provisions under section 1128B(b) of the Social Security Act (the Act), the Federal anti-kickback statute, as well as developing new OIG Special Fraud Alerts.

DATES: To ensure consideration, public comments must be received no later than 5 p.m. on January 27, 2025.

ADDRESSES: You may submit comments electronically at *https://www.regulations.gov.* Follow the ''Submit a comment'' instructions and refer to file code OIG–1124–N.

For information on viewing public comments, please see the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Benjamin Wallfisch, (202) 339–7980.

SUPPLEMENTARY INFORMATION: Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *https://www.regulations.gov.*

I. Background

A. OIG Safe Harbor Provisions

Section 1128B(b) of the Act (42 U.S.C. 1320a–7b(b)), the Federal anti-kickback statute, provides for criminal penalties for whoever knowingly and willfully offers, pays, solicits, or receives remuneration to induce or reward, among other things, referrals for or purchases of items or services reimbursable under any of the Federal health care programs, as defined in section 1128B(f) of the Act (42 U.S.C. 1320a–7b(f)). The offense is classified as a felony and is punishable by a fine of up to $100,000 and imprisonment for up to 10 years. Violations of the Federal anti-kickback statute also may result in the imposition of civil monetary penalties under section 1128A(a)(7) of the Act (42 U.S.C. 1320a–7a(a)(7)), program exclusion under section 1128(b)(7) of the Act (42 U.S.C. 1320a–7(b)(7)), and liability under the False Claims Act (31 U.S.C. 3729–33).

Because of the broad reach of the statute, stakeholders expressed concern that some relatively innocuous business arrangements were covered by the statute and, therefore, potentially subject to criminal prosecution. In response, Congress enacted section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100–93 (note to section 1128B of the Act; 42 U.S.C. 1320a–7b), which requires the development and promulgation of regulations, the so-called safe harbor provisions, that would specify various payment and business practices that would not be subject to sanctions under the Federal anti-kickback statute, even though they potentially may be capable of inducing referrals of business for which payment may be made under a Federal health care program. Since July 29, 1991, there has been a series of final regulations published in the **Federal Register** establishing safe harbors to protect various payment and business practices.[1] These safe harbor provisions have been developed ''to limit the reach of the statute somewhat by permitting certain non-abusive arrangements, while encouraging beneficial and innocuous arrangements.'' [2] Health care providers and others may voluntarily seek to comply with the conditions of an applicable safe harbor so that they have the assurance that their payment or business practice will not be subject to sanctions under the Federal anti-kickback statute. The safe harbor regulations promulgated by OIG are found at 42 CFR part 1001.

B. OIG Special Fraud Alerts

OIG periodically issues Special Fraud Alerts to give continuing guidance to health care industry stakeholders about practices that OIG considers to be suspect or of particular concern.[3] Special Fraud Alerts encourage industry compliance by giving stakeholders guidance that can be applied to their own practices. OIG Special Fraud Alerts are published in the **Federal Register**, on OIG's website, or both, and are intended for extensive distribution.

In developing Special Fraud Alerts, OIG relies on several sources and consults directly with experts in the subject field, including those within OIG, other agencies of HHS, other Federal and State agencies, and those in the health care industry.

C. Section 205 of the Health Insurance Portability and Accountability Act of 1996

Section 205 of HIPAA, Public Law 104–191, and section 1128D of the Act (42 U.S.C. 1320a–7d), requires the Department to develop and publish an annual notification in the **Federal Register** formally soliciting proposals for developing additional or modifying existing safe harbors to the Federal anti-kickback statute and for issuing Special Fraud Alerts.

In developing or modifying safe harbors under the Federal anti-kickback statute, and in consultation with the Department of Justice, OIG thoroughly reviews the range of factual circumstances that may receive protection by the proposed or modified safe harbor. In doing so, OIG seeks to identify and develop safe harbors that protect beneficial and innocuous arrangements and safeguard Federal health care programs and their beneficiaries from the harms caused by fraud and abuse.

II. Solicitation of New and Modified Safe Harbor Recommendations and Special Fraud Alert Proposals

OIG seeks recommendations regarding the development of additional or modified safe harbor regulations and the issuance of new Special Fraud Alerts. A detailed explanation of justifications for, or empirical data supporting, a suggestion for a new or modified safe harbor or for the issuance of a new Special Fraud Alert would be helpful

[1] *See, e.g.,* Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 85 FR 77684 (Dec. 2, 2020).

[2] Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 FR 35952, 35958 (July 29, 1991).

[3] *See, e.g.,* Special Fraud Alert: OIG Alerts Practitioners To Exercise Caution When Entering Into Arrangements With Purported Telemedicine Companies (July 20, 2022), *https://oig.hhs.gov/documents/root/1045/sfa-telefraud.pdf.*

and should, if possible, be included in any response to this solicitation.

A. Criteria for Modifying and Establishing Safe Harbor Provisions

In accordance with section 205 of HIPAA, we will consider various factors in reviewing proposals for additional or modified safe harbor provisions, such as the extent to which the proposals may result in an increase or decrease in:

- access to health care services,
- the quality of health care services,
- patient freedom of choice among health care providers,
- competition among health care providers,
- the cost to Federal health care programs,
- the potential overutilization of health care services, and
- the ability of health care facilities to provide services in medically underserved areas or to medically underserved populations.

In addition, we will consider other factors including, for example, the existence (or nonexistence) of any potential financial benefit to health care professionals or providers that may influence their decision whether to: (1) order a health care item or service or (2) arrange for a referral of health care items or services to a particular practitioner or provider.

B. Criteria for Developing Special Fraud Alerts

In determining whether to issue additional Special Fraud Alerts, we will consider whether and to what extent the practices that would be identified in a new Special Fraud Alert may result in any of the consequences set forth above, as well as the volume and frequency of the conduct that would be identified in the Special Fraud Alert.

Christi A. Grimm,

Inspector General.

[FR Doc. 2024–27710 Filed 11–26–24; 8:45 am]

BILLING CODE 4152–01–P

Notices

Federal Register
Vol. 89, No. 229
Wednesday, November 27, 2024

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

ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

Notice of Public Meeting of the Assembly of the Administrative Conference of the United States

AGENCY: Administrative Conference of the United States

ACTION: Notice.

SUMMARY: The Assembly of the Administrative Conference of the United States (ACUS) will meet during a one-day hybrid plenary session to consider three proposed recommendations and to conduct other business. Written comments may be submitted in advance, and the meeting will be accessible to the public.

DATES: The meeting will take place on Thursday, December 12, 2024, from 9:30 a.m.–4 p.m. ET. The meeting may adjourn early if all business is concluded prior to the stated end time.

ADDRESSES: For those attending in person, the meeting will be held at The U.S. Small Business Administration Eisenhower Conference Room, 409 Third Street SW, Washington, DC 20416. There will be a virtual attendance option. Information on how the public can access the meeting will be available on the agency's website prior to the meeting at *https://www.acus.gov/event/82nd-plenary-session.*

FOR FURTHER INFORMATION CONTACT: Shawne McGibbon, General Counsel (Designated Federal Officer), Administrative Conference of the United States, Suite 706 South, 1120 20th Street NW, Washington, DC 20036; Telephone 202–480–2080; email *smcgibbon@acus.gov.*

SUPPLEMENTARY INFORMATION: The Administrative Conference of the United States makes recommendations to federal agencies, the President, Congress, and the Judicial Conference of the United States regarding the improvement of administrative procedures (5 U.S.C. 594). ACUS's membership, when meeting in plenary session, constitutes the Assembly of the Conference (5 U.S.C. 595).

Agenda: Three proposed recommendations will be considered by the Assembly. In addition, there will be updates on past, current, and pending ACUS initiatives, as well as other business. Summaries of the recommendations appear below:

Using Algorithmic Tools in Regulatory Enforcement. This proposed recommendation provides best practices for using artificial intelligence, predictive analytics, and other algorithmic tools to support agencies' regulatory enforcement efforts. It addresses the potential benefits and risks of using algorithmic tools to detect, investigate, and prosecute noncompliance with the law and identifies policies, practices, and organizational structures that agencies can put in place to ensure they enforce the law fairly, accurately, and efficiently.

Public Engagement in Agency Rulemaking Under the Good Cause Exemption: This proposed recommendation provides best practices for public engagement when agencies find good cause to forgo notice-and-comment rulemaking procedures under the Administrative Procedure Act. It encourages agencies to use direct final rulemaking, interim final rulemaking, and alternative methods of public engagement to ensure robust public participation even when they rely properly on the good cause exemption.

Nonlawyer Assistance and Representation. This proposed recommendation provides best practices for agencies to increase the availability of nonlawyer representation and assistance to participants in their adjudicative systems. It provides guidance on the establishment of rules authorizing qualification or, as appropriate, accreditation of nonlawyer representatives; ways to make such processes accessible and transparent; and strategies for coordinating with other government agencies and nongovernmental organizations to increase the availability of representation and assistance.

Additional information about the proposals and the agenda, as well as any changes or updates to the same, can be found at the 82nd Plenary Session page on ACUS's website prior to the start of the meeting at: *https://www.acus.gov/event/82nd-plenary-session.*

Public Participation: ACUS welcomes the virtual attendance of the public at the meeting. Members of the public wishing to view the meeting are asked to RSVP online at the 82nd Plenary Session web page shown above no later than two days before the meeting to ensure adequate bandwidth and accessibility. A link to a livestream of the meeting will be posted the morning of the meeting on the 82nd Plenary Session web page. A video recording of the meeting will be available on ACUS's website shortly after the conclusion of the event at *https://youtube.com/channel/UC1Gu44Jq1U7XsGdC9Tfl_zA.*

Written Comments: Persons who wish to comment on any of the proposed recommendations may do so by submitting a written statement either by email to *info@acus.gov* with ''December 2024 Plenary Session Comments'' in the subject line of the email, or by U.S. Mail addressed to: December 2024 Plenary Session Comments, Administrative Conference of the United States, Suite 706 South, 1120 20th Street NW, Washington, DC 20036. Written submissions must be received no later than 10:00 a.m. (EDT), Friday, December 6, 2024, to ensure consideration by the Assembly.

(Authority: 5 U.S.C. 595)

Dated: November 22, 2024.

Shawne McGibbon,

General Counsel.

[FR Doc. 2024–27867 Filed 11–26–24; 8:45 am]

BILLING CODE 6110–01–P

AGENCY FOR INTERNATIONAL DEVELOPMENT

Notice of Advisory Committee Public Meeting

AGENCY: Agency for International Development (USAID).

ACTION: Notice of advisory committee public meeting and request for public comment.

SUMMARY: Pursuant to the Federal Advisory Committee Act (FACA), notice is hereby given of Advisory Committee on Voluntary Foreign Aid (ACVFA) public meeting on Thursday, December 12, 2024.

ADDRESSES: To view additional information related to ACVFA please visit *https://www.usaid.gov/organization/advisory-committee.*

The meeting will feature remarks by the USAID Administrator and the ACVFA Chair, and two discussion panels featuring ACVFA members on (1) development and national security, and (2) ongoing challenges and opportunities for USAID policy and programming.

You may submit comments regarding the work of ACVFA to *acvfa@usaid.gov.* Include ''Public Comment, ACVFA Meeting, December 12, 2024'' in the subject line. All public comments and questions will be included in the official record of the meeting and posted publicly on the USAID website.

American Sign Language interpretation will be provided during the public meeting. If you require a reasonable accommodation, please email *reasonableaccommodations@usaid.gov.* Include ''Request for Reasonable Accommodation, ACVFA Meeting, December 12, 2024'' in the subject line.

The entirety of this meeting is open to the public. You may register to watch the live public meeting at this link: *https://usaid.zoomgov.com/webinar/register/WN_JQF23hAxRFmqPNJZLt1ZfQ.*

FOR FURTHER INFORMATION CONTACT: Karen Vargas, Designated Federal Officer for ACVFA, at *kvargas@usaid.gov* or 202–705–5769.

SUPPLEMENTARY INFORMATION: ACVFA is USAID's external advisory committee, bringing together representatives from private voluntary organizations, nongovernmental organizations, academia, civil society, and the private sector to foster understanding, communication, and cooperation in the area of foreign aid.

Pursuant to its charter, ACVFA is holding an annual public meeting on December 12, 2024, from 10:30 a.m.–12 p.m. ET. This meeting is free and open to the public. The Committee welcomes public participation and comment via the web and/or email addresses provided above.

Karen Vargas,

ACVFA Designated Federal Officer.

[FR Doc. 2024–27793 Filed 11–26–24; 8:45 am]

BILLING CODE 6116–01–P

DEPARTMENT OF AGRICULTURE

Forest Service

Intent To Renew the Northwest Forest Plan Area Advisory Committee

AGENCY: Forest Service, United States Department of Agriculture (USDA).

ACTION: Notice of intent to renew the Charter for the Northwest Forest Plan Area Advisory Committee.

SUMMARY: In accordance with the Federal Advisory Committee Act (FACA), as amended, the United States Department of Agriculture announces its intent to renew the Charter for the Northwest Forest Plan Area Advisory Committee (Committee). The Charter for the Northwest Forest Plan Area Advisory Committee is being renewed so that the Committee may provide continued advice and recommendations on landscape management approaches and implementation of such approaches that promote sustainability, climate change adaptations, and wildfire resilience while providing for increasing use of and demands from National Forest System lands in the Northwest Forest Plan area. The Committee will be governed by the provisions of FACA. Duration of the Committee is for two years unless renewed by the Secretary of Agriculture.

ADDRESSES: USDA Forest Service, 1220 Southwest 3rd Avenue, Ste. G015, Portland, OR 97204. Committee information can also be found on the Northwest Forest Plan Federal Advisory Committee website at *https://www.fs.usda.gov/detail/r6/landmanagement/planning/?cid=fseprd1076013* or by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: Inquiries may be sent to Ann Eberhart Goode, U.S. Department of Agriculture, Forest Service, by phone at (707) 562–8738 or email at *ann.goode@usda.gov* or Delaney Caslow, U.S. Department of Agriculture, Forest Service, by phone at (503) 804–3545 or email at *delaney.caslow@usda.gov.* Individuals who use telecommunications devices for the hearing impaired may call 711 to reach the Telecommunications Relay Service, 24 hours a day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION: In accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. app. 2), with the concurrence of the General Services Administration (GSA), and subject to the approval of the Secretary of Agriculture, the USDA Forest Service intends to renew the Federal Advisory Committee for sustainable, climate-adapted, wildfire-resilient landscapes across the Northwest Forest Plan (NWFP) area. The Committee will be a discretionary advisory committee. The Committee will operate under the provisions of the FACA and will report to the Secretary of Agriculture through the Chief of the Forest Service. The purpose of the Committee is to provide advice and recommendations on landscape management approaches and implementation of such approaches that promote sustainability, climate change adaptations, and wildfire resilience while providing for increasing use of and demands from National Forest System lands in the NWFP area. Accordingly, the Committee will be asked to perform the following duties or fulfill other requests made by the Secretary of Agriculture or the Chief of the Forest Service by offering recommendations on:

1. Planning and implementation options that complement the national Wildfire Crisis Strategy to assist the USDA Forest Service to transition to greater proactive wildfire risk reduction and address key obstacles related to existing vegetation management.

2. Approaches to address the dynamic nature of ecosystems, utilize adaptive management, monitoring, and integration of future uncertainty into land management planning.

3. Application of the best available science regarding the following primary issues: (a) the ecological importance of old forests; (b) climate change, fire, and associated disturbance processes; (c) terrestrial and aquatic reserved land use allocations and the relationship between the two; (d) the climatic diversity of forests encompassed by the NWFP area; and (e) habitat connectivity at multiple scales in light of changed conditions.

4. Incorporation of traditional ecological knowledge and indigenous perspectives and values into Federal forest planning and management.

5. Communication tools and strategies to: (a) help provide greater understanding of landscape or programmatic level planning and implementation options and requirements and (b) enhance outreach efforts, public engagement, meaningful Tribal consultation and participation, targeted outreach to underserved communities, and stakeholder collaboration within the scope of the Committee.

6. Issue preliminary discrete recommendations in sequence with Forest Service NWFP planning and implementation timelines.

All deliverables will be submitted to the Designated Federal Official (DFO) at USDA Forest Service, 1220 Southwest 3rd Avenue, Ste. G015, Portland, OR 97204.

The Committee will meet approximately four to six times annually or as often as necessary and at such times as designated by the DFO. Subcommittees may meet more frequently. Attendance may be in-person, by telephone, or by other electronic means. Meetings of the Committee whether in person, by telephone or electronic means shall be announced 15 calendar days in advance in the **Federal Register**. As required by the FACA, the Committee will hold open meetings unless the Secretary determines that a meeting or a portion of a meeting may be closed to the public in accordance with subsection C of section 522(b) of title 5, United States Code. All proceedings and relevant documents will be posted and made accessible to the public. No individual who is currently registered as a Federal lobbyist is eligible to serve as a member of the Committee.

Overview and Membership

The Committee will be comprised of up to 23 members approved by the Secretary of Agriculture, and each will serve a two-year term. The Committee membership will be fairly balanced in terms of the points of view represented and functions to be performed. Members of the Committee will serve without compensation but may be reimbursed for travel expenses while performing duties on behalf of the Committee, subject to approval by the DFO and the Department. The Committee should represent to the extent possible, a balance across the three states covered by the NWFP (Oregon, Washington, and California) and reflect the demographic diversity of the NWFP area. The Committee shall include representation from experts in the following interest areas:

(1) *Science:* Up to 9 members who represent the scientific community, and have an understanding in the following disciplines and how they relate to the NWFP area:

(a) Forest ecology
(b) Vegetation management
(c) Fire ecology
(d) Terrestrial wildlife ecology
(e) Aquatic and riparian ecosystems and species
(f) Climate change
(g) Social science
(h) Adaptive management and planning
(i) Indigenous Traditional Ecological Knowledge (ITEK) practitioners

(2) *Organizations:* Up to 8 members who represent a broad array of organizations with an interest in NWFP forests:

(a) National, regional, or local conservation organizations with staff and active programs in the Pacific Northwest
(b) Forest products industry
(c) Recreation organization
(d) Organization involved in outreach with underserved communities
(e) Forest collaborative groups
(f) Wildlife organization
(g) Watershed organization

(3) *Government and public:* Up to 6 members who represent governmental entities or the public at large:

(a) Member of the affected public at large
(b) Represent state governments
(c) Represent counties
(d) Represent American Indian Tribes

Meeting locations will be compliant with the Americans with Disabilities Act, and the USDA provides reasonable accommodation to individuals with disabilities where appropriate. If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpretation, assistive listening devices, or other reasonable accommodation to the person listed under the **FOR FURTHER INFORMATION CONTACT** section or contact USDA's TARGET Center at (202) 720–2600 (voice and TTY) or USDA through the Federal Relay Service at (800) 877–8339. Additionally, program information may be made available in languages other than English.

USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Equal opportunity practices in accordance with USDA policies shall be followed in all membership appointments to the Committee. To ensure that the recommendations of the Committee have taken into account the needs of the diverse groups served by USDA, membership shall include, to the extent practicable, individuals with demonstrated ability to represent the many communities, identities, races, ethnicities, backgrounds, abilities, cultures, and beliefs of the American people, including underserved communities. Persons with disabilities who require alternative means of communication for program information (Braille, large print, audiotape, American Sign Language, etc.) should contact the responsible agency or USDA's TARGET Center at (202) 720–2600 (voice and TTY) or contact USDA through the Federal Relay Service at (800) 877–8339. Additionally, program information may be made available in languages other than English. USDA is an equal opportunity provider, employer, and lender.

Dated: November 21, 2024.

Cikena Reid,

USDA Committee Management Officer.

[FR Doc. 2024–27781 Filed 11–26–24; 8:45 am]

BILLING CODE 3411–15–P

COMMISSION ON CIVIL RIGHTS

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

AGENCY: Commission on Civil Rights.

ACTION: Notice of public meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Colorado Advisory Committee (Committee) to the U.S. Commission on Civil Rights will convene a monthly virtual business meeting on Wednesday, December 18, 2024, at 3:00 p.m. Mountain Time. The purpose of the meeting is to review the final version of its report on public school attendance zones in Colorado. The committee will vote on the report and discuss next steps.

DATES: Wednesday, December 18, 2024, at 3:00 p.m. Mountain Time.

ADDRESSES: The meeting will be held via Zoom.

Meeting Link (Audio/Visual): https://tinyurl.com/279ffjudv; password: USCCR–CO

Join by Phone (Audio Only): 1–833–435–1820; Meeting ID: 160 614 2807#

FOR FURTHER INFORMATION CONTACT: Barbara Delaviez, Designated Federal Official, at *bdelaviez@usccr.gov.* or by phone at 202–539–8246.

SUPPLEMENTARY INFORMATION: Any interested member of the public may attend the meeting via the link above. Before adjourning the meeting, the committee chair will announce that any member of the public may make a brief

oral statement, as time allows. Per the Federal Advisory Committee Act, public minutes of the meeting will include a list of persons who are present at the meeting. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Closed captioning is available by selecting ''CC'' in the meeting platform. To request additional accommodations, please email *ebohor@usccr.gov* at least 10 business days prior to each meeting.

Members of the public are entitled to submit written comments; the comments must be received in the regional office within 30 days following the scheduled meeting. Written comments may be emailed to Barbara Delaviez at *bdelaviez@usccr.gov;* please include Colorado Committee in the subject line of the transmitting email. Persons who desire additional information may contact the Regional Programs Coordination Unit at 1–312–353–8311.

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

Agenda

I. Welcome and Roll Call
II. Report Stage: Discuss and Vote on Report—Public School Attendance Zones
III. Discuss Next Steps
IV. Public Comment
V. Adjournment

Dated: November 21, 2024.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2024–27736 Filed 11–26–24; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Utah Advisory Committee; Cancellation

AGENCY: Commission on Civil Rights.

ACTION: Notice; cancellation of meeting.

The Commission on Civil Rights published a notice in the **Federal Register** concerning a meeting of the Utah Advisory Committee. The meeting, scheduled for Wednesday, November 20, 2024, at 3 p.m. MT, has been cancelled. The notice is in the **Federal Register** on Tuesday, November 19, 2024, in FR Document Number 2024–26723 at 89 FR 91319–91320.

FOR FURTHER INFORMATION CONTACT: Liliana Schiller, Support Services Specialist, at *lschiller@usccr.gov* or (202) 770–1856.

Dated: November 21, 2024.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2024–27738 Filed 11–26–24; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

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

AGENCY: Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that a meeting of the Puerto Rico Advisory Committee to the Commission will convene by virtual web conference on Wednesday, December 11, 2024, at 3:30 p.m. Atlantic Time/Eastern Time. The purpose is to continue discussion on their project on the civil rights impacts of the Insular Cases in Puerto Rico.

DATES: December 11, 2024, Wednesday, at 3:30 p.m. Atlantic Time (3:30 p.m. ET).

ADDRESSES: Meeting will be held via Zoom.

Registration Link (Audio/Visual): https://tinyurl.com/rbhrynke; Passcode, if needed: USCCR–PR.

Join by Phone (Audio Only): 1–833–435–1820 USA Toll Free; Meeting ID: 161 027 9371 #.

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

SUPPLEMENTARY INFORMATION: This meeting will take place in Spanish with English interpretation. This committee meeting is available to the public through the registration link above. Any interested member of the public may listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. Per the Federal Advisory Committee Act, public minutes of the meeting will include a list of persons who are present at the meeting. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Closed captioning will be available for individuals who are deaf, hard of hearing, or who have certain cognitive or learning impairments. To request additional accommodations, please email *ebohor@usccr.gov* at least 10 business days prior to the meeting.

Members of the public are entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to Victoria Moreno at *vmoreno@usccr.gov.* Persons who desire additional information may contact the Regional Programs Coordination Unit at 1–312–353–8311.

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

Agenda

1. Welcome & Roll Call
2. Committee Discussion on Project Regarding the Civil Rights Impacts of the Insular Cases in Puerto Rico
3. Next Steps
4. Public Comment
5. Other Business
6. Adjourn

Dated: November 22, 2024.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2024–27852 Filed 11–26–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

International Trade Administration

[Application No. 19–5A001]

Export Trade Certificate of Review

ACTION: Notice of application for an amended Export Trade Certificate of Review for National Pecan Shellers Association (NPSA), Application No. 19–5A001.

SUMMARY: The Secretary of Commerce, through the Office of Trade and Economic Analysis (OTEA) of the International Trade Administration, has received an application for an amended Export Trade Certificate of Review (Certificate). This notice summarizes the proposed application and seeks public comments on whether the Certificate should be issued.

FOR FURTHER INFORMATION CONTACT: Amanda Reynolds, Acting Director, OTEA, International Trade Administration, (202) 482–5131 (this is not a toll-free number) or email at *etca@trade.gov.*

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (15 U.S.C. 4011–21) authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. An Export Trade Certificate of Review protects the holder and the members identified in the Certificate from State and Federal government antitrust actions and from private treble damage antitrust actions for the export conduct specified in the Certificate and carried out in compliance with its terms and conditions. The regulations implementing Title III are found at 15 CFR part 325. OTEA is issuing this notice pursuant to 15 CFR 325.6(a), which requires the Secretary of Commerce to publish a summary of the application in the **Federal Register**, identifying the applicant and each member and summarizing the proposed export conduct.

Request for Public Comments

Interested parties may submit written comments relevant to the determination whether a Certificate should be issued. If the comments include any privileged or confidential business information, it must be clearly marked and a nonconfidential version of the comments (identified as such) should be included. Any comments not marked as privileged or confidential business information will be deemed to be nonconfidential.

Written comments should be sent to *ETCA@trade.gov.* An original and two (2) copies should also be submitted no later than 20 days after the date of this notice to: Office of Trade and Economic Analysis, International Trade Administration, U.S. Department of Commerce, Room 21028, Washington, DC 20230.

Information submitted by any person is exempt from disclosure under the Freedom of Information Act (5 U.S.C. 552). However, nonconfidential versions of the comments will be made available to the applicant if necessary for determining whether or not to issue the Certificate. Comments should refer to this application as ''Export Trade Certificate of Review, application number 19–5A001.''

Summary of the Application

Applicant: National Pecan Shellers Association, 4348 Carter Creek Pkwy Ste 101, Bryan, TX 77802.

Contact: Catherine Clark and Kelsey Wallis, Managing Staff at Texas Pecan Growers Association.

Application No.: 19–5A001.

Date Deemed Submitted: November 13, 2024.

Proposed Amendment: National Pecan Shellers Association seeks to amend its Certificate as follows:

1. Add the following entities as Exporting Members of the Certificate within the meaning of section 325.2(l) of the Regulations (15 CFR 325.2(l)):

- Pecaninis Inc., San Antonio, TX
- Rancho Pecana, El Paso, TX

2. Remove the following companies as Members of the Certificate:

- Exporting Members
  - Chase Pecan, LP, San Saba, TX
  - John B. Sanfilippo & Son, Inc., Elgin, IL
  - Lamar Pecan Company, Hawkinsville, GA
- Non-exporting Members
  - The Kellen Company, Atlanta, GA (Independent Third Party)

3. Change the location of the following Non-exporting Member of the Certificate:

- Pecan Export Trade Council's location changes from Atlanta, GA to Bryan, TX

NPSA's proposed amendment of its Certificate would result in the following Membership list:

Exporting Members

- Arnco, Inc. dba Carter Pecan, Panama City Beach, FL
- Diamond Foods LLC, Stockton, CA
- Easterlin Pecan Co, Montezuma, GA
- HNH Nut Company, Visalia, CA
- Hudson Pecan Co., Inc., Ocilla, GA
- Humphrey Pecan LLC, San Antonio, TX
- La Nogalera USA Inc., El Paso, TX
- Navarro Pecan Company, Corsicana, TX
- Pecan Grove Farms, Dallas, TX
- Pecan Star & Nut Corp, San Antonio, TX
- Pecaninis Inc., San Antonio, TX
- Rancho Pecana, El Paso, TX
- South Georgia Pecan Company, Valdosta, GA
- Southern Roots Nut Company, LLC, Las Cruces, NM

Non-exporting Members

- Pecan Export Trade Council, Bryan, TX

Dated: November 22, 2024.

Amanda Reynolds,

Acting Director, Office of Trade and Economic Analysis, International Trade Administration, U.S. Department of Commerce.

[FR Doc. 2024–27866 Filed 11–26–24; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

National Council on Weights and Measures 2025 Interim Meeting

AGENCY: National Institute of Standards and Technology, Commerce.

ACTION: Notice.

SUMMARY: The 2025 Interim Meeting of the National Council on Weights and Measures (NCWM) will be held in-person at the Francis Marion Hotel, Charleston, South Carolina from Sunday, January 12, 2025, through Wednesday, January 15, 2025. This notice contains information about the most significant agenda items of the NCWM committees. As a result, the items are not consecutively numbered.

DATES: The 2025 NCWM Interim Meeting will be held from Sunday, January 12, 2025, through Wednesday, January 15, 2025. The meeting schedule will be available on the NCWM website at *www.ncwm.com.*

ADDRESSES: This meeting will be held at the Francis Marion Hotel, with an address at 387 King Street, Charleston, South Carolina 29403.

FOR FURTHER INFORMATION CONTACT: Dr. Katrice Lippa, NIST, Office of Weights and Measures, 100 Bureau Drive, Stop 2600, Gaithersburg, MD 20899–2600. You may also contact Dr. Lippa at (301) 975–3116 or by email at *katrice.lippa@nist.gov.* The meeting is open to the public, but the payment of a registration fee is required. Please see the NCWM website (*www.ncwm.com*) to view the

meeting agendas, registration forms, and hotel reservation information.

SUPPLEMENTARY INFORMATION: Publication of this notice on the NCWM's behalf is undertaken as a public service and does not itself constitute an endorsement by the National Institute of Standards and Technology (NIST) of the content of the notice. NIST participates in the NCWM as an NCWM member and pursuant to 15 U.S.C. 272(b)(10) and (c)(4) and in accordance with Federal policy (*e.g.,* OMB Circular A–119 ''Federal Participation in the Development and Use of Voluntary Consensus Standards'').

The NCWM is an organization of weights and measures officials of the states, counties, and cities of the United States, and representatives from the private sector and federal agencies. These meetings bring together government officials and representatives of business, industry, trade associations, and consumer organizations on subjects related to the field of weights and measures technology, administration, and enforcement. NIST hosted the first meeting of the NCWM in 1905. Since then, the council has provided a model of cooperation between Federal, State, and local governments and the private sector. NIST participates in the NCWM to provide technical insights and expertise and encourage cooperation between the private sector, federal agencies, and the states in the development of legal metrology requirements. NIST also promotes uniformity in state laws, regulations, and testing procedures used in the regulatory control of commercial weighing and measuring devices, packaged goods, and for other trade and commerce issues.

The NCWM has established multiple committees, task groups, and other working bodies to address legal metrology issues of interest to, *inter alia,* regulatory officials, industry representatives, and consumers. Comments will be taken by the various NCWM committees on agenda items during the open hearing portions of the meeting identified in the meeting schedule. At this stage, the items are proposals. The open hearing sessions are accessible to all registered attendees of the meeting, including both NCWM members and non-members. The meeting also includes committee work sessions in which the committees may, *inter alia,* accept comments, withdraw or carryover agenda items that need additional maturation, and develop recommendations for the agenda items for consideration and possible adoption in July 2025 at the NCWM 110th Annual Meeting.

These notices are intended to make interested parties aware of significant agenda items and alert them to the committees' intentions to share reports on the status of each at the 2025 NCWM Interim Meeting. The notices are also presented to invite the participation of manufacturers, experts, consumers, users, and others who may be interested in these efforts.

The following are brief descriptions of significant agenda items that will receive further consideration by the standing committees at the upcoming 2025 NCWM Interim Meeting. The full agenda of each standing committee is provided in NCWM Publication 15 (*ncwm.com/publication-15*). Comments will be taken on recommendations intended to amend NIST Handbook 44, ''Specifications, Tolerances, and Other Technical Requirements for Weighing and Measuring Devices'' (NIST HB 44), NIST Handbook 130, ''Uniform Laws and Regulations in the Areas of Legal Metrology and Fuel Quality'' (NIST HB 130), and NIST Handbook 133, ''Checking the Net Contents of Packaged Goods'' (NIST HB 133). The NIST Handbooks are regularly adopted by the states, either by reference or through administrative procedures.

NCWM S&T Committee

The NCWM Specifications and Tolerances Committee (S&T Committee) will consider proposed amendments to NIST HB 44, including those identified below. A detailed technical review by the NIST Office of Weights and Measures of the S&T Committee agenda items will be made available prior to the 2025 NCWM Interim Meeting in the 2025 NIST OWM Interim Technical Analysis at *https://www.nist.gov/pml/owm/publications/owm-technical-analysis.*

SCL—Scales

SCL–25.1 S.5.2. Parameters for Accuracy Class, S.6. Marking Requirements, and UR.3. Use Requirements

The S&T Committee will consider a new proposal submitted by NIST Office of Weights and Measures. The proposal is to amend the requirements to establish a minimum capacity for scales and require that information to be marked on new scales.

SCL–25.3 UR.3.14. Zero-Balance Recorded Weight for Forklift Scales

The S&T Committee will consider a new proposal submitted by the Pennsylvania Bureau of Ride and Measurement Standards. The proposal is to add a requirement for forklift scales that would require these devices to indicate and record a zero-balance condition prior to determining the weight of the load on the device.

FMT—Farm Milk Tanks

FMT–25.1 UR.1. Installation

The S&T Committee will consider a new proposal submitted by the USDA–AMS-Dairy Programs. The proposal amends the current section 4.42. Farm Milk Tanks Code paragraph UR.1. Installation to require the leveling legs on stationary farm milk tanks to be permanently attached to the floor by cement as a means to prevent any adjustment to the leveling legs after calibration. The proposal removes the option for defining the correct position of each leg on the floor for tanks that are not permanently mounted in the facility.

Item Block 1 (B1)

TXI—Taximeters and TNS—Transportation Network Measurement Systems

B1–TXI–25.1 5.54 Transportation-For-Hire Systems

The S&T Committee will consider a new proposal submitted by the NCWM Transportation-for-Hire Systems Task Group. The proposal would revise section 5.54., currently titled ''Taximeters,'' and rename it ''Transportation-For-Hire Systems.'' The new revised section would combine the existing requirements for taximeters in section 5.54. with those that are currently in section 5.60. Transportation Network Measurement Systems to create a single section addressing both types of vehicle for hire applications.

B1–TNS–25.1 Section 5.60. Transportation Network Measurement Systems—Tentative Code

The S&T Committee will consider a new proposal submitted by the Transportation-for-Hire Systems Task Group. The proposal would consolidate section 5.60. Transportation Network Measurement Systems with section 5.54. Taximeters. Both sets of requirements would be incorporated into an updated and renamed section 5.54., and section 5.60. would be removed from NIST HB 44.

OTH—Other Items

OTH–25.1 2.26. Weigh-in-Motion Systems Used for Vehicle Direct Enforcement

The S&T Committee will consider a proposal submitted by New York City

Department of Transportation, NY State Department of Agriculture and Markets, NJ Office of Weights and Measures, Oregon Department of Agriculture, Washington DC Department of Transportation, C2SMART, and Kistler. The proposal is to include a new Section 2.26. Weigh-in-Motion Systems Used for Vehicle Direct Enforcement to NIST HB 44 that provides standards that can be used by local and State agencies to certify Weigh-In-Motion (WIM) systems used for automated enforcement of gross vehicle weight limits.

NCWM L&R Committee

The NCWM Laws and Regulations Committee (L&R Committee) will consider proposed amendments to NIST HB 130, including those identified below. A detailed technical review by the NIST Office of Weights and Measures of the L&R Committee agenda items will be made available prior to the 2025 NCWM Interim Meeting in the 2025 NIST OWM Interim Analysis at *https://www.nist.gov/pml/owm/publications/owm-technical-analysis.*

MOS—NIST Handbook 130

NET–24.2. 2.16.3.1. Tare Weights; Part (c) Allowable difference

The L&R Committee will further consider a proposal to clarify the existing language for the method of sale for stamped or stenciled tare weights of Liquefied Petroleum Gas cylinders. This will include changes to existing language within NIST HB 130 that references tolerances for cylinders. It is intended to resolve the discrepancy that exists between NIST Handbook 130 and Title 49 of the Code of Federal Regulations with respect to the allowable differences between the stamped tare weight and the actual tare weight of cylinders used for compressed or liquefied gases in refillable cylinders.

OTH—NIST Handbook 130

OTH–24.1 X. Uniform Shipping Law

The L&R Committee will further consider a proposal that has been designated as an ''Assigned'' item, meaning that further development will be done by the NCWM Uniform Shipping Law Task Group. This proposal provides model language for inclusion in NIST HB 130 that would establish Uniform Shipping Laws meant to ensure accurate shipment of goods. This regulation includes language authorizing the enforcement of these regulations, empowers the state to promulgate regulations as needed to carry out the provisions of the Act, and provides for civil and criminal penalties. The development of this item will include outreach to stakeholders, including federal agencies.

FALS—Fuels and Lubricants Subcommittee

B2–FLR–24.1 3.12.1.X Identification of Grade & 3.12.2.X. Identification of Grade

The L&R Committee will further consider a proposal that has been designated as an ''Assigned'' item, meaning that the NCWM Fuels and Lubricants Subcommittee is being tasked to fully develop the proposal to ensure the applicable ASTM fuel grade designations are clearly identified for the marketplace. This proposal provides language for a new NIST HB 130 regulation that specifies labeling requirements that will properly identify the grade of natural gas (compressed and liquified to include blends of these products with hydrogen) when this product is dispensed and sold as a vehicle fuel. These standards will be applicable at the point fuel is dispensed into the vehicle.

Alicia Chambers,

NIST Executive Secretariat.

[FR Doc. 2024–27838 Filed 11–26–24; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XE497]

Gulf of Mexico Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The Gulf of Mexico Fishery Management Council will hold a one-day in-person meeting of its Shrimp Advisory Panel (AP).

DATES: The meeting will convene Monday, December 16, 2024, from 8 a.m. to 1:30 p.m., EST. For agenda details, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The meeting will take place at the Gulf Council office. Registration information will be available on the Council's website by visiting *www.gulfcouncil.org* and clicking on the Shrimp AP meeting on the calendar.

Council address: Gulf of Mexico Fishery Management Council, 4107 W Spruce Street, Suite 200, Tampa, FL 33607; telephone: (813) 348–1630.

FOR FURTHER INFORMATION CONTACT: Dr. Matt Freeman, Economist, Gulf of Mexico Fishery Management Council; *matt.freeman@gulfcouncil.org,* telephone: (813) 348–1630.

SUPPLEMENTARY INFORMATION: The following items are on the agenda, though agenda items may be addressed out of order (changes will be noted on the Council's website when possible.)

Monday, December 16, 2024; 8 a.m.–1:30 p.m., EST (7 a.m.–12:30 p.m. CST)

Meeting will begin with Introduction of Members, Election of Chair and Vice Chair, Adoption of Agenda and Approval of Summary from March 19–20, 2024 Meeting, and Scope of Work.

The AP will review and discuss Council Actions in Response to Motions from the March 2024 *Shrimp* AP Meeting, discuss the Draft Shrimp Framework Action: Modification of the Vessel Position Data Collection Program for the Gulf of Mexico *Shrimp* Fishery, receive a presentation on Survey Design and Estimated Costs for Position-recording Devices in the Gulf of Mexico Shrimp Fleet, and receive an update on *Shrimp* Futures Program.

Lastly, the AP will receive any public testimony and discuss other business items.

Meeting Adjourns—

The in-person meeting will be broadcast via webinar. You may register by visiting *www.gulfcouncil.org* and clicking on the *Shrimp* Advisory Panel meeting on the calendar.

The Agenda is subject to change, and the latest version along with other meeting materials will be posted on *www.gulfcouncil.org* as they become available.

Although other non-emergency issues not on the agenda may come before the Advisory Panel for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), those issues may not be the subject of formal action during this meeting. Actions will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take-action to address the emergency at least 5 working days prior to the meeting.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid or accommodations should be directed to Kathy Pereira,

kathy.pereira@gulfcouncil.org, at least 5 days prior to the meeting date.

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

Dated: November 21, 2024.

Rey Israel Marquez,

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

[FR Doc. 2024–27770 Filed 11–26–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XE471]

Fisheries of the South Atlantic; Southeast Data, Assessment, and Review (SEDAR); Public Meeting

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

ACTION: Notice of SEDAR 92 Atlantic Blueline Tilefish Life History Topical Working Group (LH–TWG) Webinar III.

SUMMARY: The SEDAR 92 assessment of the Atlantic stock of blueline tilefish will consist of a series of assessment webinars. See **SUPPLEMENTARY INFORMATION**.

DATES: The SEDAR 92 Atlantic Blueline Tilefish LH–TWG Webinar III is scheduled for December 18, 2024, from 9 a.m. to 11 a.m., Eastern. The established times may be adjusted as necessary to accommodate the timely completion of discussion relevant to the assessment process. Such adjustments may result in the meeting being extended from or completed prior to the time established by this notice.

ADDRESSES:

Meeting address: The meeting will be held via webinar. The webinar is open to members of the public. Registration for the webinar is available by contacting the SEDAR coordinator via email at *Julie.Neer@safmc.net.*

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

FOR FURTHER INFORMATION CONTACT: Julie Neer, SEDAR Coordinator, 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405; phone: (843) 571–4366; email: *Julie.Neer@safmc.net.*

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions, have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a three-step process including: (1) Data Workshop; (2) Assessment Process utilizing webinars; and (3) Review Workshop. The product of the Data Workshop is a data report which compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The product of the Assessment Process is a stock assessment report which describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The assessment is independently peer reviewed at the Review Workshop. The product of the Review Workshop is a Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, Highly Migratory Species Management Division, and Southeast Fisheries Science Center. Participants include: data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and non-governmental organizations (NGOs); international experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion at the SEDAR 92 Atlantic Blueline Tilefish LH–TWG webinar III: The Group will discuss available life history data sources and make recommendation for their use in the assessment.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

This meeting is accessible to people with disabilities. Requests for auxiliary aids should be directed to the South Atlantic Fishery Management Council office (see **ADDRESSES**) at least 10 business days prior to the meeting.

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

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

Dated: November 22, 2024.

Rey Israel Marquez,

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

[FR Doc. 2024–27839 Filed 11–26–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XE496]

Endangered and Threatened Species; Initiation of 5-Year Review of the Brazilian Guitarfish (Rhinobatos horkelii)

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

ACTION: Notice; request for information.

SUMMARY: We, NMFS, announce the initiation of a 5-year review of the endangered Brazilian guitarfish (*Rhinobatos horkelii*). The Endangered Species Act (ESA) requires us to conduct a review of listed species at least once every 5 years to determine whether a species should be removed from the list (*i.e.,* delisted), reclassified from an endangered species to a threatened species (*i.e.,* downlisted), or reclassified from a threatened species to an endangered species (*i.e.,* uplisted). The determination must be based on the best scientific and commercial data available at the time of the review. Therefore, we request relevant information (*e.g.,* biology, threats, and conservation efforts) that has become available since our previous review of the species.

DATES: To allow us adequate time to conduct the 5-year review, we must receive your information no later than January 27, 2025. While we accept new information about any listed species at any time, information received after the date stated above may not be considered for the purposes of this review.

ADDRESSES: Submit your information electronically via the Federal eRulemaking Portal. Go to *https://www.regulations.gov* and enter NOAA–NMFS–2024–0137 in the Search box. Click on the ''Comment'' icon, complete the required fields, and enter or attach your comments.

Instructions: We may not consider comments or other information if sent by any other method, to any other address or individual, or received after the date stated above. All comments and information received are a part of the public record, and we will post the comments for public viewing on *https://www.regulations.gov.* All personal identifying information (*e.g.,* name, address, *etc.*) submitted voluntarily by the sender will be publicly accessible. Do not submit confidential business information, or otherwise sensitive or protected information. We will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Malcolm Mohead, NMFS Office of Protected Resources, (301) 427–8427, *Malcolm.Mohead@noaa.gov.*

SUPPLEMENTARY INFORMATION: This notice announces our initiation of the Brazilian guitarfish (*Rhinobatos horkelii*) 5-year review. Section 4(c)(2) of the ESA requires us to conduct a review of listed species at least once every 5 years to determine whether species should be removed from the list, changed in status from an endangered species to a threatened species, or changed in status from a threatened species to an endangered species (16 U.S.C. 1533(c)(2)). Section 4(a)(1) of the ESA requires us to determine whether any species is an endangered or threatened species because of any of the following factors: (A) the present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence (16 U.S.C. 1533(a)(1)). Section 4(b)(1)(A) of the ESA requires us to make the determination based solely on the best scientific and commercial data available at the time of the review and after taking into account efforts to protect the species (16 U.S.C. 1533(b)(1)(A)). Regulations in 50 CFR 424.21 require that we publish a notice in the **Federal Register** announcing species currently under active review. Based on such reviews, we determine whether a species should be delisted or reclassified (50 CFR 424.21). Any such change (*i.e.,* delisting or reclassification) would require a separate rulemaking process.

We last performed a review of the Brazilian guitarfish in 2015. Background information on the species is available on the NMFS website at: *https://www.fisheries.noaa.gov/species/brazilian-guitarfish/overview.*

Public Solicitation of Relevant Information

To ensure that the 5-year review is based on the best scientific and commercial data available, we are soliciting information from the public, governmental agencies, Tribes, the scientific community, industry, environmental organizations, and any other interested parties. We request information that has become available since the previous review was published in 2015. Categories of requested information include: (1) species biology including, but not limited to, abundance, population trends, demographics, distribution, and diversity; (2) habitat conditions including, but not limited to, amount, distribution, suitability, and important features for conservation; (3) degree, nature, and trends of threats to the species and its habitats, especially those factors described in section 4(a)(1) of the ESA and listed above; (4) conservation efforts that have been implemented to benefit the species, including monitoring data demonstrating the effectiveness of such efforts; and (5) other information, data, or corrections including, but not limited to, taxonomic or nomenclatural changes and improved analytical methods for evaluating extinction risk.

If you wish to provide information for the review, please submit your information and materials electronically (see **ADDRESSES** section). We request that all information be accompanied by supporting documentation such as maps, bibliographic references, or reprints of pertinent publications.

Authority: 16 U.S.C. 1531 *et seq.*

Dated: November 22, 2024.

Lisa Manning,

Acting Chief, Endangered Species Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2024–27848 Filed 11–26–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XE483]

Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The Mid-Atlantic and New England Fishery Management Councils (Councils) will hold a public meeting of their joint Northeast Trawl Advisory Panel (NTAP).

DATES: The meeting will be held on Friday, December 13, 2024, from 12 p.m. to 1:30 p.m. For agenda details, see **SUPPLEMENTARY INFORMATION.**

ADDRESSES: The meeting will be held via webinar. Connection information will be posted to the calendar at *www.mafmc.org* prior to the meeting.

Council address: Mid-Atlantic Fishery Management Council, 800 N State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331; *www.mafmc.org.*

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526–5255.

SUPPLEMENTARY INFORMATION: The Councils' NTAP will meet to discuss the Operational Manual and Orientation Document. The intent of this meeting is to discuss NTAP in detail, including background, organization, purpose, and member expectation. This meeting will be an opportunity for new and existing NTAP members to discuss and learn about the goals and purposes of NTAP.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Shelley Spedden, (302) 526–5251 at least 5 days prior to the meeting date.

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

Dated: November 21, 2024.

Rey Israel Marquez,

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

[FR Doc. 2024–27769 Filed 11–26–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XE469]

Mid-Atlantic Fishery Management Council (MAFMC); New England Fishery Management Council (NEFMC) Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The Mid-Atlantic Fishery Management Council's Ecosystem and Ocean Planning Committee and New England Fishery Management Council's Habitat Committee will hold a joint public meeting.

DATES: The meeting will be held on Wednesday, December 18, 2024, from 1 p.m. to 4 p.m. For agenda details, see **SUPPLEMENTARY INFORMATION.**

ADDRESSES: The meeting will be held via webinar. Webinar connection, agenda items, and any additional information will be available at both *www.mafmc.org/council-events* and *https://www.nefmc.org/calendar.*

Council addresses: Mid-Atlantic Fishery Management Council, 800 N. State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331; *www.mafmc.org.;* New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950; telephone: (978) 465–0492; *www.nefmc.org.*

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526–5255 or Cate O'Keefe, Ph.D., Executive Director, New England Fishery Management Council; telephone: (978) 465–0492 (ext. 113).

SUPPLEMENTARY INFORMATION: The purpose of this joint meeting is for the Ecosystem and Ocean Planning Committee and Habitat Committee to provide recommendations regarding the Councils' Essential Fish Habitat (EFH) reviews and the draft EFH Review Reports being prepared for the Council. Because many of the EFH Review work products apply to the entire Northeastern US, the Committees are being convened jointly for their review. The Committees will receive an overview of the NMFS EFH Review requirements (10 components of an EFH review), and will review components related to (a) Non-Magnuson-Stevens Act fishing activities that may adversely affect EFH, (b) Non-fishing related activities that may adversely affect EFH, (c) Prey species for federally-managed fish species, (d) EFH research needs, and (e) Methods related to the description and identification of EFH.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Shelley Spedden at the Council Office, (302) 526–5251, at least 5 days prior to the meeting date.

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

Dated: November 22, 2024.

Rey Israel Marquez,

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

[FR Doc. 2024–27843 Filed 11–26–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 23–52]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense (DoD).

ACTION: Arms sales notice.

SUMMARY: The DoD is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Pamela Young at (703) 953–6092, *pamela.a.young14.civ@mail.mil,* or *dsca.ncr.rsrcmgmt.list.cns-mbx@mail.mil.*

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives with attached Transmittal 23–52, Policy Justification, and Sensitivity of Technology.

Dated: November 21, 2024.

Stephanie J. Bost,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 6001–FR–P



DEFENSE SECURITY COOPERATION AGENCY
2800 Defense Pentagon
Washington, DC 20301-2800

DEC 4 2023

The Honorable Mike Johnson
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 23-52, concerning the Army's proposed Letter(s) of Offer and Acceptance to the Government of the United Arab Emirates for defense articles and services estimated to cost $85 million. We will issue a news release to notify the public of this proposed sale upon delivery of this letter to your office.

Sincerely,

James A. Hursch
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology
4. Regional Balance (Classified document provided under separate cover)

BILLING CODE 6001–FR–C

Transmittal No. 23–52

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Government of the United Arab Emirates

(ii) *Total Estimated Value:*

Major Defense Equipment *	$45 million
Other	$40 million
Total	$85 million

Funding Source: National Funds.

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE):
Eighteen (18) AN/TPQ–50 Radar Systems—Man Portable Version

Non-MDE:
Also included are 107mm High Explosive (HE) rockets (for CONUS testing only); Computer Digital Military Laptop Radar Control Display units; 5kW Advanced Medium Mobile Power Source (AMMPS) Trailer-Mounted, Diesel Engine Driven Power Unit PU–2001; spares; mission equipment; communication and navigation

equipment; support equipment; repair parts; special tools and test equipment; technical data and publications; site survey; United States (U.S.) Government and contractor technical and logistics personnel services; and other related elements of logistics and program support.

(iv) *Military Department:* Army (AE–B–ZVL).

(v) *Prior Related Cases, if any:* None.

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None.

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Attached Annex.

(viii) *Date Report Delivered to Congress:* December 4, 2023.

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

United Arab Emirates—AN/TPQ–50 Radar

The Government of the United Arab Emirates (UAE) has requested to buy eighteen (18) AN/TPQ–50 Radar Systems—man portable version. Also included are 107mm High Explosive (HE) rockets (for CONUS testing only); Computer Digital Military Laptop Radar Control Display units; 5kW Advanced Medium Mobile Power Source (AMMPS) Trailer-Mounted, Diesel Engine Driven Power Unit PU–2001; spares; mission equipment; communication and navigation equipment; support equipment; repair parts; special tools and test equipment; technical data and publications; site survey; U.S. Government and contractor technical and logistics personnel services; and other related elements of logistics and program support. The estimated total cost is $85 million.

This proposed sale will support the foreign policy and national security of the United States by helping to improve the security of an important regional partner. The UAE is a vital U.S. partner for political stability and economic progress in the Middle East.

The proposed sale will support efforts to protect critical infrastructure and high value civilian assets, as well as military installations and forces from rocket, artillery, and mortar (RAM) and unmanned aerial system threats. It will also further enhance the United States—UAE relationship, both politically and militarily, while also increasing the UAE's effectiveness in executing military and civil defense operations that promote U.S. national interests. The UAE will use the TPQ–50 radars to recognize incoming threats from hostile nations or agents of adversary nations. The United Arab Emirates will have no difficulty absorbing this equipment and services into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The principal contractor will be SRC Inc, Syracuse, NY. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will not require the permanent assignment of any additional U.S. Government or contractor representatives to the UAE. Temporary periods of travel for two-week durations for both U.S. Government and contractor personnel will be necessary to conduct Operator/Maintainer training, as well as System Integration & Check Out (SICO)/Quality Assurance and Testing (QUAT) activities.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 23–52

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. The AN/TPQ–50 Radar System—man portable version—provides continuous 360-degree surveillance and 3–D rocket, artillery, and mortar (RAM) locations using a L band non-rotating antenna with fixed elevation beams and which is electronically steered in azimuth only. Its full azimuth coverage allows it to simultaneously detect and track multiple rounds fired from separate locations within a 700 square kilometer surveillance area. The AN/TPQ 50 radar provides Point of Origin (POO) and Point of Impact (POI) locations for hostile RAM fire and tracking of air breathing targets (ABTs) in air surveillance (AS) and multi-mission radar (MMR) modes.

2. The highest level of classification of defense articles, components, and services included in this potential sale is SECRET.

3. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software elements, the information could be used to develop countermeasures that might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

4. A determination has been made that the United Arab Emirates can provide substantially the same degree of protection for the sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

5. All defense articles and services listed in this transmittal have been authorized for release and export to the United Arab Emirates.

[FR Doc. 2024–27773 Filed 11–26–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 23–88]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense (DoD).

ACTION: Arms sales notice.

SUMMARY: The DoD is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Pamela Young at (703) 953–6092, *pamela.a.young14.civ@mail.mil,* or *dsca.ncr.rsrcmgmt.list.cns-mbx@mail.mil.*

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives with attached Transmittal 23–88, Policy Justification, and Sensitivity of Technology.

Dated: November 21, 2024.

Stephanie J. Bost,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 6001–FR–P

DEFENSE SECURITY COOPERATION AGENCY
2800 Defense Pentagon
Washington, DC 20301-2800

December 7, 2023

The Honorable Mike Johnson
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 23-88, concerning the Navy's proposed Letter(s) of Offer and Acceptance to the Government of Germany for defense articles and services estimated to cost $300 million. We will issue a news release to notify the public of this proposed sale upon delivery of this letter to your office.

Sincerely,

James A. Hursch
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology

BILLING CODE 6001–FR–C

Transmittal No. 23–88

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Government of Germany

(ii) *Total Estimated Value:*

Major Defense Equipment * ..	$158 million
Other	$142 million
Total	$300 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE):

Up to eighty (80) MK 54 All Up Round Lightweight Torpedoes (LWT)

Non-MDE:

Also included are MK 54 Mod 0 LWT spare parts; Recoverable Exercise Torpedoes (REXTORPs) with containers; handling shapes and containers; torpedo spare parts; tools for mounting and dismounting of Air Launch Accessories (ALAs); equipment for analysis of REXTORP exercise shots; REXTORP maintenance equipment; training; publications; support and test equipment; United States (U.S.) Government and contractor engineering, technical, and logistics support services; and other related elements of logistics and program support.

(iv) *Military Department:* Navy (GY–P–ALF)

(v) *Prior Related Cases, if any:* None

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Attached Annex

(viii) *Date Report Delivered to Congress:* December 7, 2023

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Germany—MK 54 Lightweight Torpedoes

The Government of Germany has requested to buy up to eighty (80) MK 54 All Up Round Lightweight Torpedoes (LWT). Also included are MK 54 Mod 0 LWT spare parts; Recoverable Exercise Torpedoes (REXTORPs) with containers; handling shapes and containers; torpedo spare parts; tools for mounting and dismounting of Air Launch Accessories (ALAs); equipment for analysis of REXTORP exercise shots; REXTORP maintenance equipment; training; publications; support and test equipment; U.S. Government and contractor engineering, technical, and logistics support services; and other related elements of logistics and program support. The estimated total program cost is $300 million.

This proposed sale will support the foreign policy and national security of the United States by improving the security of a NATO Ally that is an important force for political and economic stability in Europe.

The proposed sale will improve Germany's capability to meet current and future threats by upgrading Anti-Submarine Warfare capabilities on its P–8A aircraft. Germany will have no difficulty absorbing this equipment into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The principal contractor will be Raytheon Integrated Defense Systems, Portsmouth, RI. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will not require the assignment of any additional U.S. Government or contractor representatives to Germany; however, U.S. Government Engineering and Technical Services may be required on an interim basis for training and technical assistance.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 23–88

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. The MK 54 Torpedo is a conventional torpedo that can be launched from surface ships, rotary and fixed wing aircraft. The MK 54 is an upgrade to the MK 46 Torpedo. The upgrade to the MK 54 entails replacement of the torpedo's sonar and guidance and control systems with modem technology. The new guidance and control system uses a mixture of commercial-off-the-shelf and custom-built electronics. The warhead, fuel tank, and propulsion system from the MK 46 torpedo are re-used in the MK 54 configuration with minor modifications.

2. The highest level of classification of defense articles, components, and services included in this potential sale is SECRET.

3. If a technologically advanced adversary were to obtain knowledge of the hardware and software elements, the information could be used to develop countermeasures or equivalent systems which might reduce system effectiveness or be used in the development of a system with similar or advanced capabilities.

4. A determination has been made that Germany can provide substantially the same degree of protection for the sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

5. All defense articles and services listed in this transmittal have been authorized for release and export to the Government of Germany.

[FR Doc. 2024–27778 Filed 11–26–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 23–0U]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense (DoD).

ACTION: Arms sales notice.

SUMMARY: The DoD is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Pamela Young at (703) 953–6092, *pamela.a.young14.civ@mail.mil,* or *dsca.ncr.rsrcmgmt.list.cns-mbx@mail.mil*

SUPPLEMENTARY INFORMATION: This 36(b)(5)(C) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives with attached Transmittal 23–0U.

Dated: November 21, 2024.

Stephanie J. Bost,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 6001–FR–P

DEFENSE SECURITY COOPERATION AGENCY
2800 Defense Pentagon
Washington, DC 20301-2800

December 5, 2023

The Honorable Mike Johnson
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(5)(C) of the Arms Export Control Act (AECA), as amended, we are forwarding Transmittal No. 23-0U. This notification relates to enhancements or upgrades from the level of sensitivity of technology or capability described in the Section 36(b)(1) AECA certification 14-12 of May 13, 2014.

Sincerely,

James A. Hursch
Director

Enclosure:
1. Transmittal

BILLING CODE 6001–FR–C

Transmittal No. 23–0U

REPORT OF ENHANCEMENT OR UPGRADE OF SENSITIVITY OF TECHNOLOGY OR CAPABILITY (SEC. 36(B)(5)(C), AECA)

(i) *Purchaser:* Government of Australia

(ii) *Sec. 36(b)(1), AECA Transmittal No.:* 14–12

Date: May 13, 2014

Military Department: Navy

(iii) *Description:* On May 13, 2014, Congress was notified by Congressional certification transmittal number 14–12, of the possible sale, under Section 36(b)(l) of the Arms Export Control Act of up to 350 AIM–9X–2 Sidewinder Tactical Missiles; 35 AIM–9X Special Air Training Missiles (NATM); 95 AIM–9X–2 Captive Air Training Missiles (CATM); 22 AIM–9X–2 Tactical Guidance Units; 19 CATM–9X–2 Guidance Units; and 3 DATM–9X. Also included were containers, test sets and support equipment, spare and repair parts, publications and technical documents, personnel training and training equipment, United States (U.S.) Government and contractor technical assistance, and other related elements of logistics and program support. The estimated total cost was $534 million. Major Defense Equipment (MDE) constituted $476 million of this total.

On January 9, 2018, Congress was notified by Congressional certification transmittal number 0W–17 of the change from 350 AIM–9X–2 Sidewinder Tactical Missiles to reflect 300 AIM–9X Sidewinder Block II+ Tactical Missiles and 50 AIM–9X–2 Sidewinder Tactical Missiles. Additionally, this transmittal reported the inclusion of 11 CATM–9X–2 Missile Guidance Units. The total notified cost of MDE remained $476 million. The total notified case value remained $534 million.

On December 4, 2020, Congress was notified by Congressional certification transmittal number 0A–21 of the addition of four (4) AIM–9X Block II+ Tactical Missile Guidance Units. The total MDE value increase by $1 million to $477 million. The estimated total case value remained $534 million.

This transmittal notifies inclusion of the following MDE: an additional ten (10) AIM–9X Block II Sidewinder Tactical Guidance Units; thirty-two (32) AIM–9X Block II+ Sidewinder Tactical Guidance Units; and ninety (90) AIM–

9X Block II Sidewinder CATM Guidance Units. The estimated total value of the new items is $28 million. The net cost of MDE will increase by $28 million, resulting in a revised MDE value of $505 million. The estimated total case value will remain $534 million.

(iv) *Significance:* The proposed sale will improve Australia's capability to effectively maintain its current force projection and enhance interoperability with U.S. forces.

(v) *Justification:* This proposed sale will support the foreign policy and national security objectives of the U.S. Australia is one of our most important allies in the Western Pacific. The strategic location of this political and economic power contributes significantly to ensuring peace and economic stability in the region. It is vital to the U.S. national interest to assist our ally in developing and maintaining a strong and ready self-defense capability.

(vi) *Sensitivity of Technology:*

The AIM–9X Block II and Block II+ (Plus) SIDEWINDER Missile represents a substantial increase in missile acquisition and kinematics performance over the AIM–9M and replaces the AIM–9X Block I Missile configuration. The missile includes a high off-boresight seeker, enhanced countermeasure rejection capability, low drag/high angle of attack airframe, and the ability to integrate the Helmet Mounted Cueing System. The most current AIM–9X Block II/II+ Operational Flight Software developed for all international partner countries, which is authorized by U.S. Government export policy, provides fifth-generation infrared missile capabilities such as lock-on-after-launch, weapons data link, surface attack, and surface launch. No software source code or algorithms will be released.

The Sensitivity of Technology Statement contained in the original notification applies to additional items reported here.

The highest level of classification of defense articles, components, and services included in this potential sale is SECRET.

(vii) *Date Report Delivered to Congress:* December 5, 2023

[FR Doc. 2024–27776 Filed 11–26–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 23–15]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense (DoD).

ACTION: Arms sales notice.

SUMMARY: The DoD is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Pamela Young at (703) 953–6092, *pamela.a.young14.civ@mail.mil,* or *dsca.ncr.rsrcmgmt.list.cns-mbx@mail.mil.*

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives with attached Transmittal 23–15, Policy Justification, and Sensitivity of Technology.

Dated: November 21, 2024.

Stephanie J. Bost,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 6001–FR–P



DEFENSE SECURITY COOPERATION AGENCY
2800 Defense Pentagon
Washington, DC 20301-2800

DEC 6 2023

The Honorable Mike Johnson
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 23-15, concerning the Air Force's proposed Letter(s) of Offer and Acceptance to the Kingdom of Saudi Arabia for defense articles and services estimated to cost $582 million. We will issue a news release to notify the public of this proposed sale upon delivery of this letter to your office.

Sincerely,

James A. Hursch
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology
4. Regional Balance (Classified document provided under separate cover)

BILLING CODE 6001–FR–C

Transmittal No. 23–15

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Kingdom of Saudi Arabia

(ii) *Total Estimated Value:*

Major Defense Equipment *	$ 60 million
Other	$522 million
Total	$582 million

Funding Source: National Funds.

(iii) *Description and Quantity or Quantities of Articles or Services Under Consideration for Purchase:* The Government of Saudi Arabia has requested to buy aircraft hardware and software modifications and support to replenish and modernize its RE–3A Tactical Airborne Surveillance System (TASS) aircraft, including:

Major Defense Equipment (MDE):
Seven (7) Embedded Global Positioning System/Inertial Navigation System (GPS/INS) (EGI) Security Devices, Airborne, with Selective Availability Anti-Spoofing Module (SAASM) or M-Code Capability
Five (5) L3Harris BlackRock

Communications Intelligence Sensor Suites

Non-MDE:

Also included are KY–100M narrowband/wideband secure communications terminals; KIV–77 MODE 4/5 Identification Friend or Foe (IFF) cryptographic appliques; AN/PYQ–10 Simple Key Loaders; integrated electronic intelligence (ELINT)/signals intelligence (SIGINT) systems; L–3 Communication Systems-West (CSW) multiband receivers/transmitters; ARC–210 radios; high frequency (HF) radios; secure communications equipment; precision navigation and cryptographic devices; aircraft support and support equipment; test and integration support; equipment; spare and repair parts; consumables and accessories; repair and return support; United States (U.S.) Government and contractor engineering, technical, and logistics support services; studies and surveys; and other related elements of logistics and program support.

(iv) *Military Department:* Air Force (SR–D–QDO)

(v) *Prior Related Cases, if any:* None

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None known at this time

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Attached Annex

(viii) *Date Report Delivered to Congress:* December 4, 2023

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Saudi Arabia—RE–3A Tactical Airborne Surveillance System Aircraft Modernization

The Kingdom of Saudi Arabia has requested to buy aircraft hardware and software modifications and support to replenish and modernize its RE–3A Tactical Airborne Surveillance System (TASS) aircraft, including: seven (7) Embedded Global Positioning System/Inertial Navigation System (GPS/INS) (EGI) security devices, Airborne, with Selective Availability Anti-Spoofing Module (SAASM) or M-Code capability, and five (5) L3Harris BlackRock Communications Intelligence Sensor Suites. Also included are KY–100M narrowband/wideband secure communications terminals; KIV–77 MODE 4/5 Identification Friend or Foe (IFF) cryptographic appliques; AN/PYQ–10 Simple Key Loaders; integrated electronic intelligence (ELINT)/signals intelligence (SIGINT) systems; L–3 Communication Systems-West (CSW) multiband receivers/transmitters; ARC–210 radios; high frequency (HF) radios; secure communications equipment; precision navigation and cryptographic devices; aircraft support and support equipment; test and integration support; equipment; spare and repair parts; consumables and accessories; repair and return support; U.S. Government and contractor engineering, technical, and logistics support services; studies and surveys; and other related elements of logistics and program support. The estimated total cost is $582 million.

This proposed sale will support the foreign policy goals and national security objectives of the United States by improving the security of a partner country that is a force for political stability and economic progress in the Gulf Region.

The proposed sale will improve Saudi Arabia's surveillance capability to counter current and future regional threats, strengthen its homeland defense, and improve interoperability with systems operated by U.S. forces and other Gulf Region partners. Saudi Arabia will have no difficulty absorbing these systems into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The principal contractor will be L3 Technologies, Greenville, TX. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will not require the assignment of any additional U.S. Government or contractor representatives to Saudi Arabia.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 23–15

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. The Embedded Global Positioning System/Inertial Navigation System (GPS/INS) (EGI) with Selective Availability Anti-Spoofing Module (SAASM)—or M-Code receiver when available—and Precise Positioning Service (PPS) is a self-contained navigation system that provides the following: acceleration, velocity, position, attitude, platform azimuth, magnetic and true heading, altitude, body angular rates, time tags, and coordinated universal time (UTC) synchronized time. SAASM or M-Code enables the GPS receiver access to the encrypted P(Y or M) signal, providing protection against active spoofing attacks.

2. The L3Harris BlackRock is a communications intelligence (COMINT) system comprised of multiple Direction Finding (DF) antenna arrays, a Radio Frequency (RF) distribution system, software defined tuners, and a reconfigurable processing solution hosting the applications. The BlackRock provides COMINT processing of over 100 simultaneous signals for complete situational awareness of modern communications environments.

3. The KY–100M is a lightweight terminal for secure voice and data communications. The KY–100M provides wideband/narrowband half-duplex communication. Operating in tactical ground, marine, and airborne applications, the KY–100M enables secure communication with a broad range of radio and satellite equipment.

4 The Electronic Intelligence (ELINT) system is composed of Automatic (L3H Corvus) and Manual (SNC Small SwaP Digital SIGINT system) ELINT systems utilizing Left-Hand Side LHS) and Right-Hand Side (RHS) Interferometer arrays, signal tuners, processing/high speed data storage components, Radio Frequency (RF) distribution system, LHS and RHS steerable beam antennas and a 360-degree spin Direction Finding (DF) antennas.

5. The AN/APQ–10C Simple Key Loader is a handheld fill device for securely receiving, storing, and transferring data between cryptographic and communications equipment.

6. The L–3 Communication Systems-West (CSW) Multiband Receiver/Transmitter is a lightweight, handheld military radio that provides an integrated capability to receive and view battlefield video with advanced tactical voice and data communications.

7. The ARC–210 UHF/VHF secure radio with HAVE QUICK II/SATURN is a voice communications radio system that can operate in either normal, secure, and/or jam-resistant modes.

8. The highest level of classification of defense articles, components, and services included in this potential sale is SECRET.

9. If a technologically advanced adversary were to obtain knowledge of the hardware and software elements, the information could be used to develop countermeasures or equivalent systems which might reduce system effectiveness or be used in the development of a system with similar or advanced capabilities.

10. A determination has been made that the Government of Saudi Arabia can provide substantially the same degree of protection for the sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

11. All defense articles and services listed in this transmittal are authorized for release and export to Saudi Arabia.

[FR Doc. 2024–27774 Filed 11–26–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 23–0X]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense (DoD).

ACTION: Arms sales notice.

SUMMARY: The DoD is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Pamela Young at (703) 953–6092, *pamela.a.young14.civ@mail.mil,* or *dsca.ncr.rsrcmgmt.list.cns-mbx@mail.mil*

SUPPLEMENTARY INFORMATION: This 36(b)(5)(C) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives with attached Transmittal 23–0X.

Dated: November 21, 2024.

Stephanie J. Bost,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 6001–FR–P

DEFENSE SECURITY COOPERATION AGENCY
2800 Defense Pentagon
Washington, DC 20301-2800

December 5, 2023

The Honorable Mike Johnson
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(5)(C) of the Arms Export Control Act (AECA), as amended, we are forwarding Transmittal No. 23-0X. This notification relates to enhancements or upgrades from the level of sensitivity of technology or capability described in the Section 36(b)(1) AECA certification 20-57 of September 2, 2020.

Sincerely,

James A. Hursch
Director

Enclosure:
1. Transmittal

BILLING CODE 6001–FR–P

Transmittal No. 23–0X

REPORT OF ENHANCEMENT OR UPGRADE OF SENSITIVITY OF TECHNOLOGY OR CAPABILITY (SEC. 36(B)(5)(C), AECA)

(i) *Purchaser:* Government of Spain

(ii) *Sec. 36(b)(1), AECA Transmittal No.:* 20–57

Date: September 2, 2020

Implementing Agency: Air Force

(iii) *Description:* On September 2, 2020, Congress was notified by Congressional certification transmittal number 20–57, of the possible sale under Section 36(b)(1) of the Arms Export Control Act, of one hundred (100) AIM–120C–7/8 Advanced Medium Range Air-to-Air Missiles (AMRAAM) and one (1) AMRAAM Guidance Section (spare). Also included were KGV–135A encryption devices; containers; weapon support and support equipment; spare and repair parts; publications and technical documentation; United States (U.S.) Government and contractor engineering, technical, and logistics support services; and other related elements of logistical and program support. The estimated total cost was $248.5 million. Major Defense Equipment (MDE) constituted $237.0 million of this total.

This transmittal notifies the addition of the following MDE items: six hundred fifty-five (655) AIM–120 C–8 Advanced Medium Range Air-to-Air Missiles (AMRAAM) or AIM–120 C–8 AMRAAM Extended Range Missiles (AMRAAM–ER); four (4) AIM–120C–8 AMRAAM Instrumented Test Vehicles (ITV); and thirteen (13) AIM–120 C–8 AMRAAM Guidance Sections (AMRAAM GS). Also included are AIM–120 Captive Air Training Missiles (CATM) and spare control sections; Common Munitions Built-in-Test (BIT)/ Reprogramming Equipment (CMBRE); classified software delivery and support; transportation support; and studies and surveys. The estimated total value of the new items is $1.6835 billion. The estimated MDE value will increase by $1.5485 billion to a revised $1.7855 billion. The estimated non-MDE value will increase by $0.135 billion to a revised $0.1465 billion. The estimated total case value will increase to $1.932 billion.

(iv) *Significance:* This notification is being provided as the additional MDE items were not enumerated in the original notification. The inclusion of this MDE represents an increase in capability over what was previously notified. The proposed sale will improve Spain's capability to meet current and future threats by increasing its stocks of AMRAAMs for its fighter aircraft fleets and air defense in support of its national defense and will further strengthen interoperability with the U.S..

(v) *Justification:* This proposed sale will support the foreign policy and national security objectives of the United States by supporting the security and defense needs of a NATO Ally which is an important force for political stability and economic progress in Europe.

(vi) *Sensitivity of Technology:* The Advanced Medium Range Air-to-Air Missile-Extended Range (AMRAAM–ER) variant utilizes an AIM–120C–7 or C–8 seeker and warhead joined with a new control section and rocket rotor (for surface launch mode applications). This provides extended range and altitude as well as higher speed and maneuverability. Common Munitions Built-in-Test (BIT)/Reprogramming Equipment (CMBRE) is supporting equipment.

The Instrumented Test Vehicle (ITV) is a captive carry test vehicle used primarily for flight test integration. The ITV verifies and assesses the aircraft's ability to safely support an AMRAAM launch through the aircraft interface mechanism and the aircraft datalink antenna.

The Sensitivity of Technology Statement contained in the original notification applies to additional items reported here.

The highest level of classification of defense articles, components, and services included in this potential sale is SECRET.

(vii) *Date Report Delivered to Congress:* December 5, 2023

[FR Doc. 2024–27775 Filed 11–26–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Department of the Navy

Department of the Navy Science and Technology Board; Notice of Federal Advisory Committee Meeting

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

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: The DoD is publishing this notice to announce that the following Federal Advisory Committee meeting of the Department of the Navy Science and Technology Board (DoN S&T Board) will take place.

DATES: An open meeting will be held on Tuesday, December 3, 2024, from 10 a.m. to 10:30 a.m. Eastern Time Zone (ET).

ADDRESSES: The Open session will be held virtually via video conference. Information for accessing the video conference will be provided after registering. (Pre-meeting registration is required. See guidance in **SUPPLEMENTARY INFORMATION** ''Meeting Accessibility''.)

FOR FURTHER INFORMATION CONTACT: Ms. Maria Proestou, Designated Federal Officer (DFO), Office of the Assistant Secretary of the Navy (Research, Development & Acquisition), Pentagon, Washington, DC 20350–1000, 703–692–8278, *don-stb@us.navy.mil.*

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of chapter 10 of title 5 U.S.C. (commonly known as the Federal Advisory Committee Act (FACA), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), title 41 Code of Federal Regulations (CFR) 102–3.140 and 102–3.150. Due to circumstances beyond the control of the Designated Federal Officer, the DoN S&T Board was unable to provide public notification required by 41 CFR 102–3.150(a) concerning its December 3, 2024 meeting. Accordingly, the Advisory Committee Management Officer for the Department of Defense, pursuant to 41 CFR 102–3.150(b), waives the 15-calendar day notification requirement.

Purpose of the Meeting: The purpose of the meeting will be for the Board to vote on two completed study topics, Electronic Warfare for Terminal Defense and Ship Maintenance.

Agenda: On December 3, 2024, the Chair of the Board will convene the open session in order to discuss and vote on forwarding two completed studies to the Board's sponsor, the Secretary of the Navy.

Availability of Materials for the Meeting: A copy of the agenda or any updates to the agenda for the meeting on December 3, 2024, as well as supporting documents, can be found on the website: *https://www.secnav.navy.mil/rda/S&TBoard/Pages/default.aspx.*

Meeting Accessibility: The open session will be held by videoconference. All members of the public who wish to attend must register by contacting DON S&T Board at *don-stb@us.navy.mil.* Once registered, the web address and/or audio number will be provided. If there are any questions or concerns, please send them to *don-stb@us.navy.mil* no later than November 26, 2024.

Written Statements: Pursuant to 41 CFR 102–3.105 and 102–3.140, and section 1009(a)(3) of title 5 U.S.C.,

written statements to the committee may be submitted at any time or in response to a stated planned meeting agenda by email to *don-stb@us.navy.mil* with the subject line, ''Comments for DON S&T Board Meeting.''

Dated: November 22, 2024

A.J. Gioiello,

Lieutenant Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2024–27812 Filed 11–26–24; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2024–SCC–0142]

Agency Information Collection Activities; Comment Request; EDFacts Data Collection School Years 2025–26, 2026–27, and 2027–28 (With 2024–25 Continuation)

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

ACTION: Notice.

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

DATES: Interested persons are invited to submit comments on or before January 27, 2025.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2024–SCC–0142. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the regulations.gov site is not available to the public for any reason, the Department will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. Please note that comments submitted after the comment period will not be accepted. Written requests for information or comments submitted by postal mail or delivery should be addressed to the Manager of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 4C210, Washington, DC 20202–1200.

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

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

Title of Collection: EDFacts Data Collection School Years 2025–26, 2026–27, and 2027–28 (with 2024–25 Continuation).

OMB Control Number: 1850–0925.

Type of Review: A revision of a currently approved ICR.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 61.

Total Estimated Number of Annual Burden Hours: 126,880.

Abstract: EDFacts is a U.S. Department of Education (ED) initiative, conducted by the National Center for Education Statistics (NCES), to collect, analyze, report on, and promote the use of high-quality, pre-kindergarten through grade 12 (pre-K–12) performance data. By centralizing data provided by state education agencies about state level data, local education agencies, and schools, NCES uses the EDFacts data to report on students, schools, staff, services, and education outcomes at the state, district, and school levels. The centralized approach provides ED users with the ability to efficiently analyze and report on submitted data and has reduced the reporting burden for state and local data producers through the use of streamlined data collection, analysis, and reporting tools. EDFacts collects information on behalf of ED grant and program offices for approximately 170 data groups for all 50 states, Washington DC, Puerto Rico, and seven outlying areas and freely associated states (American Samoa, Federated States of Micronesia, Guam, Marshall Islands, Commonwealth of the Northern Mariana Islands, Republic of Palau, and the U.S. Virgin Islands), the Department of Defense Education Activity (DoDEA), and the Bureau of Indian Education (BIE).

This request is to collect EDFacts data for the 2025–26, 2026–27, and 2027–28 school years. This collection package will be available for public comment during two open periods, a 60-day and a 30-day, after which revisions will be made accordingly. As part of the public comment period review, ED requests that SEAs and other stakeholders respond to the directed questions found in Attachment D. Due to overlap in the timing of data collection activities between consecutive years of the EDFacts collection, we are carrying over in this submission the approved SY 2024–25 data collection, which is scheduled to end in February 2026.

Dated: November 22, 2024.

Stephanie Valentine,

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

[FR Doc. 2024–27845 Filed 11–26–24; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2024–SCC–0101]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; School Pulse Panel 2025–26 and 2026–27 (SPP 2025–26, SPP 2026–27) Preliminary Field Activities

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

ACTION: Notice.

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

DATES: Interested persons are invited to submit comments on or before December 27, 2024.

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

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

SUPPLEMENTARY INFORMATION: The Department is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: School Pulse Panel 2025–26 and 2026–27 (SPP 2025–26, SPP 2026–27) Preliminary Field Activities.

OMB Control Number: 1850–0975.

Type of Review: A revision of a currently approved ICR.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 6,339.

Total Estimated Number of Annual Burden Hours: 2,503.

Abstract: The School Pulse Panel (SPP) is a data collection that was originally designed to collect voluntary responses from a nationally representative sample of public schools to better understand how schools, students, and educators were responding to the ongoing stressors of the coronavirus pandemic. The School Pulse Panel is conducted by the National Center for Education Statistics (NCES), part of the Institute of Education Sciences (IES), within the United States Department of Education. Initially, the purpose of the study was to collect extensive data on issues brought to light by the COVID–19 pandemic, as well as other important education-related issues that could inform data-driven policy decisions, in U.S. public schools. Due to the immediate need to collect pandemic-era information from schools as described in Executive Order 14000, an emergency clearance was issued to develop and field the first several monthly collections of the SPP in 2021 and a full review of the SPP data collection was performed in 2022 (OMB# 1850–0969). SPPs innovative design and timely dissemination of findings have been used and cited frequently among Department of Education senior leadership, the White House Domestic Policy Council, the USDAs Food and Nutrition Service, the Centers for Disease Control and Prevention, Congressional deliberations, and the media. The growing interest from stakeholders resulted in a request for funding to create an established NCES quick-turnaround data collection vehicle to become a mainstay for NCES. Funding for a mainstay collection was approved in late 2022, and NCES conducted a new collection during the 2023–24 school year (OMB# 1850–0975).

The School Pulse Panel study is one of the few reliable, nationally representative, quick-turnaround studies that produces data on U.S. public schools. The sample design for the 2025–26 collection will roughly be the same as the 2024–25 collection with 4,000 public schools randomly selected to an initial sample and 4,000 in a reserve sample. It is expected these schools will come from roughly 3,000 districts. The goal is national representation from about 1,200 responding schools each month in order to report out national estimates. School staff will be asked to provide requested data monthly during the 2025–26 school year. This approach provides the ability to collect detailed information on various topics while also assessing changes over time for items that are repeated from year to year. Given the demand for data collection, the content of the survey is expected to change monthly. For the 2025–26 school year, the survey may ask school staff about a wide range of topics, including but not limited to staffing; learning recovery; absenteeism; usage of federal funds; and overall principal experiences.

This package includes preliminary activities, including contacting and obtaining research approvals from public school districts with an established research approval process (special contact districts) where applicable; notifying sampled schools and districts of their selection for the survey; and inviting them to complete a short Screener Survey to establish points of contact. In spring of 2025, a clearance for main study data collection activities that will include instruments for the first quarter of collections will be submitted for 60-day and 30-day public comment. Subsequent quarterly content submissions will be submitted for 30-day public comment.

This request is to conduct the SPP 2025–26 preliminary activities. Substantial edits and additional materials may be added to this package after the 60-day public comment period is complete, in time for the subsequent 30-day public comment period that will begin Fall 2024. Materials for SPP are cleared under two OMB Number sequences. Materials for SPP 2022 and SPP 2024–25 were cleared under OMB# 1850–0969, while SPP 2023–24 and now SPP 2025–26 are cleared under OMB# 1850–0975.

Dated: November 22, 2024.

Stephanie Valentine,

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

[FR Doc. 2024–27846 Filed 11–26–24; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Proposed Agency Information Collection: Supplemental Labor Management Office (SLMO) Driver Attestation

AGENCY: U.S. Department of Energy.

ACTION: Notice of request for comments.

SUMMARY: The Department of Energy (DOE) invites public comment on a proposed collection of information that DOE is developing for submission to the Office of Management and Budget (OMB) pursuant to the Paperwork Reduction Act of 1995. The information collection requests a three-year approval of its collection, titled BPA Supplemental Labor Management Office (SLMO) Driver Authorization, OMB Control Number 1910–NEW. The proposed collection will ask contract personnel to certify they have

completed the requirements to drive a government vehicle on behalf of BPA and presented credentials to their contract company that they are licensed for the type of license their role requires.

DATES: Comments regarding this collection must be received on or before December 27, 2024. If you anticipate that you will be submitting comments but find it difficult to do so within the period allowed by this notice, please advise the OMB Desk Officer of your intention to make a submission as soon as possible. The Desk Officer may be telephoned at 202–881–8585.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments may be sent to Bonneville Power Administration, Attn: Stephanie Noell, Privacy Program, CGI–7, PO Box 3621, Portland, OR 97208–3621, or by email at *privacy@bpa.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Attn: Stephanie Noell, Privacy Program, by email at *privacy@bpa.gov,* or by phone at (503) 230–3881.

SUPPLEMENTARY INFORMATION: This information collection request contains:

(1) *OMB No.:* 1910–NEW;

(2) *Information Collection Request Title:* BPA Supplemental Labor Management Office (SLMO) Driver Authorization;

(3) *Type of Request:* New;

(4) *Purpose:* The purpose of the Information Collection Request is to collect information from BPA contractors at Bonneville Power Administration (BPA) sites pertaining to authorization to operate BPA owned/leased/provided motor vehicles by contracted labor personnel;

(5) *Annual Estimated Number of Respondents:* 250;

(6) *Annual Estimated Number of Total Responses:* 250;

(7) *Annual Estimated Number of Burden Hours:* 250;

(8) *Annual Estimated Reporting and Recordkeeping Cost Burden:* $17,150.

Statutory Authority: The Bonneville Project Act codified in 16 U.S.C. 832a, the Federal Columbia River Transmission System Act of 1974 codified in 16 U.S.C. 838 *et seq.,* the Pacific Northwest Electric Power Planning and Conservation Act in 16 U.S.C. 839 *et seq.,* Department of Energy Establishment Act 42 U.S.C. 7101 *et seq.,* and 41 CFR 101–39.300 General Services Administration (GSA) Interagency Fleet Management System (IFMS).

Signing Authority: This document of the Department of Energy was signed on November 12, 2024, by Candice D. Palen, Information Collection Clearance Manager, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC on November 22, 2024.

Treena V. Garrett,

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

[FR Doc. 2024–27835 Filed 11–26–24; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 15300–001]

BOST1 Hydroelectric LLC; Notice of Surrender of Preliminary Permit

Take notice that BOST1 Hydroelectric LLC., permittee for the proposed Heard County Pumped Storage Project, has requested that its preliminary permit be terminated. The permit was issued on October 19, 2023,[1] and would have expired on September 30, 2027. The project would have been located approximately 1.8 miles west of the City of Enon Grove, Heard County, Georgia.

The preliminary permit for Project No. 15300 will remain in effect until the close of business, December 20, 2024. But, if the Commission is closed on this day, then the permit remains in effect until the close of business on the next day in which the Commission is open.[2] New applications for this site may not be submitted until after the permit surrender is effective.

[1] 185 FERC ¶ 61,041 (2023).

[2] 18 CFR 385.2007(a)(2) (2024).

Dated: November 20, 2024.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2024–27768 Filed 11–26–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP21–465–004]

Driftwood Pipeline, LLC; Notice of Request for Extension of Time

Take notice that on November 13, 2024, Driftwood Pipeline, LLC (Driftwood Pipeline) requested that the Commission grant an extension of time, until October 21, 2027, to construct and place into service its Line 200 and Line 300 Project (Project), located in Beauregard and Calcasieu Parishes, Louisiana, as authorized in the April 21, 2023 Order Issuing Certificate (Order).[1] The Order required Driftwood Pipeline to complete construction of the Project and make it available for service within two years of the date of the Order, or by April 21, 2025.

Driftwood Pipeline states that it has experienced delays resulting from unforeseen circumstances, including litigation delays from an appeal of the Certificate Order in the United States Court of Appeals for the District of Columbia Circuit and uncertainty associated with impending changes in company leadership and other personnel related to a change in ownership of Driftwood Pipeline's parent company. Driftwood Pipeline states that these issues further complicated efforts to reach a final investment decision, and thus additional time is required for completing construction of the Project and placing it into service.

This notice establishes a 15-calendar day intervention and comment period deadline. Any person wishing to comment on Driftwood Pipeline's request for an extension of time may do so. No reply comments or answers will be considered. If you wish to obtain legal status by becoming a party to the proceedings for this request, you should, on or before the comment date stated below, file a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the Natural Gas Act (NGA) (18 CFR 157.10).

[1] *Driftwood Pipeline LLC,* 183 FERC ¶ 61,049 (2023), *as amended, Driftwood Pipeline LLC,* Errata Notice, Docket Nos. CP21–465–000, *et al.* (May 2, 2023).

As a matter of practice, the Commission itself generally acts on requests for extensions of time to complete construction for NGA facilities when such requests are contested before order issuance. For those extension requests that are contested,[2] the Commission will aim to issue an order acting on the request within 45 days.[3] The Commission will address all arguments relating to whether the applicant has demonstrated there is good cause to grant the extension.[4] The Commission will not consider arguments that re-litigate the issuance of the certificate order, including whether the Commission properly found the project to be in the public convenience and necessity and whether the Commission's environmental analysis for the certificate complied with the National Environmental Policy Act.[5] At the time a pipeline requests an extension of time, orders on certificates of public convenience and necessity are final and the Commission will not re-litigate their issuance.[6] The Director of the Office of Energy Projects, or his or her designee, will act on all of those extension requests that are uncontested.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*). From the Commission's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

User assistance is available for eLibrary and the Commission's website during normal business hours from FERC Online Support at (202) 502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov.*

The Commission strongly encourages electronic filings of comments in lieu of paper using the ''eFile'' link at *http://www.ferc.gov.* In lieu of electronic filing, you may submit a paper copy which must reference the Project docket number.

To file via USPS: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To file via any other courier: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Comment Date: 5 p.m. eastern time on December 5, 2024.

Dated: November 20, 2024.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2024–27777 Filed 11–26–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EF25–2–000]

Western Area Power Administration; Notice of Filing

Take notice that on November 15, 2024, Western Area Power Administration submitted a tariff filing per 300.10: UGP_PSMBP–ED_WAPA213–20240930 to be effective 1/1/2025.

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

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

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Comment Date: 5:00 p.m. Eastern Time on December 15, 2024.

Dated: November 20, 2024.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2024–27772 Filed 11–26–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EF25–1–000]

Western Area Power Administration; Notice of Filing

Take notice that on November 15, 2024, Western Area Power Administration submitted a tariff filing per 300.10: RMR_LAP_WAPA212–20241115 to be effective January 1, 2025.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken but will

[2] Contested proceedings are those where an intervenor disputes any material issue of the filing. 18 CFR 385.2201(c)(1).

[3] *Algonquin Gas Transmission, LLC,* 170 FERC ¶ 61,144, at P 40 (2020).

[4] *Id.* at P 40.

[5] Similarly, the Commission will not re-litigate the issuance of an NGA section 3 authorization, including whether a proposed project is not inconsistent with the public interest and whether the Commission's environmental analysis for the permit order complied with NEPA.

[6] *Algonquin Gas Transmission, LLC,* 170 FERC ¶ 61,144, at P 40 (2020).

not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

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

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Comment Date: 5 p.m. eastern time on December 15, 2024.

Dated: November 20, 2024.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2024–27771 Filed 11–26–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

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

Filings Instituting Proceedings

Docket Numbers: RP25–198–000.

Applicants: Maritimes & Northeast Pipeline, L.L.C.

Description: Compliance filing: Joint Petition for Approval of Settlement Agreement to be effective N/A.

Filed Date: 11/21/24.

Accession Number: 20241121–5001.

Comment Date: 5 p.m. ET 12/3/24.

Docket Numbers: RP25–199–000.

Applicants: Kern River Gas Transmission Company.

Description: 4(d) Rate Filing: 2024 Leap Year Reversal Filing to be effective 1/1/2025.

Filed Date: 11/21/24.

Accession Number: 20241121–5047.

Comment Date: 5 p.m. ET 12/3/24.

Docket Numbers: RP25–200–000.

Applicants: Southern Natural Gas Company, L.L.C.

Description: Compliance filing: SNG Operational Transactions Filing 2024 to be effective N/A.

Filed Date: 11/21/24.

Accession Number: 20241121–5053.

Comment Date: 5 p.m. ET 12/3/24.

Docket Numbers: RP25–201–000.

Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: 4(d) Rate Filing: List of Non-Conforming Service Agreements (SRE Interim) to be effective 12/22/2024.

Filed Date: 11/21/24.

Accession Number: 20241121–5059.

Comment Date: 5 p.m. ET 12/3/24.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings

Docket Numbers: RP24–164–005.

Applicants: Carolina Gas Transmission, LLC.

Description: Compliance filing: CGT–RP24–164 Rate Case Settlement Compliance Filing to be effective 6/1/2024.

Filed Date: 11/21/24.

Accession Number: 20241121–5025.

Comment Date: 5 p.m. ET 12/3/24.

Any person desiring to protest in any the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

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

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

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: November 21, 2024.

Carlos D. Clay,

Acting Deputy Secretary.

[FR Doc. 2024–27808 Filed 11–26–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2322–069]

Brookfield White Pine Hydro, LLC; Notice of Reasonable Period of Time for Water Quality Certification Application

On November 8, 2024, Maine Department of Environmental Protection (Maine DEP) submitted to the Federal Energy Regulatory Commission (Commission) notice that it received a request for a Clean Water Act section 401(a)(1) water quality certification as defined in 40 CFR 121.5, from Brookfield White Pine Hydro, LLC, in conjunction with the above captioned project on October 21, 2024. Pursuant to section 5.23(b) of the Commission's regulations,[1] we hereby notify Maine DEP of the following:

Date of Receipt of the Certification Request: October 21, 2024.

Reasonable Period of Time to Act on the Certification Request: October 21, 2025.

If Maine DEP fails or refuses to act on the water quality certification request on or before the above date, then the certifying authority is deemed waived pursuant to section 401(a)(1) of the Clean Water Act, 33 U.S.C. 1341(a)(1).

Dated: November 20, 2024.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2024–27779 Filed 11–26–24; 8:45 am]

BILLING CODE 6717–01–P

[1] 18 CFR 5.23(b).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

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

Docket Numbers: EG25–34–000.
Applicants: Enbridge Solar (Orange Grove), LLC.
Description: Enbridge Solar (Orange Grove), LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.
Filed Date: 11/5/24.
Accession Number: 20241105–5265.
Comment Date: 5 p.m. ET 11/26/24.

Docket Numbers: EG25–39–000.
Applicants: Bluegrass Solar, LLC.
Description: Bluegrass Solar, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.
Filed Date: 11/21/24.
Accession Number: 20241121–5100.
Comment Date: 5 p.m. ET 12/12/24.

Docket Numbers: EG25–40–000.
Applicants: Burksol LLC.
Description: Burksol LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.
Filed Date: 11/21/24.
Accession Number: 20241121–5148.
Comment Date: 5 p.m. ET 12/12/24.

Docket Numbers: EG25–41–000.
Applicants: Desert Willow Energy Storage, LLC.
Description: Desert Willow Energy Storage, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.
Filed Date: 11/21/24.
Accession Number: 20241121–5152.
Comment Date: 5 p.m. ET 12/12/24.

Docket Numbers: EG25–42–000.
Applicants: Anole Energy Storage, LLC.
Description: Anole Energy Storage, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.
Filed Date: 11/21/24.
Accession Number: 20241121–5166.
Comment Date: 5 p.m. ET 12/12/24.

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

Docket Numbers: ER25–500–000.
Applicants: Scatter Wash Energy Storage LLC.
Description: Baseline eTariff Filing: Baseline new to be effective 11/21/2024.
Filed Date: 11/20/24.
Accession Number: 20241120–5176.
Comment Date: 5 p.m. ET 12/11/24.

Docket Numbers: ER25–501–000.
Applicants: PJM Interconnection, L.L.C.
Description: 205(d) Rate Filing: Original GIA Service Agreement No. 7407; Project Identifier No. AF2–383 to be effective 10/23/2024.
Filed Date: 11/21/24.
Accession Number: 20241121–5023.
Comment Date: 5 p.m. ET 12/12/24.

Docket Numbers: ER25–502–000.
Applicants: PJM Interconnection, L.L.C.
Description: 205(d) Rate Filing: Rev to OA, Sch. 12 & RAA, Sch. 17 RE 3Q 2024 Member Lists to be effective 9/30/2024.
Filed Date: 11/21/24.
Accession Number: 20241121–5044.
Comment Date: 5 p.m. ET 12/12/24.

Docket Numbers: ER25–503–000.
Applicants: Public Service Company of Colorado.
Description: 205(d) Rate Filing: 2024–11–21–PSC–UPI–T–2024–8–Farren–SISA–853–0.0.0 to be effective 1/20/2025.
Filed Date: 11/21/24.
Accession Number: 20241121–5062.
Comment Date: 5 p.m. ET 12/12/24.

Docket Numbers: ER25–504–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: 205(d) Rate Filing: 2024–11–21_SA 6522 MISO-Manitowoc Public Utilities Third SSR Agrmt Lakefront 9 to be effective 2/1/2025.
Filed Date: 11/21/24.
Accession Number: 20241121–5071.
Comment Date: 5 p.m. ET 12/12/24.

Docket Numbers: ER25–505–000.
Applicants: Nevada Gold Energy LLC.
Description: Initial rate filing: Nevada Gold Energy Reactive Power Filing to be effective 1/21/2025.
Filed Date: 11/21/24.
Accession Number: 20241121–5136.
Comment Date: 5 p.m. ET 12/12/24.

Docket Numbers: ER25–506–000.
Applicants: Appalachian Power Company.
Description: 205(d) Rate Filing: OATT—Revise Attachment K, AEP Texas Inc. Rate Update to be effective 12/31/9998.
Filed Date: 11/21/24.
Accession Number: 20241121–5139.
Comment Date: 5 p.m. ET 12/12/24.

Docket Numbers: ER25–507–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: 205(d) Rate Filing: 2024–11–21_Att X Queue Cap Proposal and Exemptions to Queue Cap Proposal to be effective 1/31/2025.
Filed Date: 11/21/24.
Accession Number: 20241121–5143.
Comment Date: 5 p.m. ET 12/12/24.

Docket Numbers: ER25–508–000.
Applicants: American Electric Power Service Corporation, PJM Interconnection, L.L.C.
Description: 205(d) Rate Filing: American Electric Power Service Corporation submits tariff filing per 35.13(a)(2)(iii: AEP submits two Facilities Agreements re: ILDSA, SA No. 1336 to be effective 11/1/2024.
Filed Date: 11/21/24.
Accession Number: 20241121–5146.
Comment Date: 5 p.m. ET 12/12/24.

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

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

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

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: November 21, 2024.

Carlos D. Clay,

Acting Deputy Secretary.

[FR Doc. 2024–27807 Filed 11–26–24; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OMS–2024–0127; FRL–12438–01–OMS]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Background Checks for Contractor Employees (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Background Checks for Contractor Employees (EPA ICR Number 2159.09, OMB Control Number 2030–0043) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through November 30, 2024. Public comments were previously requested via the **Federal Register** on May 29, 2024, during a 60-day comment period. This notice allows for 30 days for public comments.

DATES: Comments must be submitted on or before December 27, 2024.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OMS–2024–0127, to EPA online using *www.regulations.gov* (our preferred method), by email *oei.docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

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

FOR FURTHER INFORMATION CONTACT: Brandon R. Hawkins, Policy and Oversite Branch, Office of Acquisition Solutions (3802R), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: 202–250–8897; email address: *Hawkins.Brandon.R@epa.gov.*

SUPPLEMENTARY INFORMATION: This is a request for approval of a proposed extension of the ICR, which is currently approved through November 30, 2024. An agency may not conduct, or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Public comments were previously requested via the **Federal Register** on May 29, 2024 during a 60-day comment period. This notice allows for an additional 30 days for public comments. Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *https://www.epa.gov/dockets.*

Abstract: The EPA uses contractors to perform services throughout the nation with regard to environmental emergencies involving the release, or threatened release, of oil, radioactive materials, or hazardous chemicals that may potentially affect communities and the surrounding environment. The Agency may request contractors responding to any of these types of incidents to conduct background checks and apply Government-established suitability criteria in 5 CFR 731.104, *Appointments Subject to Investigation;* 5 CFR 732.201, *Sensitivity Level Designations and Investigative Requirements;* and 5 CFR 736.102, *Notice to Investigative Sources* when determining whether employees are acceptable to perform on given sites or on specific projects. In addition to emergency response contractors, EPA may require background checks for contractor personnel working in sensitive sites or sensitive projects. The background checks and application of the Government's suitability criteria must be completed prior to contract employee performance. The contractor shall maintain records associated with all background checks. Background checks cover citizenship or valid visa status, criminal convictions, weapons offenses, felony convictions, and parties prohibited from receiving Federal contracts.

Form Numbers: None.

Respondents/affected entities: Private Contractors.

Respondent's obligation to respond: Required to obtain a benefit per 5 CFR 731.104, 732.201, and 736.102.

Estimated number of respondents: 1,000 (total).

Frequency of response: Triennial.

Total estimated burden: 1,000 hours (per year). Burden is defined at 5 CFR 1320.03(b). *Total estimated cost:* $208,720 (per year), which includes $0 annualized capital or operation & maintenance costs.

Changes in the Estimates: There is no change in the hours in the total estimated respondent burden compared with the ICR currently approved by OMB.

Courtney Kerwin,

Director, Information Engagement Division.

[FR Doc. 2024–27731 Filed 11–26–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2020–0020; FRL–12443–01–OMS]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Annual Public Water Systems Compliance Report (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Annual Public Water Systems Compliance Report (EPA ICR Number 1812.08, OMB Control Number 2020–0020) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through November 30, 2024. Public comments were previously requested via the **Federal Register** on March 13, 2024 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

DATES: Comments may be submitted on or before December 27, 2024.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OECA–2020–0020, to EPA online using *www.regulations.gov* (our preferred method), by email to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the

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

FOR FURTHER INFORMATION CONTACT: Michael Chen, Monitoring, Assistance, and Media Programs Division, Office of Compliance, MC–2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–3371; email address: *chen.michael@epa.gov.*

SUPPLEMENTARY INFORMATION: This is a proposed extension of the ICR, which is currently approved through November 30, 2024. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Public comments were previously requested via the **Federal Register** on March 13, 2024 during a 60-day comment period (89 FR 18407). This notice allows for an additional 30 days for public comments. Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: Section 1414(c)(3)(A) of the Safe Drinking Water Act requires that each state that has primary enforcement authority under the Act shall prepare, make readily available to the public, and submit to the Administrator of EPA, an annual report of violations of national primary drinking water regulations in the state. The states' reports are to include violations of maximum contaminant levels, treatment requirements, variances and exemptions, and monitoring requirements determined to be significant by the Administrator after consultation with the states. To minimize a state's burden in preparing its annual statutorily required report, EPA issued guidance that explains what Section 1414(c)(3)(A) requires and provides model language and reporting templates. EPA also annually makes available to the states a computer query that generates for each state (from information states are already separately required to submit to EPA's national database on a quarterly basis) the required violations information in a table consistent with the reporting template in EPAs guidance.

Form Numbers: None.

Respondents/affected entities: Entities that are potentially affected by this action are states that have primacy enforcement authority and meet the definition of ''state'' under the SDWA.

Respondent's obligation to respond: Mandatory under Section 1414(c)(3)(A) of SDWA.

Estimated number of respondents: 55 (total).

Frequency of response: Annually.

Total estimated burden: 4,400 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $730,000 (per year), which includes $0 annualized capital or operation & maintenance costs.

Changes in the Estimates: There is no change in burden hours from the most recently approved. This is due to two considerations. First, the requirements under SDWA have not changed over the past three years and are not anticipated to change over the next three years. Secondly, the number of states, territories or tribes with primacy has not changed, and is not anticipated to change over the next three years, so there is no significant change in the overall burden. The costs have increased solely due to increases in labor rates, see Tables 1 and 2 for further information.

Courtney Kerwin,

Director, Information Engagement Division.

[FR Doc. 2024–27730 Filed 11–26–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2014–0838; FRL–12379–01–OCSPP]

Agency Information Collection Activities; Proposed Renewal of an Existing ICR Collection and Request for Comment; Assessment of Environmental Performance Standards and Ecolabels for Federal Procurement

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA), this document announces the availability of and solicits public comment on the following Information Collection Request (ICR) that EPA is planning to submit to the Office of Management and Budget (OMB): ''Assessment of Environmental Performance Standards and Ecolabels for Federal Procurement,'' identified by EPA ICR No. 2516.05 and OMB Control No. 2070–0199. This ICR represents a renewal of an existing ICR that is currently approved through September 30, 2025. Before submitting the ICR to OMB for review and approval under the PRA, EPA is soliciting comments on specific aspects of the information collection that is summarized in this document. The ICR and accompanying material are available in the docket for public review and comment.

DATES: Comments must be received on or before January 27, 2025.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2014–0838, through the Federal eRulemaking Portal at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Carolyn Siu, Mission Support Division (7602M), Office of Program Support, Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (703) 719–1649; email address: *siu.carolyn@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. What information is EPA particularly interested in?

Pursuant to PRA section 3506(c)(2)(A) (44 U.S.C. 3506(c)(2)(A)), EPA specifically solicits comments and information to enable it to:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility.

2. Evaluate the accuracy of the Agency's estimates of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

3. Enhance the quality, utility, and clarity of the information to be collected.

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic,

mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

II. What information collection activity or ICR does this action apply to?

Title: Assessment of Environmental Performance Standards and Ecolabels for Federal Procurement.

EPA ICR No.: 2516.05.

OMB Control No.: 2070–0199.

ICR status: This ICR is currently approved through September 30, 2025. Under the PRA, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the Code of Federal Regulations (CFR), after appearing in the **Federal Register** when approved, are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: This ICR covers the information collection activities associated with the Agency's evaluation of private sector standards and ecolabels per EPA's Framework for the Assessment of Environmental Performance Standards and Ecolabels for Federal Purchasing (Framework), formerly referred to as the Guidelines. EPA's goal in developing this Framework is to create a transparent, fair, and consistent approach to selecting product environmental performance standards and ecolabels to support the Agency's mission and federal sustainable acquisition goals and mandates. The fundamental aim of this Framework is to establish a cross-sector approach to be used in recognizing private sector environmental performance standards (and consequently, environmentally preferable products and services meeting these standards) for use in federal purchasing.

Burden statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 8.5 hours per response. Burden is defined in 5 CFR 1320.3(b).

The ICR, which is available in the docket along with other related materials, provides a detailed explanation of the collection activities and the burden estimate that is only briefly summarized here:

Respondents/affected entities: Entities potentially affected are standard development organizations, ecolabel programs, and certification entities that manage product or service environmental performance standards and/or ecolabels that could be considered for use in United States federal sustainable procurement efforts.

Respondent's obligation to respond: Voluntary. See 15 U.S.C. 3701 and 42 U.S.C. 13103(b)(11).

Forms: EPA Form No. 9600–038.

Frequency of response: On Occasion.

Total estimated number of potential respondents: 100.

Total estimated average number of responses for each respondent: 2.

Total estimated annual burden hours: 613 hours.

Total estimated annual respondent costs: $49,284 which includes $0 for capital investment or maintenance and operational costs.

III. Are there changes in the estimates from the last approval?

There is a decrease in burden of 94 hours. The burden decrease is a result of the decrease of respondents that were not previously assessed per EPA Framework. This change is an adjustment.

IV. What is the next step in the process for this ICR?

EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. EPA will issue another **Federal Register** document pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: November 21, 2024.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2024–27816 Filed 11–26–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OEI–2006–0037; FRL–12444–01–OMS]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Exchange Network Grants Progress Reports (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Exchange Network Grants Program (EPA ICR Number 2207.09, OMB Control Number 2025–0006) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through November 30, 2024. Public comments were previously requested via the **Federal Register** on September 19, 2024 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

DATES: Comments may be submitted on or before December 27, 2024.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA ICR Number 2207.09, OMB Control Number 2025–0006 to EPA online using *www.regulations.gov* (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

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

FOR FURTHER INFORMATION CONTACT: Erin McGown, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; email address: *mcgown.erin@epa.gov.*

SUPPLEMENTARY INFORMATION: This is a proposed extension of the ICR, which is currently approved through November 30, 2024. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Public comments were previously requested via the **Federal Register** on September 19, 2024 (89 FR 76826) during a 60-day comment period. This notice allows for an additional 30 days for public comments. Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: The Environmental Protection Agency's (EPA) Office of Mission Support provides funding via grants to EPA's Exchange Network partners (states, territories, and federally recognized Indian tribes) to support the development of the Exchange Network (EN). The EN facilitates the sharing of environmental data, especially through shared and reusable services; streamlines data collection and exchanges to improve timeliness for decision making; increases the quality and access to environmental data; reduces burden and costs for co-regulators and the regulated community; supports better decisions on environmental and health issues; and increases capacity for environmental data management for tribes and U.S. territories. As part of the terms and conditions of the EN grant program, recipients are required to submit the following forms: (i) Semi-Annual Progress Reports (EPA Form 5300–26) twice annually throughout the lifetime of the project, Final Progress Report (EPA Form 5300–26) within 120 calendar days after the period of performance end date, and the IT Component and Project Registration Form, at the time of grant close-out. The information gathered on items (i) and (ii) help EPA to ensure that projects are on schedule to meet identified project goals and produce high quality environmental outputs. The registration form (item iii) provides a detailed summary of the completed project and any developed/reused IT components; this information is made available to future applicants to inform the development of their proposed projects, promote the reuse of technologies, and connect to potential project partners and mentors.

Form Numbers: 5300–26.

Respondents/affected entities: Employees of state, tribal, or territorial environmental government offices.

Respondent's obligation to respond: Required to obtain or retain a benefit (2 CFR part 200, ''Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards).

Estimated number of respondents: 223 (149 semi-annually for the semi-annual progress report form; 38 annually for the IT Component and Project Registration Form, and 38 annually for the Final Progress Report Form).

Frequency of response: EPA assumes that each grant recipient will submit two Semi-Annual Progress Report Forms each year the grant is active. In addition, the grantees will submit the Final Progress Report to RENC no later than 120 days after the grant performance period end date. At this time, the IT Component and Project Registration Form will likewise be submitted.

Total estimated burden: 493 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $29,530 (per year), includes $0 annualized capital or operation & maintenance costs.

Changes in the Estimates: There is a slight decrease of 15 (493 hours in 2024 vs 508 hours in 2021) hours in the total estimated respondent burden as compared with the ICR currently approved by OMB. The number of open active grants each year was estimated at 149, which matches the 2021 estimate, as the number of new assistance agreements has remained consistent since 2021. Estimates for the Final Progress Reporting Form is also very similar to the 2021 estimate, with only a slight increase in the number of expected closed-out grants (from 36 in 2021 to 38 in 2024). This slight increase reflects an expectation for more EN assistance agreements to close out in the upcoming years, as projects which were initially delayed due to workplace changes associated with COVID–19 are now being completed. The slight decrease in burden hours for respondents can be attributed primarily to the retiring of the Quality Assurance Reporting Form, which was previously required within 90 days of each new assistance agreement. There was a new form added for this ICR, which was not present in the 2021 version. The IT Component and Project Registration Form is a fillable PDF form, that is submitted by the grantee to their Regional Exchange Network Coordinator (RENC) at the time of grant close-out. As this form is due at the time of grant close-out, the estimated number matches the estimated number of Final Progress Reports (38). This new form is estimated to take 2 hours to complete, which is a decrease of 0.6 compared to the retired Quality Assurance Reporting Form.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2024–27729 Filed 11–26–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2024–0057; FRL–11683–10–OCSPP]

Certain New Chemicals; Receipt and Status Information for October 2024

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is required under the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to make information publicly available and to publish information in the **Federal Register** pertaining to submissions under TSCA section 5, including notice of receipt of a Premanufacture notice (PMN), Significant New Use Notice (SNUN) or Microbial Commercial Activity Notice (MCAN), including an amended notice or test information; an exemption application (Biotech exemption); an application for a test marketing exemption (TME), both pending and/or concluded; a notice of commencement (NOC) of manufacture (including import) for new chemical substances; and a periodic status report on new chemical substances that are currently under EPA review or have recently concluded review. This document covers the period from October 1, 2024 to October 31, 2024.

DATES: Comments identified by the specific case number provided in this document must be received on or before December 27, 2024.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2024–0057, through the *Federal eRulemaking Portal* at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI)

or other information whose disclosure is restricted by statute. Additional instructions on commenting and visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Jim Rahai, Project Management and Operations Division (MC 7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–8593; email address: *rahai.jim@epa.gov. For general information contact:* The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. What action is the Agency taking?

This document provides the receipt and status reports for the period from October 1, 2024 to October 31, 2024. The Agency is providing notice of receipt of PMNs, SNUNs, and MCANs (including amended notices and test information); an exemption application under 40 CFR part 725 (Biotech exemption); TMEs, both pending and/or concluded; NOCs to manufacture a new chemical substance; and a periodic status report on new chemical substances that are currently under EPA review or have recently concluded review.

EPA is also providing information on its website about cases reviewed under the amended TSCA, including the section 5 PMN/SNUN/MCAN and exemption notices received, the date of receipt, the final EPA determination on the notice, and the effective date of EPA's determination for PMN/SNUN/MCAN notices on its website at: *https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/status-pre-manufacture-notices.* This information is updated on a weekly basis.

B. What is the Agency's authority for taking this action?

Under the Toxic Substances Control Act (TSCA), 15 U.S.C. 2601 *et seq.,* a chemical substance may be either an ''existing'' chemical substance or a ''new'' chemical substance. Any chemical substance that is not on EPA's TSCA Inventory of Chemical Substances (TSCA Inventory) is classified as a ''new chemical substance,'' while a chemical substance that is listed on the TSCA Inventory is classified as an ''existing chemical substance.'' (See TSCA section 3(11).) For more information about the TSCA Inventory please go to: *https://www.epa.gov/tsca-inventory.*

Any person who intends to manufacture (including import) a new chemical substance for a non-exempt commercial purpose, or to manufacture or process a chemical substance in a non-exempt manner for a use that EPA has determined is a significant new use, is required by TSCA section 5 to provide EPA with a PMN, MCAN, or SNUN, as appropriate, before initiating the activity. EPA will review the notice, make a risk determination on the chemical substance or significant new use, and take appropriate action as described in TSCA section 5(a)(3).

TSCA section 5(h)(1) authorizes EPA to allow persons, upon application and under appropriate restrictions, to manufacture or process a new chemical substance, or a chemical substance subject to a significant new use rule (SNUR) issued under TSCA section 5(a)(2), for ''test marketing'' purposes, upon a showing that the manufacture, processing, distribution in commerce, use, and disposal of the chemical will not present an unreasonable risk of injury to health or the environment. This is referred to as a test marketing exemption, or TME. For more information about the requirements applicable to a new chemical go to: *https://www.epa.gov/chemicals-under-tsca.*

Under TSCA sections 5 and 8 and EPA regulations, EPA is required to publish in the **Federal Register** certain information, including notice of receipt of a PMN/SNUN/MCAN (including amended notices and test information); an exemption application under 40 CFR part 725 (biotech exemption); an application for a TME, both pending and concluded; NOCs to manufacture a new chemical substance; and a periodic status report on the new chemical substances that are currently under EPA review or have recently concluded review.

C. Does this action apply to me?

This action provides information that is directed to the public in general.

D. Does this action have any incremental economic impacts or paperwork burdens?

No.

E. What should I consider as I prepare my comments for EPA?

1. *Submitting confidential business information (CBI).* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *https://www.epa.gov/dockets/commenting-epa-dockets.*

II. Status Reports

In the past, EPA has published individual notices reflecting the status of TSCA section 5 filings received, pending, or concluded. In 1995, the Agency modified its approach and streamlined the information published in the **Federal Register** after providing notice of such changes to the public and an opportunity to comment (see the **Federal Register** of May 12, 1995 (60 FR 25798) (FRL–4942–7)). Since the passage of the Lautenberg amendments to TSCA in 2016, public interest in information on the status of section 5 cases under EPA review and, in particular, the final determination of such cases, has increased. In an effort to be responsive to the regulated community, the users of this information, and the general public, to comply with the requirements of TSCA, to conserve EPA resources and to streamline the process and make it more timely, EPA is providing information on its website about cases reviewed under the amended TSCA, including the section 5 PMN/SNUN/MCAN and exemption notices received, the date of receipt, the final EPA determination on the notice, and the effective date of EPA's determination for PMN/SNUN/MCAN notices on its website at: *https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/status-pre-manufacture-notices.* This information is updated on a weekly basis.

III. Receipt Reports

For the PMN/SNUN/MCANs that have passed an initial screening by EPA during this period, Table I provides the following information (to the extent that such information is not subject to a CBI claim) on the notices screened by EPA

during this period: The EPA case number assigned to the notice that indicates whether the submission is an initial submission, or an amendment, a notation of which version was received, the date the notice was received by EPA, the submitting manufacturer (*i.e.,* domestic producer or importer), the potential uses identified by the manufacturer in the notice, and the chemical substance identity.

As used in each of the tables in this unit, (S) indicates that the information in the table is the specific information provided by the submitter, and (G) indicates that this information in the table is generic information because the specific information provided by the submitter was claimed as CBI. Submissions which are initial submissions will not have a letter following the case number. Submissions which are amendments to previous submissions will have a case number followed by the letter ''A'' (*e.g.* P–18–1234A). The version column designates submissions in sequence as ''1'', ''2'', ''3'', etc. Note that in some cases, an initial submission is not numbered as version 1; this is because earlier version(s) were rejected as incomplete or invalid submissions. Note also that future versions of the following tables may adjust slightly as the Agency works to automate population of the data in the tables.

TABLE I—PMN/SNUN/MCANS APPROVED * FROM 10/01/2024 TO 10/31/2024

Case No.	Version	Received date	Manufacturer	Use	Chemical substance
P–18–0127A	2	10/01/2024	Takasago	(S) Fragrance in fine fragrance, consumer products, household products (laundry detergent), shower gels and shampoos.	(S) Heptane, 2-methoxy-2-methyl-.
P–21–0007A	2	10/25/2024	CBI	(G) Catalyst	(G) Reaction products of Aluminoxanes, Me, Me group-terminated and (alkylcycloalkenyl) dialkylzirconium.
P–21–0008A	2	10/25/2024	CBI	(G) Catalyst	(G) Reaction products of Aluminoxanes, Me, Me group-terminated and cycloalkylene dialkyl tetrahydro indenyl zirconium.
P–22–0068A	4	10/04/2024	Aditya Birla Chemicals (USA), LLC.	(S) An epoxy component used in a reaction with other components to produce an epoxy article.	(S) 2-Propanamine, 1,1'-[(1-methylethylidene)bis(oxy)]bis-.
P–23–0014A	2	10/25/2024	CBI	(G) Intermediate in production of fragrance.	(G) [Polyalkyl-methylenepolyhydro-polycyclic] alkyl acetate.
P–23–0086A	7	10/15/2024	CBI	(G) Additive for surfactant performance enhancement; intermediate used in the manufacturing of detergents.	(S) 1,2-Benzisothiazole, 3-methyl-,1,1-dioxide.
P–24–0006A	7	10/14/2024	CBI	(S) Oilfield Production Scale Inhibitor.	(G) Propenoic acid, methyl- [phosphinicobis(oxyethanediyl)] ester, telomer with methyl -methylpropenoate, (phosphonooxy) ethyl methylpropenoate, propenoic acid, sodium methyl-[(oxopropen-yl) amino]-propanesulfonate and sodium sulfite, sodium salt, peroxydisulfuric acid sodium salt -initiated.
P–24–0160A	3	09/30/2024	CBI	(G) Photoacid generator use at customer sites.	(G) Iodonium, bis (dialkyl carbomonocycle) salt with alkyl carbomonocycle hetero acid.
P–24–0186A	4	10/21/2024	SGP Ventures, Inc.	(S) Epoxy used to fill holes in printed circuit boards.	(S) 2-Oxiranemethanamine, N-[2-methyl-4-(2-oxiranylmethoxy) phenyl]-N-(2-oxiranylmethyl)-.
P–24–0193A	2	10/10/2024	CBI	(G) Dispersive use	(G) Perfluorosulfonic acid polymer, with perfluoro dioxolane.
P–24–0196	1	09/30/2024	Toray Resin Co.	(S) Additives for architectural paints (elongation improvers).	(S) 2-Pyrrolidinone, polymer with 2-oxepanone.
P–24–0196A	2	10/15/2024	Toray Resin Co.	(S) Additives for architectural paints (elongation improvers).	(S) 2-Pyrrolidinone, polymer with 2-oxepanone.
P–25–0001A	2	10/21/2024	Polyfil, Inc.	(G) UV initiated crosslinker	(G) Alkoxy benzophenone.
P–25–0001A	3	10/28/2024	CBI	(G) UV crosslinker initiator	(G) Alkoxy benzophenone.
P–25–0003	1	10/24/2024	CBI	(G) Contained use for microlithography for electronic device manufacturing.	(G) Phenoxathiin ium, 10-phenyl-, tricycloalkylcarbomonocyclesulfonate (1:1).
P–25–0004	1	10/25/2024	CBI	(G) Contained use for microlithography for electronic device manufacturing.	(G) Sulfonium, triphenyl-, heteropolyclyclecarboxylate (1:1).
P–25–0005	1	10/28/2024	CBI	(G) For use in coatings for metal parts.	(G) Cashew, nutshell liq., polymer with [(aminoalkyl)imino] bis[alkanol], bisphenol and epichlorohydrin, reaction products with dialkanolamine, alkyl carboxylates (salts) alkanesulfonates (salts).
P–25–0006	1	10/28/2024	CBI	(G) For use in coatings for metal parts.	(G) Phenol, 4,4-(1-alkylidene) bis-, polymer with [(aminoalkyl)imino] bis[alkanol] and 2-(chloromethyl) oxirane, 3-alkyloxy-2-hydroxypropyl ethers, reaction products with dialkanolamine, alkyl carboxylates (salts). alkanesulfonates (salts).
P–25–0007	1	10/28/2024	CBI	(G) For use in coatings for metal parts.	(G) Phenol, 4,4-(1-alkylidene) bis-, polymer with [(aminoalkyl)imino] bis[alkanol] and 2-(chloromethyl) oxirane, 4-alkylphenyl ethers, reaction products with dialkanolamine, alkyl carboxylates (salts) alkanesulfonates (salts).

TABLE I—PMN/SNUN/MCANS APPROVED * FROM 10/01/2024 TO 10/31/2024—Continued

Case No.	Version	Received date	Manufacturer	Use	Chemical substance
P–25–0008	1	10/28/2024	CBI	(G) For use in coatings for metal parts.	(G) Benzenediol, polymer with [(aminoalkyl)imino] bis[alkanol], 2- (chloromethyl)oxirane and 4,4-(1-alkylidene) bis[phenol], 4-alkylphenyl ethers, reaction products with dialkanolamine, alkyl carboxylates (salts) alkanesulfonates (salts).
P–25–0009	1	10/28/2024	CBI	(G) For use in coatings for metal parts.	(G) Cashew, nutshell liq., polymer with [(aminoalkyl)imino] bis[alkanol], bisphenol, epichlorohydrin and benzenediol, reaction products with dialkanolamine, alkyl carboxylates (salts) alkanesulfonates (salts).
P–25–0010	1	10/28/2024	CBI	(G) For use in coatings for metal parts.	(G) Benzenediol, polymer with [(aminoalkyl)imino] bis[alkanol], 2- (chloromethyl)oxirane and 4,4-(1-alkylidene) bis[phenol], 3-alkyloxy-2-hydroxypropyl ethers, reaction products with dialkanolamine, alkyl carboxylates (salts) alkanesulfonates (salts).
P–25–0012	1	10/30/2024	Bedoukian Research, Inc.	(G) Site limited chemical intermediate.	(G) Alkanoic acid, 4-bromo-, ethyl ester.
SN–22–0010A	4	10/24/2024	CBI	(S) Monomer chemical, reactive diluent in UV coating formulations (existing use, approved by PMN P–18–0392, additive in UV adhesive formulations (new use).	(S) 2-Oxazolidinone, 3-ethenyl-5-methyl-.
SN–25–0001	1	10/16/2024	Ishihara Corporation (USA).	(S) Black pigment for architectural paint; Pigment used for non-spray applications (e.g., to make articles such as plastics, resins, fabrics, and textiles, use in adhesives).	(S) Calcium manganese titanium oxide.

In Table II of this unit, EPA provides the following information (to the extent that such information is not claimed as CBI) on the NOCs that have passed an initial screening by EPA during this period: The EPA case number assigned to the NOC including whether the submission was an initial or amended submission, the date the NOC was received by EPA, the date of commencement provided by the submitter in the NOC, a notation of the type of amendment (*e.g.,* amendment to generic name, specific name, technical contact information, etc.) and chemical substance identity.

TABLE II—NOCS APPROVED * FROM 10/01/2024 TO 10/31/2024

Case No.	Received date	Commencement date	If amendment, type of amendment	Chemical substance
J–24–0016	10/16/2024	09/24/2024	N	(G) Chromosomally modified Saccharomyces cerevisiae.
J–24–0017	10/16/2024	09/24/2024	N	(G) Chromosomally modified Saccharomyces cerevisiae.
J–24–0018	10/16/2024	09/24/2024	N	(G) Chromosomally modified Saccharomyces cerevisiae.
J–24–0019	10/16/2024	09/24/2024	N	(G) Chromosomally modified Saccharomyces cerevisiae.
P–20–0183	10/29/2024	10/05/2024	N	(G) Aryl ether epoxide, homopolymer, ether with alkanolamine.
P–21–0181	10/15/2024	09/17/2024	N	(S) 1,3-Benzenedicarboxamide, N1, N3-bis(3-methylphenyl)-5-[[(3-methylphenyl) amino] sulfonyl]-.
P–22–0095	10/14/2024	10/13/2024	N	(G) Glycolipids.
P–22–0155	10/23/2024	10/14/2024	N	(G) 2-alkyl-1,2-heteropolycycle-3-one.
P–23–0094	10/08/2024	09/10/2024	N	(G) Polymer of benzenedicarboxylic acid, substituted-benzenedicarboxylic acid, branched-alkyldiol, alkyldiol and triisocyanato.
P–23–0164	10/07/2024	10/06/2024	N	(S) Bismuth, 1,1′,1″,1‴-(1,2-ethanediyldinitrilo) tetrakis[2-propanol] 2-(2-ethoxyethoxy) ethanol neodecanoate polypropylene glycol complexes.
P–23–0167	10/21/2024	09/22/2024	N	(G) Bisalkyldiacid fluorophosphate salt.
P–24–0131	10/30/2024	10/28/2024	N	(S) Heptanoic acid, 2-octyldodecyl ester.

In Table III of this unit, EPA provides the following information (to the extent such information is not subject to a CBI claim) on the test information that has been received during this time period: The EPA case number assigned to the test information; the date the test information was received by EPA, the type of test information submitted, and chemical substance identity.

TABLE III—TEST INFORMATION RECEIVED FROM 10/01/2024 TO 10/31/2024

Case No.	Received date	Type of test information	Chemical substance
L–24–0191	10/16/2024	Final Report	(S) 1-Propene, 1-chloro-3,3,3-trifluoro-, (1Z).
P–08–0200	10/29/2024	Required Annual Reporting per Consent Order	(G) Partially fluorinated amphiphilic condensation polymer.

TABLE III—TEST INFORMATION RECEIVED FROM 10/01/2024 TO 10/31/2024—Continued

Case No.	Received date	Type of test information	Chemical substance
P–08–0643	10/29/2024	Required Annual Reporting per Consent Order	(G) Fluorinated acrylic copolymer.
P–08–0748	10/29/2024	Required Annual Reporting per Consent Order	(G) Fluorinated acrylic copolymer.
P–09–0245	10/29/2024	Required Annual Reporting per Consent Order	(G) Partially fluorinated alcohol, reaction products with phosphorous oxide (P2O5), ammonium salts.
P–10–0058	10/29/2024	Required Annual Reporting per Consent Order	(G) Partially fluorinated alcohol substituted glycol.
P–11–0091	10/29/2024	Required Annual Reporting per Consent Order	(G) Fluorinated Acrylic Alkylamino Copolymer.
P–11–0526	10/29/2024	Required Annual Reporting per Consent Order	(G) Amphoteric fluorinated surfactant.
P–12–0450	10/29/2024	Required Annual Reporting per Consent Order	(G) Partially fluorinated alcohol, reaction products with phosphorus oxide (P2O5), amine salts.
P–14–0712	10/08/2024	Quarterly Testing of Substance Using EPA Method 8290A.	(S) Waste plastics, pyrolyzed, C5–55 fraction.
P–14–0712	10/30/2024	Testing of Substance Described Using EPA Method 8290A.	(S) Waste plastics, pyrolyzed, C5–55 fraction.
P–16–0543	10/01/2024	Exposure Monitoring Data	(G) Halogenophosphoric acid metal salt.
P–16–0543	10/22/2024	Exposure Monitoring Data	(G) Halogenophosphoric acid metal salt.
P–22–0042	10/02/2024	Bacterial Reverse Mutation Test (OECD Test Guideline 471).	(G) Alkanedione, [[[(substituted)aryl] thio] aryl]-, 2-(O-acetyloxime).
P–22–0042	10/16/2024	The summary of range finding study for OECD422 and protocol.	(G) Alkanedione, [[[(substituted)aryl] thio] aryl]-, 2-(O-acetyloxime).
P–22–0042	10/18/2024	Notice of test scheduling	(G) Alkanedione, [[[(substituted)aryl] thio] aryl]-, 2-(O-acetyloxime).

If you are interested in information that is not included in these tables, you may contact EPA's technical information contact or general information contact as described under **FOR FURTHER INFORMATION CONTACT** to access additional non-CBI information that may be available.

Authority: 15 U.S.C. 2601 *et seq.*

Dated: November 21, 2024.

Pamela Myrick,

Director, Project Management and Operations Division, Office of Pollution Prevention and Toxics.

[FR Doc. 2024–27717 Filed 11–26–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2023–0124; FRL–12445–OMS–01]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; NESHAP for Aerospace Manufacturing and Rework Facilities (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), NESHAP for Aerospace Manufacturing and Rework Facilities (EPA ICR Number 1687.13, OMB Control Number 2060–0314) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through November 30, 2024. Public comments were previously requested via the **Federal Register** on May 18, 2023 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

DATES: Comments may be submitted on or before December 27, 2024.

ADDRESSES: Submit your comments, referencing Docket ID Number Docket ID Number EPA–HQ–OAR–2023–0124, to EPA online using *www.regulations.gov* (our preferred method), by email to *a-and-r-docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

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

FOR FURTHER INFORMATION CONTACT: Muntasir Ali, Sector Policies and Program Division (D243–05), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–0833; email address: *ali.muntasir@epa.gov.*

SUPPLEMENTARY INFORMATION: This is a proposed extension of the ICR, which is currently approved through November 30, 2024. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Public comments were previously requested via the **Federal Register** on May 18, 2023 during a 60-day comment period (88 FR 31748). This notice allows for an additional 30 days for public comments. Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *https://www.epa.gov/dockets.*

Abstract: The National Emission Standards for Hazardous Air Pollutants (NESHAP) for the regulations published at 40 CFR part 63, subpart GG were proposed on June 6, 1994; promulgated on September 1, 1995; and amended on

both December 7, 2015 and August 3, 2016. These regulations apply to existing and new aerospace manufacturing and rework facilities where the total hazardous air pollutants (HAP) emitted are greater than or equal to 10 tons per year of any combination of HAP, or where the total HAP emitted are greater than or equal to 25 tons per year of any combination of HAP. New facilities include those that commenced construction or reconstruction after the date of proposal. Operations covered include: cleaning, primer and top coat application, depainting, chemical milling maskant application, handling and storage of waste, and specialty coating operations. This information is being collected to assure compliance with 40 CFR part 63, subpart GG.

In general, all NESHAP standards require initial notifications, performance tests, and periodic reports by the owners/operators of the affected facilities. They are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility or any period during which the monitoring system is inoperative. These notifications, reports, and records are essential in determining compliance, and are required of all affected facilities subject to NESHAP.

Form Numbers: None.

Respondents/affected entities: Aerospace manufacturing and rework facilities.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart GG).

Estimated number of respondents: 144 (total).

Frequency of response: Initially, semiannually, annually.

Total estimated burden: 154,000 total hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $16,800,000 (per year), includes $224,000 annualized capital or operation & maintenance costs.

Changes in the Estimates: There is no significant change in burden from the most recently approved ICR as currently identified in the OMB Inventory of Approved Burdens. This is due to two considerations. First, the regulations have not changed over the past three years and are not anticipated to change over the next three years. Second, the growth rate for this industry is very low or non-existent, so there is no significant change in the overall burden. There is an increase in capital and operation & maintenance costs due to an adjustment to increase from 2007 to 2022 $ using the CEPCI Equipment Cost Index.

Courtney Kerwin,

Director, Information Engagement Division.

[FR Doc. 2024–27727 Filed 11–26–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2020–0078; FRL–12448–01–OMS]

Agency Information Collection Activities Submission to the Office of Management and Budget for Review and Approval; Comment Request; Toxic Chemical Release Reporting (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Toxic Chemical Release Reporting, (EPA ICR Number 2613.07, OMB Control Number 2070–0212) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR which is currently approved through June 30, 2025. Public comments were previously requested via the **Federal Register** on September 18, 2024, during a 60-day comment period. This notice allows for an additional 30 days for public comments.

DATES: Comments may be submitted on or before December 27, 2024.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OPPT–2020–0078, to EPA online using *www.regulations.gov* (our preferred method) or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 2821T, 1200 Pennsylvania Ave. NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

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

FOR FURTHER INFORMATION CONTACT: Katherine Sleasman, Office of Program Support (7602M), Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 566–1206; email address: *sleasman.katherine@epa.gov*.

SUPPLEMENTARY INFORMATION: This is a proposed extension of the ICR which is currently approved through June 30, 2025. An agency may not conduct, or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Public comments were previously requested via the **Federal Register** on September 18, 2024 during a 60-day comment period (89 FR 76470). This notice allows for an additional 30 days for public comments. Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: Pursuant to section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA), certain facilities that manufacture, process, or otherwise use specified toxic chemicals in amounts above reporting threshold levels as provided in 40 CFR 372.25 must submit annually to EPA and to their designated state or Indian country officials toxic chemical release forms containing information specified by EPA; (see 42 U.S.C. 11023). In addition, pursuant to section 6607 of the Pollution Prevention Act (PPA), facilities reporting under section 313 of EPCRA must also report pollution prevention and waste management data, including recycling information, for such chemicals; (see 42 U.S.C. 13106). EPA compiles and stores these reports in a publicly accessible database known as the Toxics Release Inventory (TRI). Regulations at 40 CFR part 372, subpart B, require facilities that meet the above criteria to report annually.

This ICR consolidates the following final rule ICRs titled: ''Rule-Related ICR Amendment; Changes to Reporting Requirements for Per- and

Polyfluoroalkyl Substances; Community Right-to-Know Toxic Chemical Release Reporting, Final Rule (RIN 2070–AK97)'' (OMB Control Number 2070–0225; EPA ICR Number 2724.02), ''Addition of Natural Gas Processing Facilities to the Toxics Release Inventory (TRI) (Final Rule)'' (OMB Control Number 2070–0206; EPA ICR Number 2560.02); and ''Parent Company Definition for TRI Reporting (Final Rule)'' (OMB Control Number 2070–0216; EPA ICR Numer 2597.02) into this renewal ICR. Upon OMB approval of this ICR, EPA intends to discontinue OMB Control Numbers 2070–0225, 2070–0206, and 2070–0216.

Form numbers: 9350–1, 9350–2, and 9350–3.

Respondents/affected entities: Entities potentially affected are those that apply to owners and operators of facilities covered under EPCRA section 313(a). EPCRA section 313(a) includes facilities that meet the following three criteria: have 10 or more full-time employee equivalents (*i.e.,* a total of 20,000 hours worked per year or greater; see 40 CFR 372.3). The full list of potentially affected entities by North American Industry Classification System (NAICS) codes for facilities that must report to TRI (including exemptions and/or limitations), if all other reporting thresholds are met, can be found at 40 CFR 372.23.

Respondent's obligation to respond: Mandatory (40 CFR 372.23).

Estimated number of respondents: 24,742 (total).

Frequency of response: Annual.

Total estimated burden: 3,600,970 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $285,304,888 (per year), which includes $0 annualized capital or operation & maintenance costs.

Changes in the estimates: There is an overall average decrease of 698 Form Rs and an increase of 1600 Form As estimated to be submitted to EPA as a result of EPA's exercise of its discretionary authority to apply TRI reporting requirements to 2,990 particular facilities, for specified chemicals. There is a decrease of 15,858 burden hours. This is an adjustment to the estimates.

Courtney Kerwin,

Director, Information Engagement Division.

[FR Doc. 2024–27824 Filed 11–26–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–R08–SFUND–2024–0475; FRL–12324–01–R8]

Proposed Settlement With Bona Fide Prospective Purchaser, Miners Point Ventures, LLC, Central City, Clear Creek Superfund Site, Colorado

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed settlement; request for public comment.

SUMMARY: Notice is hereby given by the U.S. Environmental Protection Agency (EPA), Region 8, of an administrative settlement agreement for response action by bona fide prospective purchaser entered into voluntarily by the United States of America (''United States'') on behalf of the United States Environmental Protection Agency (''EPA''), the State of Colorado (''State'') and Miners Point Ventures, LLC (''Purchaser'') in connection with the Central City, Clear Creek Superfund Site in Idaho Springs, Clear Creek County, Colorado (''Site''). It is now subject to public comment, after which EPA may modify or withdraw its consent if comments received disclose facts or considerations that indicate that the proposed agreement is inappropriate, improper, or inadequate.

DATES: Comments must be submitted on or before December 27, 2024.

ADDRESSES: The proposed agreement and additional background information relating to the agreement will be available upon request. Any comments or requests or for a copy of the proposed agreement should be addressed to Crystal Kotowski-Edmunds, Enforcement Specialist, Superfund and Emergency Management Division, Environmental Protection Agency, Region 8, Mail Code 8SEM–PAC, 1595 Wynkoop Street, Denver, Colorado 80202, telephone number: (303) 312–6124, email address: *edmunds.crystal@epa.gov,* and should reference the Central City, Clear Creek Site. You may also send comments, identified by Docket ID No. EPA–R08–SFUND–2024–0475, to *https://www.regulations.gov.* Follow the online instructions for submitting comments.

FOR FURTHER INFORMATION CONTACT: Amelia Piggott, Attorney, Office of Regional Counsel, Environmental Protection Agency, Region 8, Mail Code 8ORC–LEC, 1595 Wynkoop, Denver, Colorado 80202, telephone number:(303) 312–6410, email address: *piggott.amelia@epa.gov.*

SUPPLEMENTARY INFORMATION: This settlement provides for the performance of a response action by Purchaser and the payment for certain response costs incurred by the United States and the State of Colorado at or in connection with property within the Site (''Property''). Uncovered mine waste containing lead and arsenic is located on the Property. EPA and the State previously installed engineering controls to a mine waste pile on the Property to ensure lead and aresenic-laden mine waste do not erode into Clear Creek. Uncovered mine waste remains on the Property. Purchaser anticipates developing the Property into a mining-related tourist attraction that will include operation of a gondola that will transport tourists to recreational hiking trails. In order to ensure the development will be protective of human health and the environment, the Purchaser will conduct risk assessment work.

For thirty (30) days following the date of publication of this document, EPA will receive electronic comments relating to the proposed agreement. EPA's response to any comments received will be available for public inspection by request. Please see the **ADDRESSES** section of this document for instructions.

Aaron Urdiales,

Division Director, Superfund and Emergency Management Division, Region 8.

[FR Doc. 2024–27724 Filed 11–26–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–12428–01–R6]

Clean Air Act Operating Permit Program: Order on Petitions for Objection to State Operating Permit for Flint Hills Resources Ingleside LLC, San Patricio County, Texas

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of final order on petition.

SUMMARY: The Environmental Protection Agency (EPA) Administrator signed an Order dated November 14, 2024, granting in part and denying in part two petitions dated July 10, 2024 (collectively the Petitions), from the Environmental Integrity Project, Ingleside on the Bay Coastal Watch Association, and TCHD Consulting LLC (the Petitioners). The Petitions requested that the EPA object to a Clean Air Act (CAA) title V operating permit issued by the Texas Commission on

Environmental Quality (TCEQ) to Flint Hills Resources LLC, for its Ingleside Terminal located in San Patricio County, Texas.

FOR FURTHER INFORMATION CONTACT: Jonathan Ehrhart, EPA Region 6 Office, Air Permits Section, (214) 665–2295, *ehrhart.jonathan@epa.gov.* The final order and petitions are available electronically at: *https://www.epa.gov/title-v-operating-permits/title-v-petition-database.*

SUPPLEMENTARY INFORMATION: The EPA received two petitions from Environmental Integrity Project, Ingleside on the Bay Coastal Watch Association, and TCHD Consulting LLC dated July 10, 2024, requesting that the EPA object to the issuance of operating permit No. O3454, issued by TCEQ to Flint Hills Resources LLC, for its Ingleside Terminal located in San Patricio County, Texas. On November 14, 2024, the EPA Administrator issued an Order granting in part and denying in part the petitions. The order itself explains the basis for the EPA's decision.

Sections 307(b) and 505(b)(2) of the CAA provide that a petitioner may request judicial review of those portions of an order that deny issues in a petition. Any petition for review shall be filed in the United States Court of Appeals for the appropriate circuit no later than January 27, 2025.

Dated: November 21, 2024.

David Garcia,

Director, Air and Radiation Division, Region 6.

[FR Doc. 2024–27732 Filed 11–26–24; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1298; FR ID 264211]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

DATES: Written PRA comments should be submitted on or before January 27, 2025. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *nicole.ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele, (202) 418–2991.

SUPPLEMENTARY INFORMATION: The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

OMB Control Number: 3060–1298.

Title: Volunteer Service Agreement Form, FCC Form A–384.

Form No.: FCC Form A–384.

Type of Review: Revision of a currently approved collection.

Respondents: Individuals or households.

Number of Respondents and Responses: 140 respondents and 140 responses.

Estimated Time per Response: 0.25 hours.

Frequency of Response: One-time reporting requirement.

Obligation to Respond: Mandatory. The statutory authority to collect this information derives from 5 U.S.C. 3111, Acceptance of volunteer service.

Total Annual Burden: 35 hours.

Total Annual Cost: No Cost.

Needs and Uses: The Civil Service Reform Act of 1978 authorized Federal agencies to establish programs designed to provide educationally related work assignments for students in a non-pay status. The Act provides that heads of agencies may accept, subject to regulations issued by the Office of Personnel Management, volunteer service for the United States if the service (l) is performed by a student, with permission of the institution at which the student is enrolled; (2) is to be uncompensated; and (3) will not displace any employee. Form A–384 establishes the responsibility of students, their institutions, and the FCC as a precondition to accepting individuals as unpaid volunteers.

Federal Communications Commission.

Marlene Dortch,

Secretary. Office of the Secretary.

[FR Doc. 2024–27855 Filed 11–26–24; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0706; FR ID 263015]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s). Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with

a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments should be submitted on or before January 27, 2025. If you anticipate that you will be submitting comments but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0706.

Title: Sections 76.952 and 76.990, Cable Act Reform.

Type of Review: Extension a currently approved collection.

Respondents: Business or other for-profit entities; State, Local or Tribal Government.

Number of Respondents and Responses: 70 respondents; 70 responses.

Estimated Time per Response: 1–8 hours.

Frequency of Response: On occasion reporting requirement; Third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection of information is contained in the Telecommunications Act of 1996, Public Law 104–104, Sections 301 and 302, 110 Stat. 56, 114–124.

Total Annual Burden: 210 hours.

Total Annual Cost: None.

Needs and Uses: The information collection requirements contained in 47 CFR 76.952 state that all cable operators must provide to the subscribers on monthly bills the name, mailing address and phone number of the franchising authority, unless the franchising authority in writing requests that the cable operator omits such information. The cable operator must also provide subscribers with the FCC community unit identifier for the cable system in their communities. 47 CFR 76.990(b)(1) requires that a small cable operator may certify in writing to its franchise authority at any time that it meets all criteria necessary to qualify as a small operator. Upon request of the local franchising authority, the operator shall identify in writing all of its affiliates that provide cable service, the total subscriber base of itself and each affiliate, and the aggregate gross revenues of its cable and non-cable affiliates. Within 90 days of receiving the original certification, the local franchising authority shall determine whether the operator qualifies for deregulation and shall notify the operator in writing of its decision, although this 90-day period shall be tolled for so long as it takes the operator to respond to a proper request for information by the local franchising authority. An operator may appeal to the Commission a local franchise authority's information request if the operator seeks to challenge the information request as unduly or unreasonably burdensome. If the local franchising authority finds that the operator does not qualify for deregulation, its notice shall state the grounds for that decision. The operator may appeal the local franchising authority's decision to the Commission within 30 days.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2024–27711 Filed 11–26–24; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than December 12, 2024.

A. Federal Reserve Bank of Atlanta (Erien O. Terry, Assistant Vice President) 1000 Peachtree Street NE, Atlanta, Georgia 30309. Comments can also be sent electronically to *Applications.Comments@atl.frb.org:*

1. *Nitin Shah and Mili N. Shah, both of Lawrenceville, Georgia;* as a group acting in concert, to retain voting shares of Embassy Bancshares, Inc., and thereby indirectly retain voting shares of Embassy National Bank, both of Lawrenceville, Georgia.

B. Federal Reserve Bank of Kansas City (Jeffrey Imgarten, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri, 64198–0001. Comments can also be sent electronically to *KCApplicationComments@kc.frb.org:*

1. *Michael Scott Crowe, Sr., as co-trustee of the Robert E. Oliphant Trust, both of Kansas City, Missouri;* to retain control of voting shares of Country Agencies & Investments, Inc., and thereby indirectly retain control of voting shares of Bank of Odessa, both of Odessa, Missouri.

The Robert E. Oliphant Trust has previously been permitted to control voting shares of Country Agencies & Investments, Inc.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2024–27847 Filed 11–26–24; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

[Docket No. OP–1862]

Federal Reserve Bank Services

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) has approved the private-sector adjustment factor (PSAF) for 2025 of $31.9 million and the 2025 fee schedules for Federal Reserve priced services and electronic access. These actions were taken in

accordance with the Monetary Control Act of 1980, which requires that, over the long run, fees for Federal Reserve priced services be established based on all direct and indirect costs, including the PSAF.

DATES: The new fee schedules become effective January 1, 2025.

FOR FURTHER INFORMATION CONTACT: For questions regarding the fee schedules: Ian Spear, Deputy Associate Director, (202) 452–3959; Anjana Ravi, Manager, (202) 530–6286; Division of Reserve Bank Operations and Payment Systems. For questions regarding the PSAF: Casey Clark, Associate Director, (202) 912–7978; Jamie Noonan, Assistant Director, (202) 530–6296; Grace Milbank, Lead Financial Institution Policy Analyst, (202) 263–4828; Division of Reserve Bank Operations and Payment Systems. For users of TTY–TRS, please call 711 from any telephone, anywhere in the United States. Copies of the 2025 fee schedules for Check Services are available from the Board, the Federal Reserve Banks, or the Federal Reserve Financial Services (FRFS) website at *www.FRBservices.org.*

SUPPLEMENTARY INFORMATION:

I. Private-Sector Adjustment Factor, Priced Services Cost Recovery, and Overview of 2025 Price Changes

A. *Overview*—Each year, as required by the Monetary Control Act of 1980 (MCA), the Reserve Banks set fees for priced services provided to financial institutions. These fees are set to recover, over the long run, all direct and indirect costs and imputed costs, including financing costs, taxes, and certain other expenses, as well as the return on equity (profit) that would have been earned if a private-sector business provided the services.[1] The imputed costs and imputed profit are collectively referred to as the private-sector adjustment factor (PSAF).

From 2014 through 2023, the Reserve Banks recovered 102.6 percent of their total expenses (including imputed costs) and targeted after-tax profits or return on equity (ROE) for the mature services. During that period, Check Services, the Fedwire® Funds Service, the National Settlement Service (NSS), and the Fedwire® Securities Service achieved full cost recovery. The FedACH® Service achieved 99.0 percent cost recovery as a result of the Reserve Banks' development and implementation of a multiyear technology initiative to modernize the capabilities of the FedACH Service processing platform. Although the modernized platform was implemented in 2021, the Reserve Banks are continuing to invest in platform capabilities, as well as resiliency, as part of a broader enhancement strategy.[2]

In its 2019 notice entitled *Federal Reserve Actions to Support Interbank Settlement of Instant Payments* (''2019 Notice''), the Board communicated that it expects the FedNow® Service to achieve its first instance of long-run cost recovery outside the 10-year time frame typically applied to mature services. New services like the FedNow Service are not expected to initially have stable volumes, costs, and revenues.[3] Thus, FedNow Service revenue and expenses are excluded from the overall performance projections. The FedNow Service is discussed in section G.

Table 1 summarizes 2023 actual, 2024 forecasted, and 2025 budgeted annual cost recovery rates for all mature priced services. Cost recovery is forecasted to be 108.8 percent in 2024 and budgeted to be 104.1 percent in 2025.

TABLE 1—AGGREGATE MATURE PRICED SERVICES PRO FORMA COST AND REVENUE PERFORMANCE [a]

[Dollars in millions]

Year	Revenue	Total expense	Net income (ROE)	Targeted ROE	Recovery rate after targeted ROE (%)
	1 [b]	2 [c]	3 [1 − 2]	4 [d]	5 [e] [1/(2 + 4)]
2023 (actual)	507.3	467.1	40.1	8.4	106.7
2024 (forecast)	520.9	468.9	52.0	9.7	108.8
2025 (budget)	531.7	499.8	31.9	10.8	104.1

[a] Calculations in this table and subsequent pro forma cost and revenue tables may be affected by rounding. Excludes amounts related to the FedNow Service.

[b] Revenue includes imputed income on investments when equity is imputed at a level that meets minimum capital requirements and, when combined with liabilities, exceeds total assets. For 2025, the budgeted revenue assumes implementation of the fee changes.

[c] The calculation of total expense includes operating, imputed, and other expenses. Imputed and other expenses include taxes, Board of Governors priced services expenses, the cost of float, and interest on imputed debt, if any. Credits or debits related to the accounting for pension plans under ASC 715 are also included.

[d] Targeted ROE is the after-tax ROE included in the PSAF.

[e] The recovery rates in this and subsequent tables do not reflect the unamortized gains or losses that must be recognized in accordance with ASC 715. Future gains or losses, and their effect on cost recovery, cannot be projected.

[1] *See* 12 U.S.C. 248a. *See also Principles for the Pricing of Federal Reserve Bank Services,* 46 FR 1338, 1339 (Jan. 6, 1981), *available at https://www.federalreserve.gov/paymentsystems/pfs_principles.htm.* Although the Monetary Control Act does not define ''over the long run,'' the Board has generally measured long-run cost recovery for mature services to be over a 10-year rolling time frame. The Board currently views a 10-year cost recovery expectation as appropriate for assessing mature services, which are those that have achieved a critical mass of customer participation and generally have stable and predictable volumes, costs, and revenues. The 10-year recovery rate is based on the pro forma income statements for Federal Reserve priced services published in the Board's *Annual Report.* In accordance with Accounting Standards Codification (ASC) 715 *Compensation—Retirement Benefits,* the Reserve Banks recognized a $548.6 million cumulative reduction in equity related to the priced services' benefit plans through 2023. Including this cumulative reduction in equity from 2014 to 2023 results in cost recovery of 102.6 percent for the 10-year period. This measure of long-run cost recovery is also published in the Board's *Annual Report.*

[2] In alignment with the Board's *Principles for the Pricing of Federal Reserve Bank Services,* the Reserve Banks will continue to assess the tradeoffs between price stability for customers, investment in technology infrastructure to reflect desirable longer-run improvements in the ACH system, and the expectation of achieving full cost recovery for the FedACH Service over the long run.

[3] Application of the 10-year rolling time frame used to evaluate mature services to the FedNow Service would result in prohibitively high or unnecessarily volatile pricing, negatively affecting the Federal Reserve's public policy objectives in providing the service. See *Federal Reserve Actions to Support Interbank Settlement of Instant Payments, 84 FR 39297,* (Aug. 9, 2019).

Table 2 provides an overview of cost recovery budgets, forecasts, and performance for the 10-year period from 2014 to 2023, 2023 actual, 2024 budget, 2024 forecast, and 2025 budget by mature priced service.

TABLE 2—MATURE PRICED SERVICES COST RECOVERY

[Percent]

Priced service	2014–2023	2023 Actual	2024 Budget [a]	2024 Forecast	2025 Budget [b]
All mature services	102.6	106.7	103.1	108.8	104.1
Check	106.9	102.9	95.5	102.9	97.5
FedACH	99.0	108.8	106.0	109.4	106.0
Fedwire Funds and NSS	101.9	103.1	103.2	108.3	103.2
Fedwire Securities	105.7	122.3	110.9	123.2	115.7

[a] The 2024 budget figures reflect the final budgets as approved by the Board in December 2023. *See* Board of Governors of the Federal Reserve System, *2024 Federal Reserve Banks Budgets, https://www.federalreserve.gov/foia/files/2024ReserveBankBudgets.pdf.*

[b] The 2025 budget figures reflect preliminary budget information from the Reserve Banks. The Reserve Banks will submit final budget data to the Board for consideration by December 2024.

1. *2024 Forecasted Performance*—The Reserve Banks forecast that they will recover 108.8 percent of the costs of providing mature priced services in 2024, including total expense and targeted ROE, compared with a 2024 budgeted recovery rate of 103.1 percent, as shown in Table 2. Overall, the Reserve Banks forecast that they will fully recover actual and imputed costs and earn net income of $52.0 million, compared with the targeted ROE of $9.7 million. The Reserve Banks forecast that all mature services will achieve full cost recovery in 2024.

2. *2025 Private-Sector Adjustment Factor*—The 2025 PSAF for Reserve Bank mature priced services is $31.9 million.[4] This amount represents an increase of $2.7 million from the 2024 PSAF of $29.2 million. This increase is attributable to a $2.1 million increase in the cost of capital primarily driven by higher short-term debt and higher return on equity and a $0.6 million increase in sales tax.

3. *2025 Projected Performance*—The Reserve Banks project a mature priced services cost recovery rate of 104.1 percent in 2025, with a net gain of $31.9 million and targeted ROE of $10.8 million. The Reserve Banks project that each of the individual mature service lines will achieve full cost recovery in 2025 except for Check Services. Check Services are expected to under recover primarily because of anticipated volume declines. The Reserve Banks' primary risks to current projections are unanticipated volume and revenue reductions and the potential for cost overruns from new and ongoing improvement initiatives.

4. *2025 Pricing*—The following summarizes the Reserve Banks' changes to fee schedules for priced services in 2025. For the mature services, these changes collectively are an average price increase of 2.8 percent. The price changes outlined below are in line with the Reserve Banks' strategy to offset rising costs, diversify revenue sources, and continue to reduce pricing volatility.

Check Services

The Reserve Banks will increase participation fees, FedImage® fees, and certain forward paper and return paper fees. These changes will increase fixed fee revenue stability in light of declining check volumes.

FedACH Service

The Reserve Banks will increase participation fees, origination and receipt minimum fees, and FedPayments Reporter® Service fees. These changes will help address ongoing operational costs, provide greater revenue stability, and account for the additional business value provided by the service enhancements over the last several years.

Fedwire Funds Service

The Reserve Banks will increase the Fedwire Funds participation fee, the transfer fee for all three tiers, and the FedPayments® Manager Import/Export fee. These increases will account for projected declining volume growth, coupled with ongoing technology enhancements and higher operating costs.[5] In addition, the Fedwire Funds Service will introduce a new fixed fee that will serve to better align fees with customer usage as well as address challenges associated with revenue volatility.

National Settlement Service

The Reserve Banks will increase the National Settlement Service per-file and per-entry fees. These changes will help address rising operational costs.

Fedwire Securities Service

The Reserve Banks will maintain prices at existing levels for all Fedwire Securities priced services.

FedNow Service

The Reserve Banks will modify the Customer Credit Transfer, Customer Credit Transfer Return, and Request for Payment fee components of the FedNow Service to exclude ''on-us'' transactions sent from and received at the same financial institution.[6] This adjustment will both align with prevailing market practices and reduce inefficient off-network transaction activity. All other price points and discounts in the FedNow Service's fee schedule from the previous year will be maintained in 2025.

FedLine® Solutions

The Reserve Banks will increase the monthly fees for the FedLine Direct® Solution, FedLine Command® Solution, and FedComplete® Packages. These price modifications account for enhancements to services and rising operational costs. The Reserve Banks are also discontinuing FedComplete Premier and FedLine Exchange® to streamline the FedLine product suite in response to a declining customer base and to simplify internal operating, servicing, and billing processes. Lastly, the Reserve Banks are preparing to

[4] The FedNow Service launched in July 2023. Inclusive of the FedNow Service, the PSAF increases to $42.3 million for 2025. Per its 2019 Notice, the Board has determined that it is most appropriate to report FedNow Service cost recovery independently of mature priced services until the service has relatively stable revenues and costs. Thus, FedNow Service revenue is excluded from overall performance projections for 2025.

[5] Historically, Fedwire Funds volume has evolved in line with GDP forecasts.

[6] These fee modifications will take place at the parent financial institution level, as defined in the Reserve Banks' Global Customer Directory. ''On-us'' transactions include those made by the same financial institution, even if the financial institution uses multiple Routing Transit Numbers (RTNs).

implement a fee structure for services offered via Application Programming Interfaces (APIs) in 2025.

B. *Private-Sector Adjustment Factor*—The imputed debt financing costs, targeted ROE, and effective tax rate are based on a U.S. publicly traded market model.[7] The method for calculating the financing costs in the PSAF requires determining the appropriate imputed levels of debt and equity and then applying the applicable financing rates. In this process, a pro forma balance sheet using estimated assets and liabilities associated with the Reserve Banks' priced services is developed, and the remaining elements that would exist are imputed as if these priced services were provided by a private business firm. The same generally accepted accounting principles that apply to commercial-entity financial statements apply to the relevant elements in the priced services pro forma financial statements.

The portion of Federal Reserve assets that will be used to provide priced services during the coming year is determined using information about actual assets and projected disposals and acquisitions. The priced portion of these assets is determined based on the allocation of depreciation and amortization expenses of each asset class. The priced portion of actual Federal Reserve liabilities consists of post-employment and post-retirement benefits, accounts payable, and other liabilities. The priced portion of the actual net pension asset or liability is also included on the balance sheet.[8]

The equity financing rate is the targeted ROE produced by the capital asset pricing model (CAPM). In the CAPM, the required rate of return on a firm's equity is equal to the return on a risk-free asset plus a market risk premium. The risk-free rate is based on the three-month Treasury bill; the beta is assumed to be equal to 1.0, which approximates the risk of the market as a whole; and the market risk premium is based on the monthly returns in excess of the risk-free rate over the most recent 40 years. The resulting ROE reflects the return a shareholder would expect when investing in a private business firm.

For simplicity, given that state income tax rates vary, and various credits and deductions can apply at the federal or state level, an actual income tax expense is not explicitly calculated for Reserve Bank priced services. Instead, the Board targets a pretax ROE that would provide sufficient income to fulfill the priced services' imputed income tax obligations. To the extent that performance results are greater or less than the targeted ROE, income taxes are adjusted using the effective tax rate.

Capital structure. The capital structure is imputed based on the imputed funding need (assets less liabilities), subject to minimum equity constraints. Short-term debt is imputed to fund the imputed short-term funding need. Long-term debt and equity are imputed to meet the priced services long-term funding need at a ratio based on the capital structure of the U.S. publicly traded market.[9] Any equity imputed that exceeds the amount needed to fund the priced services' assets and meet the minimum equity constraints is offset by a reduction in imputed long-term debt. When imputed equity is larger than what can be offset by imputed debt, the excess is imputed as investments in Treasury securities; income imputed on these investments reduces the PSAF.

Application of the Federal Reserve Policy on Payment System Risk (PSR policy) to the Fedwire Funds Service. The Board's PSR policy incorporates the international standards for financial market infrastructures (FMIs) developed by the Committee on Payments and Market Infrastructures (CPMI) and the Technical Committee of the International Organization of Securities Commissions (IOSCO) known as the *Principles for Financial Market Infrastructures*.[10] The Board recognizes the critical role the Fedwire Services, including the Fedwire Funds Service, play in the financial system and requires them to meet or exceed the risk-management standards in the PSR policy, consistent with relevant guidance and the requirements in the MCA.[11] Principle 15 states that an FMI should identify, monitor, and manage general business risk and hold sufficient liquid net assets funded by equity to cover potential general business losses so that it can continue operations and services as a going concern if those losses materialize. Further, liquid net assets should at all times be sufficient to ensure a recovery or orderly wind-down of critical operations and services. The Fedwire Funds Service does not face the risk that a business shock would cause the service to wind down in a disorderly manner and disrupt the stability of the financial system. To foster competition with private-sector FMIs, however, the Reserve Banks' priced services will hold an amount equivalent to six months of the Fedwire Funds Service's current operating expenses as liquid financial assets and equity on the pro forma balance sheet.[12] Current operating expenses are defined as normal business operating expenses on the income statement, less depreciation, amortization, taxes, and interest on debt. Using the Fedwire Funds Service's preliminary 2025 budget, six months of current operating expenses would be $71.7 million. In 2025, equity was sufficient to meet the FDIC capital requirements and $6.7 million of equity was imputed to meet the PSR policy requirement.

Effective tax rate. Like the imputed capital structure, the effective tax rate is calculated based on data from U.S. publicly traded firms. The tax rate is the mean of the weighted average rates of the U.S. publicly traded market over the past five years.

Debt and equity financing. The imputed short- and long-term debt financing rates are derived from the nonfinancial commercial paper rates from the Federal Reserve Board's H.15 Selected Interest Rates release (AA and A2/P2) and the annual Merrill Lynch Corporate & High Yield Index rate, respectively. The equity financing rate is described above. The rates for debt

[7] Data for U.S. publicly traded firms is from the Standard and Poor's Compustat® database. This database contains information on more than 6,000 U.S. publicly traded firms, which approximates information for the entirety of the U.S. market.

[8] The pension assets are netted with the pension liabilities and reported as a net asset or net liability as required by ASC 715.

[9] The FDIC rule requires that well-capitalized institutions meet or exceed the following standards: (1) total capital to risk-weighted assets ratio of at least 10 percent, (2) tier 1 capital to risk-weighted assets ratio of at least 8 percent, (3) common equity tier 1 capital to risk-weighted assets ratio of at least 6.5 percent, and (4) a leverage ratio (tier 1 capital to total assets) of at least 5 percent. Because all of the Federal Reserve priced services' equity on the pro forma balance sheet qualifies as tier 1 capital, only requirements 1 and 4 are binding. The FDIC rule can be located at 12 CFR 324.403(b).

[10] *See* Board of Governors of the Federal Reserve System, *Federal Reserve Policy on Payment System Risk, https://www.federalreserve.gov/paymentsystems/files/psr_policy.pdf. See also* CPMI–IOSCO, *Principles for Financial Market Infrastructures* (April 2012), *https://www.bis.org/cpmi/publ/d101a.pdf.*

[11] Certain standards may require flexibility in the way they are applied to central bank–operated systems because of central banks' unique role in the financial markets and their public responsibilities. These principles include principle 2 on governance, principle 3 on the framework for the comprehensive management of risks, principle 4 on credit risk, principle 5 on collateral, principle 7 on liquidity risk, principle 13 on participant-default rules and procedures, principle 15 on general business risk, and principle 18 on access and participation requirements. *See* section I.B.1.a of the PSR policy.

[12] This requirement does not apply to the Fedwire Securities Service. There are no private-sector competitors to the Fedwire Securities Service that would be expected to meet such a requirement. Imposing such a requirement when pricing the securities services could artificially increase the cost of these services.

and equity financing are applied to the priced services' estimated imputed short-term debt, long-term debt, and equity needed to finance short- and long-term assets and meet equity requirements.

The 2025 PSAF is $31.9 million, compared with $29.2 million in 2024. The increase of $2.7 million is attributable to a net $2.1 million increase in the cost of capital and a $0.6 million increase in sales tax. The net $2.1 million increase in cost of capital is primarily driven by a $1.3 million increase in ROE imputed to meet the PSR policy requirements and higher short-term debt resulting in a $0.5 million increase in cost of debt.

The PSAF expense of $31.9 million, detailed in Table 5, includes $19.8 million for capital funding, $7.6 million for Board of Governors' expense, and $4.5 million in sales tax expense.

As shown in Table 3, 2025 total assets of $890.3 million increased by $74.2 million from 2024. The net increase in total assets includes an additional $90.7 million in imputed investments and short-term assets partially offset by a $16.5 million decrease in long-term assets.

The net increase of $90.7 million primarily consists of a $80.8 million increase in the imputed investments and a $9.9 million increase driven by short-term assets, The imputed investment increase reflects a $74 million increase from float [13] and a $6.7 million increase to comply with the PSR policy. The $9.9 million increase in short-term assets is driven by an increase in prepaid expenses.

The $16.5 million decrease in the long-term assets is primarily driven by a $38.0 million decrease in the net pension asset, partially offset by a $20.3 million increase in premises, furniture and equipment, and software and leasehold improvements.

The capital structure of the 2025 pro forma balance sheet, provided in Table 4, is composed of equity of $71.7 million, or 12.6 percent of the 2025 risk-weighted assets detailed in Table 6, and long-term debt of $96.1 million. The 2025 capital structure aligns with that of 2024, which was composed of $68.5 million of equity and $100.3 million of long-term debt. As shown in Table 5, the 2025 initially imputed equity required to fund assets and meet the publicly traded firm model capital requirements is $65.0 million. As long-term assets are marginally greater than long-term liabilities, long-term debt of $96.1 million was imputed at the observed market ratio of 59.7 percent. The equity of $65.0 million was adequate to meet the FDIC capital requirements for a well-capitalized institution. Additional equity of $6.7 million was imputed to satisfy PSR policy requirements.

The net accumulated other comprehensive loss is $563.3 million, compared with $551.0 million in 2024. The $12.3 million increase is primarily attributable to a lower discount rate. The net accumulated other comprehensive loss position does not reduce the total imputed equity required to fund priced services assets or fulfill the FDIC equity requirements for a well-capitalized institution.

TABLE 3—COMPARISON OF PRO FORMA BALANCE SHEETS FOR BUDGETED FEDERAL RESERVE MATURE PRICED SERVICES [a]

[Millions of dollars—projected average for year]

	2025	2024	Change
Short-term assets:			
Receivables	$ 44.3	$ 41.8	$ 2.5
Inventory	0.4	0.2	0.2
Prepaid expenses	34.2	24.0	10.2
Items in process of collection [13]	58.0	61.0	(3.0)
Total short-term assets	136.9	127.0	9.9
Imputed investments: [14]			
Imputed investment in Treasury securities	6.8		6.8
Imputed investment in Fed Funds	293.0	219.0	74.0
Total imputed investments	299.8	219.0	80.8
Long-term assets:			
Premises [15] *	105.3	99.4	5.9
Furniture and equipment	60.8	53.9	6.9
Software and leasehold improvements	74.5	67.0	7.5
Net pension asset	82.4	120.4	(38.0)
Deferred tax asset	130.6	129.4	1.2
Total long-term assets	453.6	470.1	(16.5)
Total assets	890.3	816.1	74.2
Short-term liabilities:			
Deferred credit items	351.0	280.0	71.0
Short-term debt	42.2	32.7	9.5
Short-term payables	36.8	33.4	3.4
Total short-term liabilities	430.0	346.0	84.0
Long-term liabilities:			
Postemployment/postretirement benefits and net pension liabilities [16]	292.5	301.2	(8.7)
Long term debt	96.1	100.3	(4.2)
Total liabilities	818.6	747.6	71.0
Equity [17]*	71.7	68.5	3.2

[13] Credit float, which represents the difference between items in process of collection and deferred credit items, occurs when the Reserve Banks debit the paying bank for transactions before providing credit to the depositing bank. Float is directly estimated at the service level.

TABLE 3—COMPARISON OF PRO FORMA BALANCE SHEETS FOR BUDGETED FEDERAL RESERVE MATURE PRICED SERVICES [a]—Continued

[Millions of dollars—projected average for year]

	2025	2024	Change
Total liabilities and equity	890.3	816.1	74.2

[a] Calculations in this table and subsequent PSAF tables may be affected by rounding. Excludes amounts related to the FedNow Service.
* Premises, postemployment/postretirement benefits and net pension liabilities, and equity restated for 2024.

TABLE 4—IMPUTED FUNDING FOR MATURE PRICED-SERVICES ASSETS [a]

[Millions of dollars]

	2025	2024
A. Short-term asset financing:		
Short-term assets to be financed:.		
Receivables	$ 44.3	$ 41.8
Inventory	0.4	0.2
Prepaid expenses	34.2	24.0
Total short-term assets to be financed	78.9	66.0
Short-term payables	36.8	33.4
Net short-term assets to be financed	42.2	32.7
Imputed short-term debt financing [18]	42.2	32.7
B. Long-term asset financing:		
Long-term assets to be financed:		
Premises *	105.3	99.4
Furniture and equipment	60.8	53.9
Software and leasehold improvements	74.5	67.0
Net pension asset	82.4	120.4
Deferred tax asset	130.6	129.4
Total long-term assets to be financed	453.6	470.1
Postemployment/postretirement benefits and net pension liabilities *	292.5	301.2
Net long-term assets to be financed *	161.1	168.9
Imputed long-term debt [21]	96.1	100.3
Imputed equity [21]	65.0	68.5
Total long-term financing *	161.1	168.9

[a] Excludes amounts related to the FedNow Service.
* Premises and postemployment/postretirement benefits and net pension liabilities, net long-term assets to be financed and total long-term financing restated for 2024.

TABLE 5—DERIVATION OF THE PSAF FOR MATURE PRICED SERVICES [a]

[Dollars in millions]

	2025		2024	
	Debt	Equity	Debt	Equity
A. Imputed long-term debt and equity:				
Net long-term assets to finance	$ 161.1	$ 161.0	$ 168.9	$ 168.9
Capital structure observed in market	59.7%	40.3%	59.4%	40.6%
Pre-adjusted long-term debt and equity	$ 96.1	$ 65.0	$ 100.3	$ 68.5
Equity adjustments: [19]				
Equity to meet capital requirements		$ 65.0		$ 68.5
Adjustment to debt and equity funding given capital requirements [20]				
Adjusted equity balance		$ 65.0		$ 68.5
Equity to meet capital requirements [21]				
Total imputed long-term debt and equity *	96.1	65.0	100.3	68.5
B. Cost of capital:				
Elements of capital costs:				
Short-term debt [22]	$ 42.2 × 5.4%	= $ 2.3	$ 32.7 × 5.4%	= $ 1.8
Long-term debt [22]	$ 96.1 × 4.4%	= 4.2	$ 100.3 × 4.0%	= $ 4.0
Equity [23]	$ 65.0 × 18.6%	= $ 12.1	$ 68.5 × 17.4%	= $ 11.9
C. Incremental cost of PSR policy:				
Equity to meet policy	$ 6.7 × 18.6%	= $ 1.3	$ = × 17.4%	= $ =
D. Other required PSAF costs:				
Sales taxes		$ 4.5		$ 3.9
Board of Governors expenses		7.6		7.6
		$ 12.1		$ 11.5
E. Total PSAF:		$ 31.9		$ 29.2

TABLE 5—DERIVATION OF THE PSAF FOR MATURE PRICED SERVICES [a]—Continued

[Dollars in millions]

	2025		2024	
	Debt	Equity	Debt	Equity
As a percent of assets		3.6%		3.6%
As a percent of expenses		3.4%		3.6%
F. Tax rates		18.91%		18.84%

[a] Excludes amounts related to the FedNow Service.
* Total imputed long-term debt restated for 2024.

TABLE 6—COMPUTATION OF 2025 CAPITAL ADEQUACY FOR FEDERAL RESERVE MATURE PRICED SERVICES [a]

[Dollars in millions]

	Assets	Risk weight	Weighted assets
Imputed investments:			
1-Year Treasury securities [24]	$ 6.7	0.0	$ =
Federal funds [25]	293.0	0.2	58.6
Total imputed investments	299.8		58.9
Receivables	44.3	0.2	8.9
Inventory	0.4	1.0	0.4
Prepaid expenses	34.2	1.0	34.2
Items in process of collection	58.0	0.2	11.6
Premises	105.3	1.0	105.3
Furniture and equipment	60.8	1.0	60.8
Software and leasehold improvements	74.5	1.0	74.5
Pension asset	82.4	1.0	82.4
Deferred tax asset	130.6	1.0	130.6
Total	890.3		567.6
Imputed equity:			
Capital to risk-weighted assets	12.6%		
Capital to total assets	8.1%		

[a] Excludes amounts related to the FedNow Service.

C. *Check Services*—Table 7 shows the 2023 actual, 2024 forecasted, and 2025 budgeted cost-recovery performance for commercial check services.

TABLE 7—CHECK SERVICES PRO FORMA COST AND REVENUE PERFORMANCE

[Dollars in millions]

Year	Revenue	Total expense	Net income (ROE)	Targeted ROE	Recovery rate after targeted ROE
	1	2	3 [1 − 2]	4	5 [1/(2 + 4)]
2023 (actual)	111.8	107.4	4.4	1.3	102.9
2024 (forecast)	110.2	105.0	5.2	2.1	102.9
2025 (budget)	107.1	107.8	(0.7)	2.1	97.5

1. *2024 Forecast*—The Reserve Banks forecast that Check Services will recover 102.9 percent of total expenses and targeted ROE, compared with a 2024 budgeted recovery rate of 95.5 percent.

Through August 2024, total commercial forward and total commercial return check volumes were 6.8 percent lower and 2.9 percent greater, respectively, than they were during the same period last year. For full-year 2024, the Reserve Banks estimate that their total forward check volume will decline 6.3 percent (compared with a budgeted decline of 8.0 percent), and their total return check volume will increase 1.6 percent (compared with a budgeted decline of 7.0 percent) from 2023 levels. The Reserve Banks expect that check volumes will continue to decline because of ongoing substitution away from checks to other payment instruments.

2. *2025 Pricing*—The Reserve Banks expect Check Services to recover 97.5 percent of total expenses and targeted ROE in 2025. The Reserve Banks project revenue to be $107.1 million, a decline of $3.1 million, or 2.8 percent from the 2024 forecast. Total expenses for Check Services are projected to be $107.8 million, an increase of $2.8 million, or 2.7 percent, from 2024 forecasted expenses.

As check volumes continue to decline, the pricing increases are intended to help stabilize check revenues, to shift the revenue mix

toward fixed fees, and to continue a value-based pricing strategy for financial institutions that use the service. To that end, the Reserve Banks will increase the pricing tiers for the fixed monthly participation fees. For the participation fees, Tier 1 will increase by $125, Tier 2 will increase by $80, Tier 3 will increase by $50, and Tier 4 will increase by $10. These fee changes support the cost of maintaining FRFS Check Services infrastructure as fewer checks are written each year and follow the Check Services business line's pricing strategy to increase the share of revenue collected through fixed fees. Table 8 displayed below shows the 2025-tiered participation fees.

TABLE 8—CHECK 21 PARTICIPATION FEE STRUCTURE

Tier[26]	Monthly fee
1	$550
2	340
3	215
4	90

The Reserve Banks will also increase the fees for each of the services in the FedImage suite by approximately 10% and merge the Back File Conversion and Electronic On-Us services with the FedImage Enhanced Truncation service into a single service at the new FedImage Enhanced Truncation price point. These changes will better reflect the value of services provided to customers and help simplify the services in the face of declining volumes. Table 9 below shows the 2025 FedImage services fees.

TABLE 9—2025 FEDIMAGE SERVICES FEES[27]

FedImage Services	2024 Fees		2025 Fees	
	Fixed/CL	Item	Fixed/CL	Item
Image Archive:				
30 business day archive		$ 0.0013		$ 0.0014
60 business day archive		0.0015		0.0017
7 Year archive/11 year archive		0.0024		0.0026
Extended RAID Storage:				
61 days to 6 months		0.0012		0.0013
61 days to 12 months		0.0029		0.0032
61 days to 24 months		0.0074		0.0081
Image Retrievals:				
Subscription Retrieval		0.0032		0.0035
Manual FedImage Requests		8.80		10.00
Back File Conversion	5.17	0.0146		
Electronic On-Us Service	5.17	0.0146	8.80	
Truncation:				
FedImage Enhanced Truncation	7.98	0.0132	8.80	0.0145
Return Retrieval		1.54		1.70
Custom Sort Fee	192.50		212.00	

Additionally, the Reserve Banks will increase certain forward paper fees. Specifically, the Reserve Banks will increase the Canadian cash letter fees for U.S. and Canadian funds by $2.00, the Canadian Amount Encoding per-

[14] Consistent with the PSR policy, the Reserve Banks' priced services will hold an amount equivalent to six months of the Fedwire Funds Service's current operating expenses as liquid net financial assets and equity on the pro forma balance sheet. Six months of the Fedwire Funds Service's projected current operating expenses is $71.7 million. In 2025, $6.7 million of additional equity was imputed to meet PSR policy requirements.

[15] Includes the allocation of Board of Governors assets to priced services of $5.2 million for 2025 and $3.5 million for 2024.

[16] Includes the allocation of Board of Governors liabilities to priced services of $1.4 million for 2025 and $1.2 million for 2024.

[17] Includes an accumulated other comprehensive loss of $563.3 million for 2025 and $551.0 million for 2024, which reflects the ongoing amortization of the accumulated loss in accordance with ASC 715. Future gains or losses, and their effects on the pro forma balance sheet, cannot be projected. See Table 5 for calculation of required imputed equity amount.

[18] Imputed short-term debt financing is computed as the difference between short-term assets and short-term liabilities. As presented in Table 5, the financing costs of imputed short-term debt, imputed long-term debt and imputed equity are the elements of cost of capital, which contribute to the calculation of the PSAF.

[19] If minimum equity constraints are not met after imputing equity based on the capital structure observed in the market, additional equity is imputed to meet these constraints. The long-term funding need was met by imputing long-term debt and equity based on the capital structure observed in the market (see Tables 4 and 6). In 2025, the amount of imputed equity met the minimum equity requirements for risk-weighted assets.

[20] Equity adjustment offsets are due to a shift of long-term debt funding to equity in order to meet FDIC capital requirements for well-capitalized institutions.

[21] Additional equity in excess of that needed to fund priced services assets is offset by an asset balance of imputed investments in Treasury securities.

[22] Imputed short-term debt and long-term debt are computed in Table 4.

[23] The 2025 ROE is equal to a risk-free rate plus a risk premium (beta * market risk premium). The 2025 after-tax CAPM ROE is calculated as 5.52% + (1.0 * 9.54%) = 15.06%. Using a tax rate of 18.9%, the after-tax ROE is converted into a pretax ROE, which results in a pretax ROE of (15.06%/(1–18.9%)) = 18.57%. Calculations may be affected by rounding.

[24] If minimum equity constraints are not met after imputing equity based on all other financial statement components, additional equity is imputed to meet these constraints. Additional equity imputed to meet minimum equity requirements is invested solely in Treasury securities. The imputed investments are similar to those for which rates are available on the Federal Reserve's H.15 statistical release, available at *https://www.federalreserve.gov/releases/h15/*.

[25] The investments are imputed based on the amounts arising from the collection of items before providing credit according to established availability schedules.

[26] This fee is charged to financial institutions that have received any Check 21 electronic or substitute check volume (forward or return) from the Reserve Banks during the month. The fee is applied at the parent financial institution level, as defined in the Reserve Banks' Global Customer Directory. Each financial institution's tier assignment is determined by the criteria described in the FedForward Standard Endpoint Tier Listing.

[27] The 2025 fees are not listed for Back File Conversion and Electronic On-Us given their consolidation into a single service at the new FedImage Enhanced Truncation price point.

item fee by $0.50, and the Mixed Forward Products (domestic paper checks) cash letter fee by $2.00 and per-item fee by $0.50. Table 10 below shows the 2025 forward paper fees.

TABLE 10—2025 FORWARD PAPER CHECK CLEARING FEES

Forward paper check	Fixed/CL	Item
Canadian—US Funds	$ 19.00	$ 6.50000
Canadian—Canadian Funds	19.00	6.50000
Canadian Amount Encoding	.....	2.50000
Mixed Paper Deposits	19.00	5.00000

The Reserve Banks will increase certain return fees and will implement a new tiered fee structure for the Large Dollar Return Item Notification (LDRIN) via the FedLine Web® Solution. The fees for the new LDRIN via FedLine Web tiers will be $3.50 for Tier 1, for customers with greater than 5,000 monthly items, and $5.00 for Tier 2, for customers with less than 5,000 monthly items. Additionally, the Return Item Reclear cash letter fee will increase by $1.00 and the per-item fee will increase by $0.10. The Qualified and Unqualified Return Item cash letter fee will increase by $2.00 and the per-item fee will increase by $0.50. Lastly, the return Item Qualification per-item fee will increase by $1.00. Table 11 below shows the 2025 return fees and new LDRIN via FedLine Web tiers.

TABLE 11—2025 RETURN LEGACY/PAPER FEES

Return paper check	Fixed/CL	Item
LDRIN via FedLine for the Web:		
Tier 1 *(Greater than 5,000 monthly)*	.....	$ 3.50
Tier 2 *(Less than 5,000 monthly)*	.....	5.00
Return Item Reclear:	.....	.....
Level 1 *(Items valued up to $100)*	$12.00	0.85
Level 2 *(Items valued up to $250)*	12.00	0.95
Level 3 *(Items valued up to $500)*	12.00	1.05
Level 4 *(Items valued up to $1,000)*	12.00	1.15
Qualified Return Items	19.00	8.50
Unqualified Return Items	19.00	8.50
Unencoded Qualification	.....	11.00

The Reserve Banks' primary risk to current projections for Check Services is a greater than expected decline in check volume due to the general reduction in check writing, substitution away from checks to other payment instruments, and competition from correspondent banks, aggregators, and direct exchanges, which could result in lower than anticipated revenue. The Reserve Banks estimate these cumulative price changes will result in a 2.8 percent average increase for Check Services customers.

D. *FedACH Services*—Table 12 shows the 2023 actual, 2024 forecasted, and 2025 budgeted cost-recovery performance for commercial FedACH Services.

TABLE 12—FEDACH SERVICES PRO FORMA COST AND REVENUE PERFORMANCE

[Dollars in millions]

Year	Revenue	Total expense	Net income (ROE)	Targeted ROE	Recovery rate after targeted ROE
	1	2	3 [1 − 2]	4	5 [1/(2 + 4)]
2023 (actual)	183.8	166.5	17.1	2.3	108.8
2024 (forecast)	189.0	169.0	20.0	3.7	109.4
2025 (budget)	194.4	179.7	14.7	3.7	106.0

1. *2024 Forecast*—The Reserve Banks forecast that FedACH Services will recover 109.4 percent of total expenses and targeted ROE, compared with a 2024 budgeted recovery rate of 106.0 percent.

Through August 2024, FedACH commercial origination and receipt volume were 7.7 percent higher and 5.3 percent higher, respectively, than they were during the same period last year. For full-year 2024, the Reserve Banks estimate that FedACH commercial origination and receipt volume will increase 6.7 percent and 4.7 percent, respectively, from 2023 levels, compared with a budgeted increase of 3.5 percent for both commercial origination and receipt.

2. 2025 *Pricing*—The Reserve Banks expect FedACH Services to recover 106.0 percent of total expenses and targeted ROE in 2025. The Reserve Banks project revenue to be $194.4 million, an increase of $5.4 million, or 2.9 percent, from the 2024 forecast. Total expenses are projected to be $179.8 million, an increase of $10.8

million, or 6.4 percent, from the 2024 forecast.

The Reserve Banks will increase the monthly ACH Participation fee from $75 to $80 per RTN. The Reserve Banks will also increase the monthly ACH Origination Minimum fee from $50 to $55 and Receipt Minimum fee from $40 to $45 per RTN.[28] The ACH Participation and Minimum Fee price changes are driven by ongoing operational costs and a continued focus on growing fixed fee revenue generation.

In addition, the Reserve Banks will increase the FedACH FedPayments Reporter Service fees from 6 to 11 percent as shown in Table 13.[29] The FedPayments Reporter Service has continued to evolve and improve with enhanced features such as new intraday generation capabilities for select reports and the integration of an upgraded Electronic Data Interchange (EDI) parser. These efforts have increased both the costs of providing the FedPayments Reporter Service and the value it offers to customers.

TABLE 13—FEDACH FEDPAYMENTS REPORTER SERVICE FEES

Tiers	2025 Monthly fee
Tier 1—Up to 50 reports	$50
Tier 2—From 51 to 150 reports	72
Tier 3—From 151 to 500 reports	133
Tier 4—From 501 to 1,000 reports	245
Tier 5—From 1,001 to 1,500 reports	355
Tier 6—From 1,501 to 2,500 reports	555
Tier 7—From 2,501 to 3,500 reports	775
Tier 8—From 3,501 to 4,500 reports	990
Tier 9—From 4,501 to 5,500 reports	1,200
Tier 10—From 5,501 to 7,000 reports	1,460
Tier 11—From 7,001 to 8,500 reports	1,700
Tier 12—From 8,501 to 10,000 reports	1,930
Tier 13—Over 10,000 reports	2,100

The Reserve Banks estimate these cumulative price changes will result in a 1.4 percent average increase for FedACH customers.

The Reserve Banks' primary risk to current projections for the FedACH Service are lower-than-projected volumes and growth due to potential customer attrition.

E. *Fedwire Funds Service and National Settlement Service*—Table 14 shows the 2023 actual, 2024 forecasted, and 2025 budgeted cost-recovery performance for the Fedwire Funds Service and the National Settlement Service.

TABLE 14—FEDWIRE FUNDS SERVICE AND NATIONAL SETTLEMENT SERVICE PRO FORMA COST AND REVENUE PERFORMANCE

[Dollars in millions]

Year	Revenue	Total expense	Net income (ROE)	Targeted ROE	Recovery rate after targeted ROE
	1	2	3 [1 − 2]	4	5 [1/(2 + 4)]
2023 (actual)	162.5	153.4	9.1	4.3	103.1
2024 (forecast)	169.2	153.1	16.1	3.0	108.3
2025 (budget)	174.4	164.9	9.5	4.1	103.2

1. *2024 Forecast*—The Reserve Banks forecast that the Fedwire Funds Service and the National Settlement Service will recover 108.3 percent of total expenses and targeted ROE, compared with a 2024 budgeted recovery rate of 103.2 percent.

Through August 2024, Fedwire Funds Service online volume has been 5.9 percent higher than it was during the same period last year. The Reserve Banks expect volume to remain near this level through the remainder of 2024. Through August 2024, the National Settlement Service settlement file volume was 0.3 percent higher than it was during the same period last year, and settlement entry volume was 0.5 percent higher. For full-year 2024, the Reserve Banks estimate that settlement file volume will decrease 0.3 percent (compared with a budgeted decrease of 0.1 percent) and settlement entry volume will increase 0.4 percent (compared with a budgeted 0.4 percent increase) from 2023 levels.

2. *2025 Pricing*—The Reserve Banks expect the Fedwire Funds Service and the National Settlement Service to recover 103.2 percent of total expenses in 2025. The Reserve Banks project revenue to be $174.4 million, an increase of $5.2 million, or 3.1 percent from the 2024 forecast. The Reserve Banks project total expenses to be $164.9 million, an increase of 11.8

[28] The FedACH Minimum Fee applies to any RTN that has originated or received a FedACH transaction during a calendar month. The customer is charged their normal item fees plus a variable amount that closes the gap to the minimum. For example, an RTN originating 10K items in a month pays $35 in item fees (10K items times $0.0035 per item) and $15 in minimum fees so that their total origination fees are $50. Another RTN paying $51 in item fees would be charged an effective minimum fee of $0. Only one minimum threshold applies in any given period, with RTNs subject to the Receipt Minimum fee only if they did not originate any items.

[29] The FedPayments Reporter Service for the FedACH Services provides financial institutions and their customers with reports of their ACH transactions processed by FedACH including valuable business information.

million, or 7.7 percent, from the 2024 forecast. Rising costs are primarily driven by the Fedwire Funds Service's ongoing transition to the ISO® 20022 messaging format.[30] In addition, the National Settlement Service continues to incur higher costs because of the expansion of its operating hours in 2022.[31]

The Reserve Banks will increase the Fedwire Funds Service participation fee from $115 to $120. In addition, all three of the gross origination and receipt tiered fees will be increased. The tier 1 fee will increase from $0.94 to $0.97, the tier 2 fee will increase from $0.29 to $0.30, and the tier 3 fee will increase from $0.19 to $0.195. Correspondingly, the volume-based incentive discount fee will increase for all three tiers. The tier 1 discount fee will increase from $0.188 to $0.194, the tier 2 discount fee will increase from $0.058 to $0.060, and the tier 3 discount fee will increase from $0.038 to $0.039. Finally, the FedPayments Manager Import/Export fee will increase from $60 to $65. The Reserve Banks will also change National Settlement Service fees for 2025. The per-file fee will increase from $35 to $40, and the per-entry fee will increase from $1.70 to $1.95.

In addition to these changes, the Reserve Banks will introduce a new volume-based fixed fee for the Fedwire Funds Service.[32] The introduction of this fee will serve to reconcile challenges associated with volatility stemming from variable revenues sources while ensuring a fee structure that is better aligned with customer usage. This fee is based on the volume tier thresholds.[33] The new volume-based fixed fee is one price point assessed at the parent level and is based on the highest volume tier of its associated affiliates.[34] This differs from the existing participation fee in that the participation fee is assessed at the sub-account level for any ABA with at least one origination or receipt transaction during the month.[35] The proposed price points for the volume-based fixed fees are as follows:

TABLE 15—FEDWIRE FUNDS SERVICE VOLUME-BASED FIXED FEE TIERS

Fixed fee level	Volume tier	Monthly fee
Tier 2	Tier 2	$250
Tier 3	Tier 3	500

As noted above, this fee will serve to reconcile challenges associated with volatility stemming from variable revenues sources while ensuring a fee structure that is better aligned with customer usage. Fedwire Funds Service fee revenue has become increasingly dependent on variable sources and this growing exposure to uncertain fee fluctuations undermines annual revenue stability. This fee will address this uncertainty by increasing the percentage of fixed fee revenue. Further, the fee is intended to be commensurate with customer usage and structured so that smaller customers are not disproportionally impacted. In addition, this fee, alongside the other fee increases noted above, serves to help balance increases in ongoing operational costs incurred by the National Settlement Service for the period between 2014 and 2023, when fees did not increase.

The Reserve Banks' primary risk to current projections for these services is lower than-projected-volumes and growth due to the market and economic environment given that historically, Fedwire Funds Service volume has reflected market conditions.[36] The Reserve Banks estimate these cumulative price changes will result in a 5.7 percent average price increase for Fedwire Funds and National Settlement Service customers.

F. *Fedwire Securities Service*—Table 16 shows the 2023 actual, 2024 forecast, and 2025 budgeted cost-recovery performance for the Fedwire Securities Service.[37]

TABLE 16—FEDWIRE SECURITIES SERVICE PRO FORMA COST AND REVENUE PERFORMANCE

[Dollars in millions]

Year	Revenue	Total expense	Net income (ROE)	Targeted ROE	Recovery rate after targeted ROE
	1	2	3 [1 − 2]	4	5 [1/(2 + 4)]
2023 (actual)	49.1	39.7	9.4	0.5	122.3
2024 (forecast)	52.5	41.8	10.7	0.8	123.2
2025 (budget)	55.7	47.3	8.4	0.9	115.7

[30] In October 2021, the Board announced that the Federal Reserve Banks will adopt the ISO 20022 message format for the Fedwire Funds Service. *See New Message Format for the Fedwire Funds Service,* 86 FR 55600 (Oct. 6, 2021).

[31] The National Settlement Service expanded its hours to 21.5 hours per day in 2022, with a new 9:00 p.m. ET open for the next business day.

[32] Volume-based pricing for Fedwire Funds was introduced in 1999. The analysis that led to volume-based pricing showed that Fedwire Funds can benefit from charging different prices to different areas of the market based on customer volume. When considering ways to increase fixed revenue, the Board re-examined this analysis and has concluded that establishing fixed revenue sources based on customer volume will benefit the Fedwire Funds service in a similar fashion to volume-based pricing for gross origination and receipt fees.

[33] Tiers are based on monthly total volume (send and receive) at the master account level: 0–14,000 messages (Tier 1); 14,001–90,000 (Tier 2), and all volume above 90,000 messages (Tier 3).

[34] For example, if a parent customer has affiliates in the Tier 2 and Tier 3 volume thresholds, the parent will be assessed the corresponding $500 Tier 3 monthly fee.

[35] The new Monthly Fixed Fee will not be applicable to customers in the Tier 1 volume level.

[36] Fedwire Funds Service volume growth reflects economic growth. For example, its volume has grown every year except for 2008 and 2009, when it contracted 2.5 percent and 5.0 percent, respectively, during the Great Recession. For historical Fedwire Funds Service volume data, *see FRBservices.org, Fedwire Funds Service—Annual Statistics, https://www.frbservices.org/resources/financial-services/wires/volume-value-stats/annual-stats.html.*

[37] The Reserve Banks provide transfer services for securities issued by the U.S. Treasury, federal government agencies, government-sponsored enterprises, and certain international institutions. Prior to 2023, the priced component of this service consisted of revenues, expenses, and volumes associated with the transfer of all non-Treasury securities. Starting in 2023, the revenues, expenses, and volumes associated with the transfer of Treasury securities are also included in the priced component of this service.

1. *2024 Forecast*—The Reserve Banks forecast that the Fedwire Securities Service will recover 123.2 percent of total expenses and targeted ROE, compared with a 2024 budgeted recovery rate of 110.9 percent.

Through August 2024, Treasury security transfer volume was 15.9 percent higher than it was during the same period last year. For full-year 2024, the Reserve Banks estimate that Treasury security transfer volume will increase 4.0 percent from 2023 levels, compared with a budgeted decrease of 7.3 percent. Through August 2024, Agency security transfer volume was 3.8 percent lower than it was during the same period last year. For full-year 2024, the Reserve Banks estimate that Agency security transfer volume will decrease 2.6 percent from 2023 levels, compared with a budgeted increase of 1.3 percent.

Through August 2024, account maintenance volume was 0.7 percent lower than it was during the same period last year. For full-year 2024, the Reserve Banks estimate that account maintenance volume will decline 1.0 percent from 2023 levels, compared with a budgeted decline of 2.6 percent. Through August 2024, the volume of Agency issues maintained was 0.5 percent lower than it was during the same period last year. For full-year 2024, the Reserve Banks estimate that the volume of Agency issues maintained will decrease 0.4 percent from 2023 levels, compared with a budgeted change of 0.0 percent.

2. *2025 Pricing*—The Reserve Banks expect the Fedwire Securities Service to recover 115.7 percent of total expenses and targeted ROE in 2025. Revenue is projected to be $55.7 million, an increase of $3.2 million, or 6.0 percent, from the 2024 revenue forecast. The Reserve Banks also project that 2025 expenses will be $47.3 million, an increase of $5.5 million, or 13.1 percent from the 2024 forecast.

The Reserve Banks will leave fee schedules for Fedwire Securities priced services unchanged in 2025. This decision considers the benefits of maintaining consistent customer pricing in the face of rising costs and higher than expected volatility in transfer volumes.

Regarding volumes, the Reserve Banks project that monthly maintenance products will maintain relatively stable volumes throughout 2025 with Issue Maintenance volume to increase slightly at 0.2 percent and Account Maintenance volume to decrease 0.6 percent in 2025. Treasury transfer volume is slated to continue its record growth trend with an anticipated 9.4 percent increase. Agency transfers are projected to increase by 0.5 percent in 2025.

The Reserve Banks project that Agency transfer volume will increase moderately compared with previous years, as interest rates fall, encouraging home-buying and mortgage refinancing. As detailed in the figures above, the volume of Treasury security transfers is projected to continue its record growth trend due primarily to debt issuance by the Treasury. The volume of accounts maintained are expected to decrease 2.5 percent, consistent with recent trends and primarily driven by a reduction in joint custody accounts. The volume of Agency issues maintained is expected to remain relatively flat and claim adjustment volume is expected to remain relatively stable consistent with recent trends.

The Reserve Banks' primary risks to current projections for the Fedwire Securities Service include variations in technology costs and product volume forecasts stemming from an uncertain macroeconomic outlook and market conditions.

G. *FedNow Service*—

1. *2024 Forecast*—The Reserve Banks forecast that the FedNow Service will generate a total of $244.9 million in expenses in 2024.

The number of transactions processed by the FedNow Service in 2024 is modest and consistent with the Federal Reserve's expectations for a new service line. From January through August 2024, the transaction volume of the FedNow Service totaled 414,827 transactions, with the number of participants growing from 400 to just under 1,000 financial institutions during this time period. Broad adoption of the FedNow Service across an industry with more than 9,000 financial institutions will be a gradual journey, similar to other new payment services like FedACH in the 1970s and 1980s. As a result, the Board has adopted a long-term outlook in evaluating the development of the FedNow Service. The Board anticipates acceleration in volume over time as more financial institutions join the network and as the Reserve Banks release new service features on an ongoing basis.[38]

2. *2025 Pricing*—In 2025, the Reserve Banks project total operating expenses to be $245.5 million, which will be an increase of $0.6 million or 0.2 percent from the 2024 forecast.[39]

The Reserve Banks will modify the Customer Credit Transfer, Customer Credit Transfer Return, and Request for Payment fee components of the FedNow Service to exclude ''on-us'' transactions sent from and received at the same financial institution.[40] This adjustment will both align with prevailing market practices and reduce inefficient off-network transaction activity. All other components of the previous year's fee schedule, inclusive of discounts, will be maintained by the Reserve Banks in 2025.[41]

H. FedLine Solutions—There are currently six FedLine Solutions channels through which customers can access the Reserve Banks' priced services: FedMail®, FedLine Exchange, FedLine Web, FedLine Advantage®, FedLine Command and FedLine Direct.[42] The Reserve Banks bundle these channels into 12 FedLine Solutions packages that are supplemented by a number of premium (or à la carte) access and accounting information options.

The Reserve Banks also offer FedComplete® Packages, which are bundled offerings of FedLine connections and a fixed number of FedACH Services, Fedwire Funds Services, and Check 21–enabled transactions. In 2025, the Reserve Banks will increase the monthly fees for FedComplete 100A Plus from $900 to $1,150 and FedComplete 200A Plus from $1,425 to $1,725. The price increases reflect the rising fees and enhancements of the package's underlying services. To simplify the FedComplete Packages and create internal efficiencies, FedComplete 100A

[38] For quarterly FedNow Service transaction data, see Board of Governors of the Federal Reserve System, *FedNow Service, https://www.federalreserve.gov/paymentsystems/fednow_about.htm.*

[39] During the time in 2023 when the FedNow Service was in production, expenses (including imputed costs) totaled $99.7 million.

[40] The modifications will take place at the parent financial institution level, as defined in the Reserve Banks' Global Customer Directory. ''On-us'' transactions include those made by the same financial institution, even if the financial institution uses multiple RTNs.

[41] These maintained fees and discounts include the FedLine connectivity discount. The FedLine connectivity discount program consists of providing credits for upgrade fees from a FedMail or FedLine Web connection to FedLine Advantage and new FedLine Advantage connection fees for the FedNow Service to qualifying institutions. Credits will be for 12 months from FedLine Advantage billing eligibility. Customers that have received discounts throughout the 2024 program will see FedLine connectivity discounts roll off in 2025 following the completion of the 12-month term.

[42] The Reserve Banks charge fees for the electronic connections that financial institutions use to access priced services and allocate the costs and revenues associated with this electronic access to the priced services. As a result, FedLine costs and revenue are allocated to the Reserve Banks' priced services on an expense ratio basis.

Premier and 200A Premier will be discontinued. Additionally, the Reserve Banks plan to discontinue the FedLine Exchange service to streamline FedLine Solution products and create internal efficiencies that simplify operating, servicing, and billing processes.[43]

The Reserve Banks will increase the monthly fees for FedLine Command Plus from $1,035 to $1,185, FedLine Direct Plus from $5,500 to $5,750, and FedLine Direct Premier from $10,500 to $11,000 per month. Price changes for the FedLine Command and FedLine Direct packages are in response to enhancements for the FedNow Service and account for the price increases from the End-of-Day Financial Institution Reconcilement Date (FIRD) File and Statement of Account Spreadsheet File (SASF) offerings.[44] FedLine Direct had additional operational costs associated with a new network vendor and hardware upgrades that have contributed to these price increases.

In 2025, the Reserve Banks are prepared to add API functionality for certain services and products.[45] The Reserve Banks are developing an initial pricing menu for priced APIs. Upon launch, each API would be assigned a core pricing scenario. Communication will be forthcoming on the timing, availability, and pricing scenarios for initial APIs.

The Reserve Banks estimate these cumulative price changes will result in a 4.8 percent average price increase for FedLine customers.

II. Analysis of Competitive Effect

All operational and legal changes considered by the Board that have a substantial effect on payment system participants are subject to the competitive impact analysis described in the Board's policy, *The Federal Reserve in the Payments System.*[46] Under this policy, the Board assesses whether changes would have a direct and material adverse effect on the ability of other service providers to compete effectively with the Federal Reserve in providing similar services due to differing legal powers or constraints or due to a dominant market position deriving from such legal differences. If any proposed changes create such an effect, the Board must further evaluate the changes to assess whether the benefits associated with the changes—such as contributions to payment system efficiency, payment system integrity, or other Board objectives—can be achieved while minimizing the adverse effect on competition.

The Board has conducted this analysis and concluded that the 2025 fees, fee structures, and changes in service will not have a direct and material adverse effect on the ability of other service providers to compete effectively with the Reserve Banks in providing similar services. When conducting the competitive effect analysis for the FedNow Service, the Board assessed whether its pricing strategy as a new service, including discounts, would have a material, adverse effect on the ability of other service providers to compete effectively with the Reserve Banks due to differing legal powers or a dominate market position as a result of such differing legal powers. The Board concluded that the pricing strategy, including discounts, followed general market practice for new services and could similarly be implemented by private sector providers unrelated to any differing legal powers. Therefore, the Reserve Banks' pricing does not have a material adverse effect on the ability of other service providers to compete effectively with the Reserve Banks in providing similar services.

The Reserve Banks expect to continue to achieve aggregate long-run cost recovery across all mature priced services.

III. 2025 Fee Schedules

FEDACH SERVICES 2025 FEE SCHEDULE

[Effective January 1, 2025. **Bold indicates changes from 2024 prices**]

	Fee
FedACH minimum monthly fee:	
Originating depository financial institution (ODFI)[47]	**$55.00.**
Receiving depository financial institution (RDFI)[48]	**$45.00.**
Origination (per item or record):	
Forward or return items	$0.0035.
SameDay Service—forward item[49]	$0.0010 surcharge.
Addenda record	$0.0015.
FedLine Web-originated returns and notification of change (NOC)[50]	$0.50.
Facsimile Exception Return/NOC[51]	$45.00.
SameDay Exception Return	$45.00.
Automated NOC	$0.20.
Volume discounts (based on monthly billed origination volume)[52] per item when origination volume is	
750,001 to 1,500,000 items per month discount	$0.0008.
more than 1,500,000 items per month discount	$0.0010.
Volume discounts (based on monthly billed receipt volume)[53] per item when receipt volume is	
10,000,001 to 15,000,000 items per month discount	$0.0002.
more than 15,000,000 items per month discount	$0.0003.
Receipt (per item or record):	
Forward Item	$0.0035.
Return Item	$0.0075.
Addenda record	$0.0015.
Volume discounts:	
Non-Premium Receivers[54] per item when volume is	
750,001 to 12,500,000 items per month[55]	$0.0017 discount.

[43] The FedLine Exchange service provides access to the E-Payments Routing Directory, which is also available to plus level customers across the FedLine channels. FedLine Solutions packages offer attended or unattended access to critical payment and information services. FedMail, FedLine Exchange, FedLine Web, and FedLine Advantage packages offer attended or manual access via a web-based interface.

[44] FedLine Direct packages allow for unattended connections at multiple connection speeds to Check, FedACH, Fedwire Funds, and Fedwire Securities transactional and information services and to most accounting information services. The FedLine Command package offers a computer-to-computer, internet protocol–based interfaces that supports an unattended connection to FedACH, most accounting information services, and the FedNow Service.

[45] APIs are a set of protocols for connecting software systems programmatically, enabling system-to-system interoperability.

[46] *See* Board of Governors of the Federal Reserve System, *Policies: The Federal Reserve in the Payments System, https://www.federalreserve.gov/paymentsystems/pfs_frpaysys.htm.*

FEDACH SERVICES 2025 FEE SCHEDULE—Continued

[Effective January 1, 2025. **Bold indicates changes from 2024 prices**]

	Fee
more than 12,500,000 items per month [56]	$0.0019 discount.
Premium Receivers, Level One [57] per item when volume is	
750,001 to 1,500,000 items per month [58]	$0.0017 discount.
1,500,001 to 2,500,000 items per month [59]	$0.0017 discount.
2,500,001 to 12,500,000 items per month [53]	$0.0018 discount.
12,500,001 to 30,000,000 items per month [53]	$0.0020 discount.
more than 30,000,000 items per month [53]	$0.0023 discount.
Premium Receivers, Level Two [60] per item when volume is	
750,001 to 1,500,000 items per month [61]	$0.0017 discount.
1,500,001 to 2,500,000 items per month [62]	$0.0017 discount.
2,500,001 to 12,500,000 items per month [56]	$0.0019 discount.
12,500,001 to 30,000,000 items per month [56]	$0.0021 discount.
more than 30,000,000 items per month [56]	$0.0024 discount.
FedACH Risk Management Services: [63]	
Monthly Package Fee (a single fee based on total number of criteria sets):	
For up to 5 criteria sets	$45.00.
For 6 through 11 criteria sets	$85.00.
For 12 through 23 criteria sets	$150.00.
For 24 through 47 criteria sets	$180.00.
For 48 through 95 criteria sets	$300.00.
For 96 through 191 criteria sets	$510.00.
For 192 through 383 criteria sets	$810.00.
For 384 through 584 criteria sets	$1,025.00.
For more than 584 criteria sets	$1,325.00.
Batch/Item Monitoring (based on total monthly volume):	
For 1 through 100,000 batches (per batch)	$0.007.
For more than 100,000 batches (per batch)	$0.0035.
FedPayments Insights Service: [64]	
Monthly Fee (a single fee based on commercial receipt volume):	
0–50,000 items per month	$75.00.
50,001–100,000 items per month	$120.00.
100,001–500,000 items per month	$180.00.
500,001–1,000,000 items per month	$260.00.
1,000,001–5,000,000 items per month	$340.00.
5,000,001–10,000,000 items per month	$450.00.
10,000,001–25,000,000 items per month	$550.00.
25,000,001–60,000,000 items per month	$625.00.
Over 60,000,000 items per month	$700.00.
Monthly FedPayments Reporter Service:	
FedPayments Reporter Service monthly package includes the following reports:	
ACH Received Entries Detail—Customer and Depository Financial Institution	
ACH Return Reason Report—Customer and Depository Financial Institution	
ACH Originated Entries Detail—Customer and Depository Financial Institution	
ACH Volume Summary by SEC Code—Customer	
ACH Customer Transaction Activity	
ACH Death Notification	
ACH International (IAT)	
ACH Notification of Change	
ACH Payment Data Information File	
ACH Remittance Advice Detail	
ACH Remittance Advice Summary	
ACH Return Item Report and File	
ACH Return Ratio	
ACH Social Security Beneficiary	
ACH Originator Setup	
ACH Report Delivery via FedLine Solution	
On Demand Report Surcharge [65]	$1.00.
Monthly Package Fee (counts reflect reports generated as well as delivered via a FedLine Solution):	
For up to 50 reports	**$50.00.**
For 51 through 150 reports	**$72.00.**
For 151 through 500 reports	**$133.00.**
For 501 through 1,000 reports	**$245.00.**
For 1,001 through 1,500 reports	**$355.00.**
For 1,501 through 2,500 reports	**$555.00.**
For 2,501 through 3,500 reports	**$775.00.**
For 3,501 through 4,500 reports	**$990.00.**
For 4,501 through 5,500 reports	**$1,200.00.**
For 5,501 through 7,000 reports	**$1,460.00.**
For 7,001 through 8,500 reports	**$1,700.00.**
For 8,501 through 10,000 reports	**$1,930.00.**
For more than 10,000 reports	**$2,100.00.**
Premier reports (per report generated): [66]	
ACH Volume Summary by SEC Code Report—Depository Financial Institution:	
For 1 through 5 reports	$10.00.
For 6 through 10 reports	$6.00.
For 11 or more reports	$1.00.
On Demand Surcharge	$1.00.
ACH Routing Number Activity Report:	
For 1 through 5 reports	$10.00.
For 6 through 10 reports	$6.00.

FEDACH SERVICES 2025 FEE SCHEDULE—Continued

[Effective January 1, 2025. **Bold indicates changes from 2024 prices**]

	Fee
For 11 or more reports	$1.00.
On Demand Surcharge	$1.00.
ACH Originated Batch Report (monthly):	
For 1 through 5 reports	$10.00.
For 6 through 10 reports	$6.00.
For 11 or more reports	$1.00.
On Demand Surcharge	$1.00.
ACH Originated Batch Report (daily):	
Scheduled Report	$0.65.
On Demand Surcharge	$1.00.
On-us inclusion:	
Participation (monthly fee per RTN)	$10.00.
Per-item	$0.0030.
Per-addenda	$0.0015.
Report delivery via encrypted email (per email)	$0.20.
Other Fees and Discounts:	
Monthly fee (per RTN):	
FedACH Participation Fee[67]	**$80.00.**
Same Day Service Origination Participation Fee[68]	$10.00.
FedACH Settlement Fee[69]	
Premium Receivers, Level One and Level Two	$60.00.
Non-Premium Receivers when volume is 1,500,000 items or less per month, Tier 2	$110.
Non-Premium Receivers when volume is more than 1,500,000 items per month, Tier 3	$250.00.
FedACH Information File Extract Fee	$180.00.
IAT Output File Sort Fee	$150.00.
Fixed Participation Fee—Automated NOCs[70]	$5.00.
Non-Electronic Input/Output fee:[71]	
CD/DVD (CD or DVD)	$50.00.
Paper (file or report)	$50.00.
Fees and Credits Established by Nacha:[72]	
Nacha Same-Day Entry fee (per item)	$0.052.
Nacha Same-Day Entry credit (per item)	$0.052 (credit).
Nacha Unauthorized Entry fee (per item)	$4.50.
Nacha Unauthorized Entry credit (per item)	$4.50 (credit).
Nacha Admin Network fee (monthly fee per RTN)	$30.50.
Nacha Admin Network fee (per entry)	$0.000185.
FedGlobal® ACH Payments:[73]	
Fixed Monthly Fee (per RTN):[74]	
Monthly origination volume more than 500 items	$185.00.
Monthly origination volume between 161 and 500 items	$60.00.
Monthly origination volume less than 161 items	$20.00.
Per-item Origination Fee for Monthly Volume more than 500 Items (surcharge):[75]	
Mexico service	$0.55.
Panama service	$0.60.
Per-item Origination Fee for Monthly Volume between 161 and 500 items (surcharge):[79]	
Mexico service	$0.80.
Panama service	$0.85.
Per-item Origination Fee for Monthly Volume less than 161 items (surcharge):[79]	
Mexico service	$1.05.
Panama service	$1.10.
Other FedGlobal ACH Payments Fees:	
Mexico service:	
Return received from Mexico[76]	$0.91 (surcharge).
Item trace[77]	$13.50.
Foreign currency to foreign currency (F3X) item originated to Mexico[79]	$0.67 (surcharge).
Panama service:	
Return received from Panama[71]	$1.00 (surcharge).
Item trace[72]	$7.00.
NOC	$0.72.
Exception Resolution Service:	
Monthly Fees (applies to cases only at the parent RTN):[78]	
Up to 5 cases	$20.00.
6–25 cases	$40.00.
26–50 cases	$60.00.
51–100 cases	$100.00.
101–1,000 cases	$250.00.
1,001–5,000 cases	$400.00.
5,001 cases and above	$500.00.
Offline Service Participant—Case Fees:[79]	
Case Open Fee	$5.00.
Case Response Fee	$5.00.
FedACH Receipt Discount Program Introduced in 2024:[80]	
Customers with more than 30 million FedACH receipt items per month:	
Per-item discount on all forward receipt items received through FedACH for the full five-year length of the agreement	$0.0002.
Percentage discount on the FedACH FedPayments Reporter Service for two years at any point during participation in the program.	50 percent.
Percentage discount on the FedACH Exception Resolution Service for two years at any point during their participation in the program.	100 percent.
Percentage discount on the FedACH FedPayments® Insights Service for two years at any point during their participation in the program.	100 percent.

FEDACH SERVICES 2025 FEE SCHEDULE—Continued

[Effective January 1, 2025. **Bold indicates changes from 2024 prices**]

	Fee
Customers with between 5 and 30 million FedACH receipt items per month:	
Per-item discount on all forward receipt items received through FedACH for the full 5-year length of the agreement	$0.0001.
Percentage discount on the FedACH FedPayments Reporter Service for two years at any point during their participation in the program.	25 percent.
Percentage discount on the FedACH Exception Resolution Service for two years at any point during their participation in the program.	50 percent.
Percentage discount on the FedACH FedPayments Insights Service for two years at any point during their participation in the program.	50 percent.

FEDWIRE FUNDS SERVICE AND NATIONAL SETTLEMENT SERVICE 2025 FEE SCHEDULES

[Effective January 1, 2025. **Bold indicates changes from 2024 prices**.]

	Fee
Fedwire Funds Service	
Monthly Participation Fee	**$120.00**
Basic volume-based pre-incentive transfer fee (originations and receipts)—per transfer for	
Tier 1: The first 14,000 transfers per month	**0.970**
Tier 2: Additional transfers up to 90,000 per month	**0.300**
Tier 3: Every transfer over 90,000 per month	**0.195**
Monthly Fixed Fee:	
Tier 2 Monthly Fixed Fee[81]	**250.00**
Tier 3 Monthly Fixed Fee[82]	**500.00**
Volume-based transfer fee with the incentive discount (originations and receipts)—per eligible transfer for[83]	
Tier 1: The first 14,000 transfers per month	**0.194**
Tier 2: Additional transfers 14,001 to 90,000 per month	**0.060**
Tier 3: Every transfer over 90,000 per month	**0.039**
Surcharge for Offline Transfers (Originations and Receipt)[84]	75.00
Surcharge for End-of-Day Transfer Originations[85]	0.26
Monthly FedPayments Manager Import/Export fee[86]	**65.00**
Surcharge on transfers >$10 million Origination and Receipt	0.14
Surcharge on transfers >$100 million Origination and Receipt	0.36
Surcharge for Payment Notification:	
Origination Surcharge[87]	0.01
Receipt Volume[88]	N/A
Delivery of Reports—Hard Copy Reports to On-Line Customers	50.00
Special Settlement Arrangements (charge per settlement day)[89]	150.00
National Settlement Service	
Basic:	
Settlement Entry Fee	**1.95**
Settlement File Fee	**40.00**
Surcharge for Offline File Origination[90]	45.00
Minimum Monthly Fee[91]	60.00

FEDWIRE SECURITIES SERVICE 2025 FEE SCHEDULE

[Effective January 1, 2025. **Bold indicates changes from 2024 prices.**]

	Fee
Basic Transfer Fee:[92 93]	
Agency Securities: Transfer or reversal originated or received	0.61
Treasury Securities: Transfer or reversal originated or received	0.61
Surcharge:[94]	
Agency Securities: Offline origination & receipt surcharge	80.00
Treasury Securities: Offline origination & receipt surcharge	80.00
Monthly Maintenance Fees:[95]	
Agency Securities: Account maintenance (per account)[96]	57.50
Agency Securities: Issue maintenance (per issue/per account)[97]	0.61
Treasury Securities: Account maintenance (per account)[98]	None
Treasury Securities: Issue maintenance (per issue/per account)[99]	None
ACAP Fees:[100 101]	
Claims Adjustment Fee	$1.00
Tracking Indicators Fee	0.10
Position Maintenance Fee (per position maintained/per business day)[102 103]	0.03
GNMA Serial Note Stripping or Reconstitution Fee[104]	9.00
Joint Custody Origination Surcharge[105 106]	46.00
Delivery of Reports—Hard Copy Reports to On-Line Customers[107]	50.00

FEDNOW SERVICE 2025 FEE SCHEDULE

[Effective January 1, 2025. **Bold indicates changes from 2024 prices.**]

	Fee
Customer Credit Transfer (per item) PACS.008 Origination	$0.045.
PACS.008 Origination—On-Us	**$0.000.**
Customer Credit Transfer Returns (per item) PACS.004 Origination	$0.045.
PACS.004 Origination—On-Us	**$0.000.**
Liquidity Management Transfer (LMT) (per-item) PACS.009 Origination	$1.00.
Request for Payment (RFP) (per-item) PAIN.013	$0.01.
PAIN.013—On-Us	**$0.000.**
PACS.008 Origination Discount	−$0.045 per item for up to 2,500 customer credit transfers per month (in 2025).
Participation Fee—General (per month)	$25.00, discounted to $0.00 in 2025.

FEDLINE 2025 FEE SCHEDULE

[Effective January 1, 2025. **Bold indicates changes from 2024 prices.**]

	Fee
FedComplete Packages (monthly) [108] [109]	
FedComplete 100A Plus [110]	**$1,150.00.**
FedComplete 200A Plus	**$1,725.00.**
FedComplete Excess Volume and Receipt Surcharge: [111]	
FedForward® [112]	$0.03700/item.
FedReturn®	$0.82000/item.
FedReceipt	$0.00005/item.
Fedwire Funds Origination	$0.97000/item.
Fedwire Funds Receipt	$0.09700/item.
FedACH Origination	$0.00350/item.
FedACH Receipt	$0.00035/item.
FedComplete credit adjustment	various.
FedComplete debit adjustment	various.
FedLine Solutions (monthly)	
FedMail [113]	$100.00.
FedLine Web [114]	$110.00.
FedLine Web Plus [106]	$160.00.
FedLine Web Premier [106]	$200.00
Includes:	
Services included in the FedLine Web Plus package	
Check File Automation	
FedLine Advantage [106] [115]	$415.00.
FedLine Advantage Plus [106] [107]	$460.00.
FedLine Advantage Premier [106] [107]	$570.00.
Includes:	
FedLine Advantage Plus package	
Two VPN devices	
Fedwire Funds FedPayments Manager Import/Export (more than 250 Fedwire transactions or more than one routing number in a given month).	
FedTransaction Analyzer (more than 250 Fedwire transactions or more than one routing number per month)	
FedLine Command Plus	**$1,185.00.**
FedLine Direct Plus [116]	**$5,750.00.**
FedLine Direct Premier [108]	**$11,000.00.**
Includes:	
Services included in the FedLine Direct Plus package	
Two 2 Mbps dedicated WAN Connections	
One Network Diversity	
Two VPN devices	
A la carte options (monthly) [117]	
Electronic Access:	
FedMail—Pack of 5	$25.00.
FedLine Subscribers—Pack of 5	$100.00.
Additional VPNs [118]	$100.00.
Additional 2 Mbps WAN connection [108]	$3,000.00.
WAN Connection Upgrade:	
10 Mbps [119]	$1,700.00.
30 Mbps [111]	$3,000.00.
50 Mbps [120]	$4,000.00.
100 Mbps [120]	$7,000.00.
200 Mbps [120]	$11,000.00.
FedLine International Setup (one-time fee)	$5,000.00.
FedLine Custom Implementation Fee (one-time fee) [120]	$2,500–$5,000.
Network Diversity	$2,500.00.
FedMail Email (for customers with FedLine Web and above) [121]	$100.00.
VPN Device Modification (one-time fee)	$200.00.
VPN Device Missed Activation Appointment (one-time fee)	$175.00.
VPN Device Expedited Hardware Surcharge (one-time fee)	$100.00.

FEDLINE 2025 FEE SCHEDULE—Continued

[Effective January 1, 2025. **Bold indicates changes from 2024 prices.**]

	Fee
VPN Device Replacement or Move (one-time fee)	$300.00.
E-Payments Automated Download Codes (Add'l Codes-Pack of 5) [122]	$75.00/month.
E-Payments Automated Download Codes (Add'l Codes-Pack of 20) [114]	$150.00/month.
E-Payments Automated Download Codes (Add'l Codes-Pack of 50) [123]	$300.00/month.
E-Payments Automated Download Codes (Add'l Codes-Pack of 100) [123]	$500.00/month.
E-Payments Automated Download Codes (Add'l Codes-Pack of 250) [123]	$1,000.00/month.
E-Payments Automated Download Codes (Add'l Codes- >250) [123]	$2,000.00/month.
Daily Statement of Account Activity and Monthly Statement of Service Charges (monthly): [123] [124]	
End-of-Day Financial Institution Reconcilement Data (FIRD) File	$200.00.
Statement of Account Spreadsheet File (SASF)	$200.00.
Cash Management Service (CMS) Plus and Intra-day Service (monthly):	
Cash Management System (CMS) Plus—Own report—up to 12 files with: [125]	
no OSRTN, respondent/sub-account activity	$75.00.
Up to nine OSRTNs, respondents and/or sub-accounts	$150.00.
10–50 OSRTNs, respondents and/or sub-accounts	$300.00.
51–100 OSRTNs, respondents and/or sub-accounts	$600.00.
101–500 OSRTNs, respondents and/or sub-accounts	$900.00.
>500 OSRTNs, respondents and/or sub-accounts	$1,200.00.
Intra-day Download Search Results in Spreadsheet Format (with AMI) [126]	$200.00.
Other:	
Replacement Copies: [127]	
Daily Statement of Account	$10.00/copy
Monthly Statement of Service Charges	$10.00/copy
Vendor Pass-Through Fee	various.
Electronic Access Credit Adjustment	various.
Electronic Access Debit Adjustment	various.

[47] Any ODFI incurring less than $55 for the following fees will be charged a variable amount to reach the minimum: Forward value and non-value item origination fees, and FedGlobal ACH origination surcharges.

[48] Any RDFI not originating forward value and non-value items and incurring less than $45 in receipt fees will be charged a variable amount to reach the minimum. Any RDFI that originates forward value and non-value items incurring less than $55 in forward value and nonvalue item origination fees will only be charged a variable amount to reach the minimum monthly origination fee.

[49] This surcharge is assessed on all forward items that qualify for same-day processing and settlement and is incremental to the standard origination item fee.

[50] The fee includes the item and addenda fees in addition to the conversion fee.

[51] The fee includes the item and addenda fees in addition to the conversion fee. Reserve Banks also assess a $45 fee for every government paper return/NOC they process.

[52] Origination volumes at these levels qualify for a waterfall discount that includes all FedACH origination items.

[53] Origination discounts based on monthly billed receipt volume apply only to those items received by FedACH receiving points and are available only to Premium Receivers.

[54] RDFIs receiving through FedACH less than 90 percent of their FedACH-originated items.

[55] This per-item discount is a reduction to the standard receipt fees listed in this fee schedule.

[56] Receipt volumes at these levels qualify for a waterfall discount that includes all FedACH receipt items.

[57] RDFIs receiving through FedACH at least 90 percent of their FedACH-originated items, but less than 90 percent of all of their ACH items originated through any operator.

[58] This per-item discount is a reduction to the standard receipt fees listed in this fee schedule.

[59] Receipt volumes at these levels qualify for a waterfall discount which includes all FedACH receipt items.

[60] RDFIs receiving through FedACH at least 90 percent of all of their ACH items originated through any operator.

[61] This per-item discount is a reduction to the standard receipt fees listed in this fee schedule.

[62] Receipt volumes at these levels qualify for a waterfall discount which includes all FedACH receipt items.

[63] Criteria may be set for both the Origination Monitoring Service and the RDFI Alert Service. Subscribers with no criteria set up will be assessed the $45 monthly package fee.

[64] Monthly commercial receipt volume is calculated based on combined volume of subscribed RTNs in an account family.

[65] Premier reports generated on demand are subject to the package/tiered fees plus a surcharge.

[66] Premier reports generated on demand are subject to the package/tiered fees plus a surcharge.

[67] The fee applies to RTNs that have received or originated FedACH transactions during a month. Institutions that receive only U.S. government transactions or that elect to use a private-sector operator exclusively are not assessed the fee.

[68] This surcharge is assessed to any RTN that originates at least one item meeting the criteria for same-day processing and settlement in a given month.

[69] The fee is applied to any RTN with activity during a month, including RTNs of institutions that elect to use a private-sector operator exclusively but also have items routed to or from customers that access the ACH network through FedACH. This fee does not apply to RTNs that use the Reserve Banks for only U.S. government transactions.

[70] Fee will be assessed only when automated NOCs are generated.

[71] Limited services are offered in contingency situations.

[72] The fees and credits listed are collected from the ODFI and credited to Nacha (admin network) or to the RDFI (same-day entry and unauthorized entry) in accordance with the ACH Rules.

[73] The international fees and surcharges vary from country to country as these are negotiated with each international gateway operator.

[74] A single monthly fee based on total FedGlobal ACH Payments origination volume.

[75] This per-item surcharge is in addition to the standard domestic origination fees listed in this fee schedule.

[76] This per-item surcharge is in addition to the standard domestic receipt fees listed in this fee schedule.

[77] U.S. ODFIs are responsible for any investigation fees should they be assessed by foreign RDFIs or downstream payment participants.

[78] The monthly fee is rolled up to the parent DI level, such that a DI that opts into the FedACH Exception Resolution Service under two separate RTNs would pay a single monthly fee based on the total number of cases opened for their two RTNs combined.

[79] A financial institution may enroll in the Service as an Offline Service Participant by designating the Reserve Bank to access and use the functionality of the application on behalf of the Offline Participant.

[80] Federal Reserve Financial Services offers a five-year discount program to financial institutions that receive at least 5 million items per month through FedACH and meet the qualifications for Premium Receiver Level One or Level Two status. View code details and text on the FedACH Receipt Discount Program page.

[81] This fee applies at the parent level to any bank which has at least 1 unit of volume in the Tier 2 Pre-Incentive Discount range and no volume in the Tier 3 Pre-Incentive Discount range.

[82] This fee applies at the parent level to any bank which has at least 1 unit of volume in the Tier 3 Pre-Inventive Discount range.

[83] The incentive discounts apply to the volume that exceeds 60 percent of a customer's historic benchmark volume. Historic benchmark volume is based on a customer's average daily activity over the previous five calendar years. If a customer has fewer than five full calendar years of previous activity, its historic benchmark volume is based on its daily activity for as many full calendar years of data as are available. If a customer has less than one year of past activity, then the customer qualifies automatically for incentive discounts for the year. The applicable incentive discounts are as follows: $0.752 for transfers up to 14,000; $0.232 for transfers 14,001 to 90,000; and $0.152 for transfers over 90,000.

Continued

[84] The offline service, which was originally scheduled to be discontinued as of December 31, 2024, will be extended to no later than February 2025 to accommodate financial institutions' readiness.

[85] This surcharge applies to originators of transfers that are processed by the Reserve Banks after 5:00 p.m. ET.

[86] This fee is charged to any Fedwire Funds participant that originates a transfer message via the FedPayments Manager Funds tool and has the import/export processing option setting active at any point during the month.

[87] Payment Notification and End-of-Day Origination surcharges apply to each Fedwire funds transfer message.

[88] Provided on billing statement for informational purposes only.

[89] This charge is assessed to settlement arrangements that use the Fedwire Funds Service to affect the settlement of interbank obligations (as opposed to those that use the National Settlement Service). With respect to such special settlement arrangements, other charges may be assessed for each funds transfer into or out of the accounts used in connection with such arrangements.

[90] An organization that is a settlement agent may be able to use the National Settlement Service offline service if it is experiencing an operational event that prevents the transmission of settlement files via its electronic connection to the Federal Reserve Banks. The Federal Reserve Banks have limited capacity to process offline settlement files. As a result, while the Federal Reserve Banks use best efforts to process offline settlement file submissions, there is no guarantee that an offline settlement file, in particular one that is submitted late in the operating day or that contains a large number of entries, will be accepted for processing. Only those persons identified as authorized individuals on the National Settlement Service 04 Agent Contact Form may submit offline settlement files. For questions related to the National Settlement Service offline service, please contact National Settlement Service Central Support Service Staff (CSSS) at 800–758–9403, or via email at *csss.staff@ny.frb.org.*

[91] Any settlement arrangement that accrues less than $60 during a calendar month will be assessed a variable amount to reach the minimum monthly fee.

[92] Restricted Securities Accounts maintained by the Reserve Banks under the Loans and Discounts program and the 31 CFR part 202 program are not assessed for monthly account maintenance fees or fees for Transfers of Book-Entry Securities to or from such Restricted Securities Accounts. Restricted Securities Accounts maintained by the Reserve Banks under the 31 CFR part 225 program are subject to monthly account maintenance fees but not fees for Transfers of Book-Entry Securities to or from such Restricted Securities Accounts.

[93] These fees are set by the Federal Reserve Banks.

[94] This surcharge is set by the Federal Reserve Banks. It is in addition to any basic transfer or reversal fee.

[95] Restricted Securities Accounts maintained by the Reserve Banks under the Loans and Discounts program and the 31 CFR. part 202 program are not assessed for monthly account maintenance fees or fees for Transfers of Book-Entry Securities to or from such Restricted Securities Accounts. Restricted Securities Accounts maintained by the Reserve Banks under the 31 CFR part 225 program are subject to monthly account maintenance fees but not fees for Transfers of Book-Entry Securities to or from such Restricted Securities Accounts.

[96] These fees are set by the Federal Reserve Banks.

[97] These fees are set by the Federal Reserve Banks.

[98] The U.S. Department of the Treasury absorbs the cost of monthly account maintenance for securities accounts that contain only Treasury securities and reimburses the Federal Reserve Banks.

[99] The U.S. Department of the Treasury absorbs the cost of monthly issue maintenance for custody holdings of Treasury securities and reimburses the Federal Reserve Banks.

[100] These fees are set by the Federal Reserve Banks.

[101] Automated Claim Adjustment Process (ACAP) fees apply to all ACAP-eligible security types. Phase 2 of the ACAP enhancement project will include expanding ACAP tracking to all coupon-paying securities issued over the Fedwire Securities Service and adding securities lending as a transaction type. For information about the ACAP enhancement project, please visit: *https://www.frbservices.org/resources/financial-services/securities/acap.*

[102] Participants are charged the Repo Position Maintenance Fee for both a Repo-Out balance and a Repo-In balance. These fees will be assessed every business day.

[103] Participants are charged the Securities Lending Position Maintenance Fee for both a Securities Borrowed balance and a Securities Lent balance. These fees will be assessed every business day. Securities lending positions will be available when Phase 2 of the ACAP enhancement project is implemented. For information about the ACAP enhancement project, please visit: *https://www.frbservices.org/resources/financial-services/securities/acap/.*

[104] This fee is set by and remitted to the Government National Mortgage Association (GNMA).

[105] The Federal Reserve Banks charge participants a Joint Custody Origination Surcharge for both Agency and Treasury securities.

[106] These fees are set by the Federal Reserve Banks.

[107] These fees are set by the Federal Reserve Banks.

[108] FedComplete Packages are all-electronic service options that bundle payment services with an access solution for one monthly fee.

[109] FedComplete customers that use the email service would be charged the FedMail Email a la carte fee and for all FedMail Subscriber 5-packs.

[110] Packages with an ''A'' include the FedLine Advantage channel.

[111] Per-item surcharges are in addition to the standard fees listed in the applicable priced services fee schedules.

[112] FedComplete customers will be charged $4 for each FedForward cash letter over the monthly package threshold. This activity will appear under billing code 51998 in Service Area 1521 on a month-lagged basis.

[113] FedMail package does not include user credentials, which are required to access priced services and certain informational services. Credentials are sold separately in packs of five via the FedMail Subscriber 5-pack.

[114] FedLine Web and Advantage packages do not include user credentials, which are required to access priced services and certain informational services. Credentials are sold separately in packs of five via the FedLine Subscriber 5-pack.

[115] Qualifying institutions who upgrade from FedMail or FedLine Web to FedLine Advantage or establish a new FedLine Advantage connection for the FedNow Service will receive 12 months of credits from FedLine Advantage billing eligibility.

[116] Early termination fees and/or expedited order fees may apply to all FedLine Direct packages and FedLine Direct à la carte options.

[117] These add-on services can be purchased only with a FedLine Solution.

[118] Additional VPNs are available for FedLine Advantage, FedLine Command, and FedLine Direct packages only.

[119] Fee is in addition to the FedLine Direct package fees or Additional 2Mbps WAN Connection fee.

[120] The FedLine Custom Implementation Fee is $2,500 or $5,000 based on the complexity of the setup.

[121] Available only to customers with a priced FedLine package and does not include user credentials, which are required to access priced services and certain informational services. Credentials are sold separately in packs of five via the FedMail Subscriber 5-pack.

[122] Five download codes are included at no cost in all Plus and Premier packages.

[123] Available for FedLine Web Plus, FedLine Web Premier, FedLine Advantage Plus, and FedLine Advantage Premier packages. It is also available for no extra fee in FedLine Command Plus and Direct packages.

[124] The End of Day Financial Institution Reconcilement Data (FIRD) and Statement of Account Spreadsheet File (SASF) are available for Master accounts only.

[125] Available with FedLine Plus and Premier packages.

[126] Available for FedLine Web Plus and Premier packages. Available for no extra fee in FedLine Advantage and higher packages.

[127] Charging the $10 Replacement Copy Fee is at the discretion of Reserve Banks.

By order of the Board of Governors of the Federal Reserve System.

Ann E. Misback,

Secretary of the Board.

[FR Doc. 2024–27831 Filed 11–26–24; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL TRADE COMMISSION

[File No. P085405]

Agency Information Collection Activities; Proposed Collection; Comment Request; Extension; Correction

AGENCY: Federal Trade Commission.

ACTION: Notice; correction.

SUMMARY: The Federal Trade Commission (''Commission'') published a document in the **Federal Register** of November 4, 2024, concerning its proposal to extend for an additional three years the Office of Management and Budget (''OMB'') clearance for information collection requirements contained in the rules and regulations under the Pay-Per-Call Rule. Shortly after publication, Commission staff learned the document contained an incorrect date. The Commission issues this correction to reflect the corrected date. The current information collection clearance expires on January 31, 2025, not January 30, 2024.

FOR FURTHER INFORMATION CONTACT: P. Connell McNulty, Attorney, Division of Marketing Practices, Bureau of Consumer Protection, Federal Trade Commission, (202) 326–2061, *pmcnulty@ftc.gov.*

SUPPLEMENTARY INFORMATION: The notice document submitted by Commission staff for publication contained a typographical error; specifically, the expiration date for the current OMB clearance was off by one year in the SUMMARY.

Correction

In notice FR Doc. 2024–25559 appearing at 89 FR 87575 in the **Federal Register** of Monday, November 4, 2024, make the following correction. On page 87576, in the last sentence of the **SUMMARY** section, the date of ''January 30, 2024'' is corrected to read ''January 31, 2025''.

Dated: November 20, 2024.

April J. Tabor,

Secretary.

[FR Doc. 2024–27794 Filed 11–26–24; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Dietary Intake of Polyunsaturated Fatty Acids and Plasma Lipid and Cardiovascular Events

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for supplemental evidence and data submission.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on *Dietary Intake of Polyunsaturated Fatty Acids and Plasma Lipid and Cardiovascular Events,* which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before December 27, 2024.

ADDRESSES:

Email submissions: epc@ahrq.hhs.gov.

Print submissions:

Mailing Address:

Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, Attn: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E53A, Rockville, MD 20857

Shipping Address (FedEx, UPS, etc.):

Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, Attn: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E77D, Rockville, MD 20857

FOR FURTHER INFORMATION CONTACT: Kelly Carper, Telephone: 301–427–1656 or Email: *epc@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Dietary Intake of Polyunsaturated Fatty Acids and Plasma Lipid and Cardiovascular Events.* AHRQ is conducting this review pursuant to section 902 of the Public Health Service Act, 42 U.S.C. 299a.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (*e.g.,* details of studies conducted). We are looking for studies that report on *Dietary Intake of Polyunsaturated Fatty Acids and Plasma Lipid and Cardiovascular Events.* The entire research protocol is available online at: *https://effectivehealthcare.ahrq.gov/products/polyunsaturated-fatty/protocol.*

This is to notify the public that the EPC Program would find the following information on *Dietary Intake of Polyunsaturated Fatty Acids and Plasma Lipid and Cardiovascular Events* helpful:

- A list of completed studies that your organization has sponsored for this topic. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*
- *For completed studies that do not have results on ClinicalTrials.gov*, a summary, including the following elements, if relevant: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.
- *A list of ongoing studies that your organization has sponsored for this topic.* In the list, please provide the *ClinicalTrials.gov* trial number or, if the trial is not registered, the protocol for the study including, if relevant, a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your organization for this topic and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on topics not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: *https://effectivehealthcare.ahrq.gov/email-updates.*

The review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

Key Questions (KQ)

KQ 1: What are the effects of different dietary polyunsaturated fatty acid intake on plasma lipid concentrations in the general population?

KQ 2: What are the effects of different dietary polyunsaturated fatty acid intake on cardiovascular events in the general population?

PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, AND SETTING)

[Study eligibility criteria based on Population, Intervention, Comparator, Outcome (PICO), and other elements]

Element	Inclusion criteria	Exclusion criteria
Population	*Both Key Questions:*	*Both Key Questions:*

PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, AND SETTING)—Continued

[Study eligibility criteria based on Population, Intervention, Comparator, Outcome (PICO), and other elements]

Element	Inclusion criteria	Exclusion criteria
	General population, without CVD, with or without modifiable CV risk factors, including ○ Dyslipidemia (including if taking lipid-lowering medications) ○ Overweight/obese ○ Hyperglycemia and related conditions, including type 2 diabetes ○ Hypertension/high blood pressure *Key Question 1:* Children and adults *Key Question 2:* Adults (≥18 years old)	• Participants with a health-related condition or taking medications that impact fat absorption, fat metabolism. • Participants taking weight loss medications, including glucagon-like peptide-1 agonists. • Undernourished, underweight, stunted, or wasted participants. • Participants who are pre- or post-bariatric surgery. • Participants with other chronic diseases (*e.g.,* cancer, gastrointestinal disease, rheumatic disease, chronic kidney disease, neurologic diseases), including type 1 diabetes. • Participants with clinical CVD (*e.g.,* history of myocardial infarction, angina, stroke, arrhythmia), including congenital heart diseases, or familial hypercholesterolemia.
Interventions	*Both Key Questions:* Dietary intake of Total n-3 or total n-6 PUFA Individual PUFA (*e.g.,* linoleic, ALA, EPA, DHA) Combination of long-chain PUFA (*e.g.,* EPA+DHA+DPA; DHA+ALA) PUFA intake must be defined or described prospectively Studies must specify daily quantity of PUFA intake *Key Question 1:* For studies in children, ○ Include multicomponent interventions (*e.g.,* diet + exercise vs. exercise) ○ Infant formula	*Both Key Questions:* • Studies that do not quantify PUFA intake as either g/day or % of total energy intake from PUFA. • Analyses with PUFA intake as a continuous variable. • Fatty acid intake via infusion (not orally). • Food products or dietary supplements not widely available to U.S. consumers. • Multi-component interventions (*e.g.,* exercise + diet vs. exercise or plant sterols + diet vs. plant sterols) that do not isolate the effect or association of PUFA. • Multi-component interventions of statins + diet where statins are being initiated. Dietary interventions among existing statin users will be included. • Interventions designed to induce weight loss or treat overweight and obesity through energy restriction or hypocaloric diets. • Interventions designed for the purposes of treating medical conditions other than modifiable CV risk factors. • DHA and/or EPA n-3 FA dose >4 g/d. • Enteral feeding.
Comparators	*Both Key Questions:*	*Both Key Questions:*
	Dietary intake of a different level of fatty acids relevant to the exposure No added/supplement PUFA Placebo supplements	Diets with a caloric intake that are significantly higher or lower than the intervention/exposure diet. Diets or interventions that vary substantially in intake of macronutrients (or other factors) other than the intervention and comparator of interest. Different PUFA dietary exposure (*e.g.,* comparison of undefined quantiles).
Outcomes	*Key Question 1:* • Plasma lipoprotein concentrations ○ LDL cholesterol (LDL-c) ○ HDL cholesterol (HDL-c) ○ Non-HDL-cholesterol ○ Triglycerides (triacylglycerol) (Tg) ○ Lipoprotein(a) ○ Apolipoprotein B (ApoB)	*Key Question 1:* • Total cholesterol (TC). • TC:HDL ratio. • LDL:HDL ratio. • Chylomicrons. • VLDL-c. • IDL-c. • Other apolipoproteins. • Lipoprotein profiles. • Evaluations of fatty acid biomarker levels.

PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, AND SETTING)—Continued

[Study eligibility criteria based on Population, Intervention, Comparator, Outcome (PICO), and other elements]

Element	Inclusion criteria	Exclusion criteria
	Key Question 2: • Cardiovascular events ○ Atherosclerotic cardiovascular disease (total) ○ Major adverse cardiac (or cerebral) events (MAC[C]E) ○ Specific cardiovascular events ▪ Myocardial infarction ▪ Coronary heart/artery disease ▪ Peripheral vascular/artery disease ○ Revascularization (for studies published after 1995) ○ Cardiovascular disease-related mortality ○ Stroke ○ Incident atrial fibrillation	*Key Question 2:* • Other cardiac or vascular related outcomes. • Participant reported events.
Subgroups/effect modifiers of interest.	*Both Key Questions:* • Specific life stages ○ Infants (for Key Question 1 only) ○ Children and adolescents (for Key Question 1 only) ○ Adults (19–64) ○ Older adults (≥65) ○ Pregnant or postpartum ○ Menopausal status • Other characteristics ○ Sex (male, female) ○ Socioeconomic status ○ Social determinants of health ○ Race/ethnicity ○ Physical activity level ○ Anthropometry ○ Health status, including type 2 diabetes ○ Percent of total energy intake replaced ○ Dietary trans fatty acid intake ○ Baseline lipid concentrations ○ Dietary cholesterol intake	None.
Design	*Key Question 1:* • Studies of adults ○ Parallel or cross-over randomized controlled trials (RCTs) ▪ n ≥25/group * • Studies of children ○ Parallel or cross-over RCTs ▪ n ≥25/group * ○ Nonrandomized comparative studies ▪ Must account for potential confounders ▪ n ≥50/group * *Key Question 2:* • Studies of adults ○ Parallel or cross-over RCTs ▪ n ≥25/group * ○ Nonrandomized comparative studies ▪ Must account for potential confounders ▪ Dietary intake must be defined or described prospectively ▪ We will aim for a minimum of about 10 observational studies for each specific PUFA—CV event pair (*e.g.,* EPA and stroke). We will thus select the largest observational studies within each category.† ▪ n ≥100/group	*Both Key Questions:* • Observational studies that do not account for confounders. • Analyses of dietary fat as a continuous variable (*e.g.,* RR per g/day intake) without an analysis at a threshold (*e.g.,* RR for > vs < threshold). • All other study designs.
Timing	*Key Question 1:* • Minimum intervention length: 4 weeks • In cross-over studies, any change in outcome measure must exclude data from the first week after end of any prior treatments	None.

PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, AND SETTING)—Continued

[Study eligibility criteria based on Population, Intervention, Comparator, Outcome (PICO), and other elements]

Element	Inclusion criteria	Exclusion criteria
	Key Question 2: • Minimum follow-up ○ If population has no CV risk factors (or unselected general population): 10 years ○ If population has one or more CV risk factors: 5 years	
Setting	• General community settings, including nursing homes, assisted living facilities, etc.	• Hospital or other acute care settings. • Institutionalized, confined settings (*e.g.,* prisons).
Publication	• English language • Published in peer-reviewed journals	

* Minimum sample size may be altered depending on the number of eligible studies found.

† Applying this approach for the 2016 AHRQ report n-3 fatty acids and cardiovascular disease (*https://doi.org/10.23970/AHRQEPCERTA223*), we included: for cardiac event outcomes, observational studies with at least 10,000 participants; for stroke outcomes, at least 3000 participants; for arrhythmia outcomes, at least 2000 participants; congestive heart failure outcomes, at least 700 participants; and for peripheral vascular disease events and MACE outcomes, at least 500 participants. In all instances, if a study meets eligibility criteria for any outcome, we will extract all outcomes of interest from that study; therefore, there will be multiple instances of studies being included for an outcome even though the study might not have met study size criteria for that specific outcome.

CV = cardiovascular; CVD = cardiovascular disease; PUFA = polyunsaturated fatty acids; ALA = alpha-linolenic acid; EPA = eicosapentaenoic aci; DHA= docosahexaenoic acid; DPA = docosapentaenoic acid; n-3 = Omega 3; n-6 = Omega 6; FA = fatty acid; c = cholesterol; LDL = low-density lipoprotein; IDL = intermediate-density lipoprotein; HDL high-density lipoprotein; TC—total cholesterol; Tg = Triglycerides/Triacylglycerols; apoA = apolipoprotein; MAC[C]E = Major adverse cardiac (or cerebro) events; BMI = body mass index; KQ = key question; N = number of participants.

Dated: November 21, 2024.

Marquita Cullom,

Associate Director.

[FR Doc. 2024–27798 Filed 11–26–24; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Closed Meeting

Pursuant to 5 U.S.C. 1009(d), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended, and the Determination of the Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, pursuant to Public Law 92–463. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—CE25–021, Research Grants for Preventing Violence and Violence Related Injury.

Dates: February 19–20, 2025.

Times: 10 a.m.–5 p.m., EST.

Place: Web Conference.

Agenda: To review and evaluate grant applications.

For Further Information Contact: Carlisha Gentles, Pharm.D., B.C.P.S., C.D.C.E.S., Scientific Review Officer, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, 4770 Buford Highway NE, Mailstop S106–9, Atlanta, Georgia 30341. Telephone: (770) 488–1504; Email: *CGentles@cdc.gov.*

The Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2024–27857 Filed 11–26–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Closed Meeting

Pursuant to 5 U.S.C. 1009(d), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended, and the Determination of the Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, pursuant to Public Law 92–463. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel; (SEP)—CE25–025, Rigorous Evaluation of Community- and Societal-Level Primary Prevention Approaches to Prevent Adverse Childhood Experiences (ACEs): Expanding the Best Available Evidence.

Dates: February 25–26, 2025.

Times: 10 a.m.–5 p.m., EST.

Place: Web Conference.

Agenda: To review and evaluate grant applications.

For Further Information Contact: Aisha L. Wilkes, M.P.H., Scientific Review Officer, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, 4770 Buford Highway NE, Mailstop S106–9, Atlanta, Georgia 30341. Telephone: (404) 639–6473; Email: *AWilkes@cdc.gov*.

The Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2024–27856 Filed 11–26–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10891]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by December 27, 2024.

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

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Medicaid Program; Medicare Savings Program Application and Eligibility Determinations; *Use:* The provisions in this collection of information request are necessary for helping to enroll individuals into the Medicare Savings Programs (MSPs) as directed by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) and for implementing the September 21, 2023 (88 FR 65230) final rule entitled, ''Streamlining Medicaid: Medicare Savings Program Eligibility Determination and Enrollment'' (hereinafter ''MSP final rule'') (CMS–2421–F; RIN 0938–AU00).

CMS did not previously estimate several costs for implementing the provisions of MIPPA related to MSPs as well as costs related to MSPs that were longstanding costs inherent to the Medicaid program that predated MIPPA. To address that oversight, we estimate such burden in this collection of information request. We also estimate burden and savings associated with the provisions in the MSP final rule. Such burden was set out in the Regulatory Impact Analysis section of the final rule.

The MSPs are essential to the health and well-being of those enrolled, promoting access to care and helping free up individuals' limited income for food, housing, and other life necessities. Through the MSPs, Medicaid pays Medicare Part B premiums each month for over 10 million individuals and Part A premiums for over 700,000 individuals. State Medicaid agencies receive applications and adjudicate eligibility for MSP coverage.

MIPPA created new requirements for states to leverage the Medicare Part D Low-Income Subsidy (LIS) program to help enroll likely-eligible individuals in MSPs, and the MSP final rule expanded those requirements. States use information collected by the Social Security Administration on the LIS application (transmitted to states with the consent of an individual completing an application) to determine eligibility for the MSPs. Under the MSP final rule, the state Medicaid agency accepts and verifies the information provided on the LIS application (to the extent allowable under the MSP final rule); communicates with the applicant or the authorized representative about any additional information needed to make an MSP determination; makes the MSP eligibility determination; enrolls the individual in an MSP, if eligible; and informs the individual about the rights and responsibilities for applying for full Medicaid eligibility. Applicants include anyone who chooses to apply for LIS and provides consent for their application to be considered for MSPs.

In addition to building on MIPPA and strengthening the LIS pathway for enrolling in MSPs, the MSP final rule streamlined MSP eligibility and enrollment processes, reduced administrative burden on states and applicants, and increased enrollment and retention of eligible individuals.

Form Number: CMS–10891 (OMB control number: 0938–TBD); *Frequency:* Occasionally; *Affected Public:* State, Local and Tribal Governments and Individuals or households; *Number of Respondents:* 3,460,750; *Total Annual Responses:* 3,460,750; *Total Annual Hours:* 5,517,157. (For policy questions regarding this collection contact: Melissa Heitt at 410–786–2484.)

William N. Parham, III

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–27871 Filed 11–26–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3471–N]

Medicare Program; Public Meeting for Air Ambulance Quality & Patient Safety Advisory Committee—December 12, 2024, February 18, 2025, and May 8, 2025

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces virtual public meetings of the Air Ambulance Quality and Patient Safety (AAQPS) Advisory Committee. The AAQPS Advisory Committee will review options to establish quality, patient safety, and clinical capability standards for each clinical capability level of air ambulances.

DATES: *Virtual Meeting Dates:* The AAQPS Advisory Committee will hold virtual meetings on December 12, 2024, February 18, 2025, and May 8, 2025, from 10:00 a.m. to 5:00 p.m., Eastern Time (E.T.).

Deadline for Submitting Requests for Special Accommodations: Requests for special accommodations must be received at least 2 weeks before each meeting.

Registration Link: The virtual meetings will be open to the public and held via the Zoom webinar platform. Virtual attendance information will be provided upon registration. To register for the virtual meeting, please visit: *https://www.cms.gov/medicare/regulations-guidance/advisory-committees/advisory-committee-air-ambulance-quality-and-patient-safety.* Attendance is open to the public subject to any technical or capacity limitations.

Deadline for Registration: All individuals who plan to attend the virtual public meeting must register to attend. Request to provide oral comments are due at least fourteen (14) calendar days prior to the meeting date. Interested parties are encouraged to register as far in advance of the meeting as possible.

A detailed agenda and materials will be available prior to the meeting on the AAQPS Advisory Committee website at: *https://www.cms.gov/medicare/regulations-guidance/advisory-committees/advisory-committee-air-ambulance-quality-and-patient-safety.*

A recording and a summary of the meeting will be made available on the AAQPS Advisory Committee website approximately 45 calendar days after the meeting.

ADDRESSES: *Virtual Meeting Location:* All meetings are open to the public and instructions to view will be posted on the AAQPS Advisory Committee website, and upon registration. If you wish to provide oral comments during the meetings you must complete a registration form on the AAQPS Advisory Committee website at: *https://www.cms.gov/medicare/regulations-guidance/advisory-committees/advisory-committee-air-ambulance-quality-and-patient-safety,* and submit a written copy of your remarks to *AAQPS@cms.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Ashley Spence, CMS, at (410) 786–2000 or via email at *AAQPS@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Secretary of the Department of Health and Human Services (HHS) and the Secretary of Transportation established the Air Ambulance Quality and Patient Safety (AAQPS) Advisory Committee on August 22, 2023, in response to section 106 of the No Surprises Act, enacted as part of the Consolidated Appropriations Act, 2021, div. BB, tit. I, Public Law 116–260 (December 27, 2020). The AAQPS Advisory Committee will be tasked with reviewing options to establish quality, patient safety, and clinical capability standards for each clinical capability level of air ambulances.

The AAQPS Advisory Committee is governed by the provisions of the Federal Advisory Committee Act (FACA), Public Law 92–463 (Oct. 6, 1972), as amended by 5 U.S.C. app. 2.

II. Advisory Committee Membership Roster

On June 2, 2023, HHS published an Invitation for Member Nominations in the **Federal Register** for the AAQPS Advisory Committee (88 FR 37253). This notice also announces the members of the AAQPS Advisory Committee.

- Jeff Richey—HHS Secretary's Designee/Representative.
- Robert Reckert—DoT Secretary's Designee/Representative.
- Ben Clayton—DoT Representative.
- Colonel Steven L. Coffee—Patient Advocate.
- Dr. Jordan Pritzker—Group Health Plans and Health Insurance Issuers.
- Dr. Mark Gamber—HHS Representative.
- Dr. William Hinckley—Healthcare Provider.
- Eileen Frazer—Accrediting bodies.
- Grace Arnold—State Insurance Regulator.
- Jason Clark—HHS Representative.
- Jason Quisling—DoT Representative.
- Jeff Houser—DoT Representative.
- Paul Julander—DoT Representative.
- Thomas Judge—DoT Representative.

III. Summary of the Agenda

During the December 12, 2024, February 18, 2025, and May 8, 2025 meetings, the AAQPS Advisory Committee will review options to establish quality, patient safety, and clinical capability standards for each clinical capability level of air ambulances. A more detailed agenda and meeting materials will be made available 3 days before the meetings on the AAQPS Advisory Committee website at *https://www.cms.gov/medicare/regulations-guidance/advisory-committees/advisory-committee-air-ambulance-quality-and-patient-safety.*

IV. Public Participation

The meetings will be open to the public for virtual attendance on a first-come, first-served basis, as there may be capacity or technical limitations. Please see the **ADDRESSES** section to view the meeting link.

The Department is committed to providing equal access to this meeting for all participants. If you need alternative formats or services because of a disability, such as sign language interpreter, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section no later than 2 weeks before each meeting.

The Department will accept oral comments, which must be limited to the objectives of the committee and limited to three (3) minutes per person. Individual members of the public who wish to present oral comments must register and provide a written copy of prepared remarks for inclusion in the meeting records and for circulation to

AAQPS Advisory Committee members. All prepared remarks submitted on time will be considered as part of the meeting's record.

V. Submitting Written Comments

Members of the public may submit written comments for consideration by the Committee at any time via email to *AAQPS@cms.hhs.gov.* Additionally, members of the public will have the opportunity to submit comments during the December 12, 2024, February 18, 2025, and May 8, 2025, virtual meetings through the chat feature of the Zoom webinar platform. Members of the public are encouraged to submit lengthy written comments (more than three sentences) to the email address above. Advance submissions that become part of the committee deliberations will become part of the official record of the meeting.

The Administrator of CMS, Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Vanessa Garcia, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Vanessa Garcia,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2024–27740 Filed 11–26–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3236]

Advisory Committee; Oncologic Drugs Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the renewal of the Oncologic Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Oncologic Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the September 1, 2026, expiration date.

DATES: Authority for the Oncologic Drugs Advisory Committee will expire on September 1, 2026, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Yvette Waples, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, *ODAC@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services and by the General Services Administration, FDA is announcing the renewal of the Oncologic Drugs Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cancer and makes appropriate recommendations to the Commissioner.

Pursuant to its charter, the Committee shall consist of a core of 13 voting members, including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of general oncology, pediatric oncology, hematologic oncology, immunology oncology, biostatistics, and other related professions. Members will be invited to serve for overlapping terms of up to 4 years. Non-Federal members of this committee will serve as Special Government Employees or representatives. Federal members will serve as Regular Government Employees or Ex-Officios. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting representative member who is identified with industry interests. There may also be an alternate industry representative.

The Commissioner or designee shall have the authority to select members of other scientific and technical FDA advisory committees (normally not to exceed 10 members) to serve temporarily as voting members and to designate consultants to serve temporarily as voting members when: (1) expertise is required that is not available among current voting standing members of the Committee (when additional voting members are added to the Committee to provide needed expertise, a quorum will be based on the combined total of regular and added members) or (2) to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking. Because of the size of the Committee and the variety in the types of issues that it will consider, FDA may, in connection with a particular committee meeting, specify a quorum that is less than a majority of the current voting members. The Agency's regulations (21 CFR 14.22(d)) authorize a committee charter to specify quorum requirements.

If functioning as a medical device panel, an additional non-voting representative member of consumer interests and an additional non-voting representative member of industry interests will be included in addition to the voting members.

Further information regarding the most recent charter and other information can be found at *https://www.fda.gov/advisory-committees/oncologic-drugs-advisory-committee/oncologic-drugs-advisory-committee-roster* or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This notice is issued under the Federal Advisory Committee Act as amended (5 U.S.C. 1001 *et seq.*). For general information related to FDA advisory committees, please visit us at *http://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: November 19, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–27797 Filed 11–26–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–4540]

Recommended Followup Testing for an Ames-Positive Drug (Active Ingredient) or Metabolite To Support First-in-Human Clinical Trials With Healthy Subjects; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Recommended Followup Testing for an Ames-Positive Drug (Active Ingredient) or Metabolite To Support First-in-Human Clinical Trials With Healthy Subjects.'' This draft guidance makes recommendations on followup testing for Ames-positive active ingredients in circumstances when a sponsor decides to continue development. The guidance recommends a consistent process of followup testing and evaluation that first should be conducted for an Ames-positive active ingredient before proceeding with first-in-human (FIH) trials in healthy human subjects. These recommendations are intended to potentially help address and lower safety concerns before proceeding with FIH trials in healthy human subjects.

DATES: Submit either electronic or written comments on the draft guidance by February 25, 2025 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–D–4540 for ''Recommended Followup Testing for an Ames-Positive Drug (Active Ingredient) or Metabolite To Support First-in-Human Clinical Trials With Healthy Subjects.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Timothy W. Robison, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 3328, Silver Spring, MD 20993, 301–796–1283.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Recommended Followup Testing for an Ames-Positive Drug (Active Ingredient) or Metabolite To Support First-in-Human Clinical Trials With Healthy Subjects.'' Positive results in the Ames test suggest potential DNA reactivity, indicating that followup testing and evaluation of an Ames-positive active ingredient are necessary to assess its in vivo mutagenic and carcinogenic potential.[1] Positive results in the Ames test are correlated with carcinogenic potential in rodents; however, this correlation is not perfect because mutations are only one of many

[1] See the International Council for Harmonisation guidance for industry ''S2(R1) Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use,'' available at *https://www.fda.gov/media/170461/download.*

stages in tumor development. In addition, the mutagenic response may be due to exceeding a detoxification threshold or the induction of oxidative damage to which bacterial cells may be more sensitive than mammalian cells in vitro or tissues in vivo.

This guidance makes recommendations on followup testing for Ames-positive active ingredients in those rare circumstances when a sponsor decides to continue development for potential approval by FDA. These recommendations are intended to potentially address and lower certain safety concerns before proceeding with FIH trials in healthy human subjects. Followup testing cannot entirely mitigate the concerns raised by an Ames-positive finding, and some residual risk remains in the absence of an adequate carcinogenicity assessment. Thus, Ames-positive active ingredients that are further developed should be those targeting serious or life-threatening diseases with unmet medical needs.

Consideration might be given to the administration of an investigational new drug containing an Ames-positive active ingredient to healthy human subjects only if the results of extensive followup testing conducted before clinical administration lowered the concern for cancer based on a weight-of-evidence (WoE) approach evaluating the potential for mutagenicity. A WoE evaluation, for instance, might find that followup testing in an in vitro mammalian cell mutation assay and in vivo mutation assay are both negative and that other considerations do not raise any other safety concerns. Positive findings in either the in vitro mammalian cell mutation assay or in vivo mutation assay would preclude testing in healthy human subjects. The sponsor also should provide a thoroughly considered rationale for why FIH trials should enroll healthy subjects in lieu of patients with the disease or condition the investigational drug product with the Ames-positive active ingredient is intended to treat. Alternatively, consideration should be given to enrolling patients with the disease or condition of interest and designing the trial in a manner that may offer a treatment benefit in addition to the usual aims of a phase 1 trial (*e.g.,* pharmacokinetics, tolerability, etc.).

The guidance recommends that a consistent process of followup testing and evaluation should first be conducted for an Ames-positive active ingredient before FIH trials are commenced in healthy subjects. An Ames-positive metabolite observed at low levels (*e.g.,* at the threshold of toxicological concern) would generally pose minimal safety concerns and may be managed differently. The recommendations explained in the guidance for followup testing are intended to inform both review staff and industry.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Recommended Followup Testing for an Ames-Positive Drug (Active Ingredient) or Metabolite To Support First-in-Human Clinical Trials With Healthy Subjects.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 for investigational new drug applications have been approved under OMB control number 0910–0014. The collections of information found in 21 CFR parts 50 and 56 pertaining to protection of human subjects have been approved under OMB control number 0910–0130.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents*, or *https://www.regulations.gov*.

Dated: November 21, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–27796 Filed 11–26–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–4643]

Assessment of Ovarian Toxicity in Premenopausal Adults During Drug Development for Oncologic Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Assessment of Ovarian Toxicity in Premenopausal Adults During Drug Development for Oncologic Products.'' This draft guidance provides recommendations to sponsors regarding the measurement of ovarian toxicity using clinical measures and biomarkers of ovarian function in relevant cancer clinical trials that enroll premenopausal adults with ovaries. Assessment of ovarian toxicity in cancer trials helps ensure that patients and clinicians have information about the possible long-term impacts of treatment on ovarian function and thus facilitate informed decision-making regarding anti-cancer agents.

DATES: Submit either electronic or written comments on the draft guidance by January 27, 2025, to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your

comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–D–4643 for ''Assessment of Ovarian Toxicity in Premenopausal Adults During Drug Development for Oncologic Products.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Suparna Wedam, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2112, Silver Spring, MD 20993, 301–796–1776, or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Assessment of Ovarian Toxicity in Premenopausal Adults During Drug Development for Oncologic Products.'' This draft guidance provides recommendations to sponsors regarding the measurement of ovarian toxicity using clinical measures and biomarkers of ovarian function in relevant cancer clinical trials that enroll premenopausal adults with ovaries. Loss of ovarian function is a potentially irreversible toxicity associated with systemic anti-cancer agents that may result in infertility and long-term morbidities related to early-onset menopause and estrogen deficiency, including vasomotor symptoms, sexual dysfunction, osteoporosis, cardiovascular disease, and cognitive dysfunction. Routine collection of ovarian toxicity data in cancer clinical trials of investigational agents is currently lacking. Assessment of ovarian toxicity in cancer trials is essential to ensure that patients and clinicians have information about the possible long-term impacts of treatment on ovarian function and thus facilitate informed decision-making regarding anti-cancer agents.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Assessment of Ovarian Toxicity in Premenopausal Adults During Drug Development for Oncologic Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 for investigational new drug applications have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 relating to new drug applications have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 relating to biologics license applications have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: November 19, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–27804 Filed 11–26–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–4040–0012]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before January 27, 2025.

ADDRESSES: Submit your comments *sagal.musa@hhs.gov* or by calling (202) 205–2634.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 4040–0012–60D and project title for reference, to Sagal Musa, email: *sagal.musa@hhs.gov,* or call (202) 205–2634 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: SF–270 Request for Advance or Reimbursement.

Type of Collection: Extension.

OMB No. 4040–0012.

Abstract: The SF–270 Request for Advance or Reimbursement is a federal form used by grant awardees to request funds either in advance or as reimbursement for project expenses. This IC expires on January 31, 2025. *Grants.gov* seeks a three-year clearance of these collections.

ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
SF–270 Request for Advance or Reimbursement.	Grant Applicants	100,000	1	1	100,000
Total		100,000	1	1	100,000

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2024–27721 Filed 11–26–24; 8:45 am]

BILLING CODE 4151–AE–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–4040–0014]

Agency Information Collection Request. 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before January 27, 2025.

ADDRESSES: Submit your comments to *sagal.musa@hhs.gov* or by calling (202) 205–2634.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 4040–0014–60D and project title for reference, to Sagal Musa, email: *sagal.musa@hhs.gov,* or call (202) 205–2634 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Federal Financial Report (SF–425) and Federal Financial Report Attachment (SF–425A).

Type of Collection: Extension.

OMB No. 4040–0014.

Abstract: Federal Financial Report (SF–425) and Federal Financial Report Attachment (SF–425A) are used by applicants to apply for Federal financial assistance. The Federal Financial Report (SF–425) and Federal Financial Report Attachment (SF–425A) forms allow the applicants to provide certain financial information as part of their grant proposals. These forms are evaluated by Federal agencies as part of the overall grant application. This IC expires on February 28, 2025. *Grants.gov* seeks a three-year clearance of these collections.

Type of Respondent: The Federal Financial Report (SF–425) and Federal Financial Report Attachment (SF–425A) forms are used by organizations to apply for Federal financial assistance in the form of grants. These forms are submitted to the Federal grant-making agencies for evaluation and review.

ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
Federal Financial Report (SF–425) and Federal Financial Report Attachment (SF–425A).	Grant-seeking organizations. Grant-seeking organizations.	100,000 ..... 100,000	1 1	1 1	100,000 100,000
Total	.....	.....	1	.....	200,000

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2024–27716 Filed 11–26–24; 8:45 am]

BILLING CODE 4151–AE–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–4040–0016]

Agency Information Collection Request. 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before January 27, 2025.

ADDRESSES: Submit your comments to *sagal.musa@hhs.gov* or by calling (202) 205–2634.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 4040–0016–60D and project title for reference, to Sagal Musa, email: *sagal.musa@hhs.gov,* or call (202) 205–2634 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: SF–429–C Real Property Status Report ATTACHMENT C (Disposition or Encumbrance Request), SF–429–B Real Property Status Report ATTACHMENT B (Request to Acquire, Improve or Furnish), SF–429–A Real Property Status Report ATTACHMENT A (General Reporting), INSTRUCTIONS FOR THE SF–429 Real Property Status Report, and SF–429 Real Property Status Report (Cover Page).

Type of Collection: Extension.

OMB No. 4040–0016.

Abstract: SF–429–C Real Property Status Report ATTACHMENT C (Disposition or Encumbrance Request), SF–429–B Real Property Status Report ATTACHMENT B (Request to Acquire, Improve or Furnish), SF–429–A Real Property Status Report ATTACHMENT A (General Reporting), INSTRUCTIONS FOR THE SF–429 Real Property Status Report, and SF–429 Real Property Status Report (Cover Page) forms allow the applicants to provide real property details as part of their grant proposals. These forms are evaluated by Federal agencies as part of the overall grant application. This IC expires on February 28, 2025. *Grants.gov* seeks a three-year clearance of these collections.

Type of Respondent: SF–429–C Real Property Status Report ATTACHMENT C (Disposition or Encumbrance Request), SF–429–B Real Property Status Report ATTACHMENT B (Request to Acquire, Improve or Furnish), SF–429–A Real Property Status Report ATTACHMENT A (General Reporting), INSTRUCTIONS FOR THE SF–429 Real Property Status Report, and SF–429 Real Property Status Report (Cover Page) forms are used by organizations to apply for Federal financial assistance in the form of grants. These forms are submitted to the Federal grant-making agencies for evaluation and review.

ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
SF–429–C Real Property Status Report ATTACHMENT C (Disposition or Encumbrance Request).	Grant-seeking organizations	100,000	1	1	50,000
SF–429–B Real Property Status Report ATTACHMENT B (Request to Acquire, Improve or Furnish).	Grant-seeking organizations	100,000	1	1	100,000
SF–429–A Real Property Status Report ATTACHMENT A (General Reporting.	Grant-seeking organizations	100,000	1	1	100,000
INSTRUCTIONS FOR THE SF–429 Real Property Status Report.	Grant-seeking organizations	100,000	1	0.5	100,000
SF–429 Real Property Status Report (Cover Page).	Grant-seeking organizations	100,000	1	1	100,000
Total	.....	.....	1	.....	450,000

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2024–27723 Filed 11–26–24; 8:45 am]

BILLING CODE 4151–AE–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–4040–0013]

Agency Information Collection Request. 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before January 27, 2025.

ADDRESSES: Submit your comments to *sagal.musa@hhs.gov* or by calling (202) 205–2634.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 4040–0013–60D and project title for reference, to Sagal Musa, email: *sagal.musa@hhs.gov,* or call (202) 205–2634 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Disclosure of Lobbying Activities (SF–LLL) and Certification Regarding Lobbying.

Type of Collection: Extension.

OMB No. 4040–0013.

Abstract: Disclosure of Lobbying Activities (SF–LLL) and Certification Regarding Lobbying are OMB-approved collections (4040–0013). These information collections are used by grant applicants. This IC expires on February 28, 2025. We are requesting a three-year clearance of these collections.

Type of respondent: The Disclosure of Lobbying Activities (SF–LLL) and Certification Regarding Lobbying forms are used by organizations to apply for Federal financial assistance in the form of grants. These forms are submitted to the Federal grant-making agencies for evaluation and review.

ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
Disclosure of Lobbying Activities (SF–LLL).	Grant Applicants	12,675	1	1	12,675
Certification Regarding Lobbying	Grant Applicants	3,952	1	0.5	1,976
Total		12,675	1		14,651

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2024–27714 Filed 11–26–24; 8:45 am]

BILLING CODE 4151–AE–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0434]

Agency Information Collection Request. 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before January 27, 2025.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 264–0041 and *PRA@HHS.GOV.*

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–0434–60D and project title for reference, to Sherrette A. Funn, email: *Sherrette.Funn@hhs.gov, PRA@HHS.GOV* or call (202) 264–0041 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Meetings, Conferences, and Seminars—Public Accommodations and Commercial Facilities—Funding and Sponsorship.

Type of Collection: Extension.

OMB No. 0990–0434—Office of the Assistant Secretary for Financial Resources, Office of Acquisitions.

Abstract: Meetings, Conferences, and Seminars—Public Accommodations and Commercial Facilities—Funding and Sponsorship: Performance of HHS mission requires the support of contractors. In some circumstances, depending on the requirements of the specific contract, the contractor is tasked to conduct meetings, conferences, and seminars. HHSAR 311.7101(a) (Responsibilities) and the clause at HHSAR 352.211–1 (Accessibility of meetings, conferences, and seminars to persons with disabilities) require contractors to provide a plan describing the contractor's ability to meet the accessibility standards in 28 CFR part 36. HHSAR 311.7202(b) (Responsibilities) and the clause at HHSAR 352.211–2 (Conference sponsorship request and conference materials disclaimer) require contractors to provide funding disclosure and a content disclaimer statement on conference materials. As a result of these clauses, HHS contractors

providing conference, meeting, or seminars services are required to provide specific information to HHS as stated in the HHS Acquisition Regulation.

The Agency is requesting a 3-year extension to collect this information from public or private businesses.

ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
	Business (Contractor)	1,067	1	1	1,067
Total		1,067	1	1	1,067

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2024–27806 Filed 11–26–24; 8:45 am]

BILLING CODE 4150–24–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute, National Institutes of Health; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Sickle Cell Disease Advisory Committee.

The meeting will be held as a virtual meeting and open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting can be accessed from the NIH Videocast at the following link: *https://videocast.nih.gov/watch=55419.*

Name of Committee: Sickle Cell Disease Advisory Committee.

Date: January 14, 2025.

Time: 10:00 a.m. to 3:00 p.m.

Agenda: NHLBI Sickle Cell Disease Program Updates and Long Term Follow-up of Participants undergoing gene therapy for SCD.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: julie.panepinto@nih.gov.

Meeting Format: Virtual Meeting.

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *https://www.nhlbi.nih.gov/advisory-and-peer-review-committees/nhlbi-sickle-cell-disease-advisory-committee* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: November 22, 2024.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–27878 Filed 11–26–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Draft Revised Human Immunodeficiency Virus (HIV) Organ Policy Equity Act Safeguards and Research Criteria for Transplantation of Organs Infected With HIV

AGENCY: National Institutes of Health, Department of Health and Human Services.

ACTION: Request for comments.

SUMMARY: The HOPE Act requires the Secretary of Health and Human Services (the Secretary) to develop and publish criteria for research involving the transplantation of organs from donors with HIV to recipients with HIV. In 2015, the National Institutes of Health (NIH), and the U.S. Department of Health and Human Services (HHS) published research criteria applicable to such transplants, which have been in effect for all transplants involving organs from donors with HIV as authorized by the HOPE Act. As amended in an HHS final rule published elsewhere in this issue of the **Federal Register**, the Secretary determined that participation in clinical research should no longer be a requirement for the transplantation of kidneys and livers from donors with HIV to recipients with HIV and amended the HHS regulations governing the operation of the Organ Procurement and Transplantation Network (OPTN) to reflect this determination. As a result, HOPE Act transplants involving kidneys and livers from donors with HIV no longer need to comply with the research criteria. Given this regulatory change, NIH proposes to delete aspects of the research criteria that are specific to kidney and liver transplantation. NIH proposes additional changes to the research criteria based on its review of scientific evidence and in consideration of prior public feedback concerning the criteria, including comments provided in the recent rulemaking procedure that modified the OPTN regulations. NIH invites the public to submit comments regarding the proposed changes to the research criteria.

DATES: To ensure that comments will be considered, comments must be received no later than 5 p.m. on December 12, 2024.

ADDRESSES: Comments may be submitted by any of the following methods:

- *Email: HOPEAct@mail.nih.gov.*
- *Fax:* 301–451–5671.
- *Regular Mail:* Dr. Jonah Odim, 5601 Fishers Lane, Room 6B21, MSC 9827, Bethesda, MD 20892–9827.
- *Hand Delivery, Overnight Mail, FedEx, and UPS:* Dr. Jonah Odim, 5601 Fishers Lane, Room 6B21, MSC 9827, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Dr. Jonah Odim, Chief Clinical Transplantation Section, Transplantation Branch, 5601 Fishers

Lane, Room 6B21, MSC 9827, Rockville, MD 20892–9827; by email at *odimj@niaid.nih.gov;* by telephone at (301) 828–7220.

SUPPLEMENTARY INFORMATION:

I. Background

A. HHS Oversight of Organ Allocation and Transplantation

HHS is responsible for overseeing the operation of the nation's OPTN, including assisting in the equitable allocation of donor organs for transplantation. 42 U.S.C. 274(b)(2)(D). The OPTN is a network of transplant centers, organ procurement organizations, and other providers who work collectively to develop, implement, and monitor organ allocation policy and performance of the organ transplant system. The OPTN is also charged with developing policies on many subjects related to organ donation and transplantation, which include establishing standards of quality pertaining to organs procured for use in transplantation. 42 U.S.C. 274(b)(2)(E).

B. HOPE Act Requirements and Implementation

The enactment of the HOPE Act in 2013, Public Law 113–51, eliminated the prohibition in the United States on transplantation of organs from persons with HIV, allowing transplantation of these organs if certain requirements are satisfied. Under the HOPE Act, organs from donors with HIV may be transplanted only in recipients living with HIV prior to receiving such an organ. 42 U.S.C. 274(b)(3)(A). Further, the HOPE Act requires that transplants of HIV-positive organs occur only in recipients with HIV who are participating in institutional review board (IRB)-approved research protocols that adhere to certain criteria, standards, and regulations. 42 U.S.C. 274(b)(3)(B)(i). However, the Secretary may lift the research and IRB requirements if the Secretary has determined that participation in such clinical research, as a requirement for such transplants, is no longer warranted. 42 U.S.C. 274(b)(3)(B)(ii).

The HOPE Act outlines the process by which the Secretary may make such a determination under 42 U.S.C. 274(b)(3)(B)(ii). Specifically, the Secretary must routinely review the results of scientific research, in conjunction with the OPTN, to determine whether the results warrant revision of the OPTN standards of quality regarding organs from donors with HIV. If the Secretary determines that those standards of quality should be revised, the Secretary must direct the OPTN to revise the standards. 42 U.S.C. 274f–5(c)(2). The Secretary is also required to revise the regulatory provision implementing the HOPE Act, 42 CFR 121.6, upon determining that revisions to the OPTN standards of quality are warranted. 42 U.S.C. 274f–5(c)(3).

C. Research Criteria for HOPE Act Transplants

In 2015, NIH published proposed research criteria for HOPE Act transplants in the **Federal Register** and solicited public comment. 80 FR 34912 (June 18, 2015). After consideration of public comments received, NIH published the ''Final Human Immunodeficiency Virus (HIV) Organ Policy Equity (HOPE) Act Safeguards and Research Criteria for Transplantation of Organs Infected With HIV'' (''2015 Research Criteria''). 80 FR 73785 (November 25, 2015). The goals of the 2015 Research Criteria were to ensure that research using organs from donors with HIV was conducted under conditions protecting the safety of research participants and the public and that the results of this research provide a basis for evaluating the safety of transplants of organs from donors with HIV in recipients with HIV. 80 FR 73785.

1. Proposed Changes to the 2015 Research Criteria

NIH is now proposing changes to the 2015 Research Criteria to reflect the Secretary's determination, published by regulation on November 27, 2024, that HOPE Act kidney and liver transplants are no longer required to be conducted as research subject to the 2015 Research Criteria and to continue to further the goals shared in 2015 with respect to HOPE Act transplants of other organs from donors with HIV that remain subject to the Research Criteria. NIH proposes to remove requirements from the Research Criteria applicable to HOPE Act kidney and liver transplants.

NIH also proposes other changes to the 2015 NIH Research Criteria for conducting HOPE Act transplants of organs other than kidneys and livers (primarily heart and lung transplants) in IRB-approved research. The proposed changes are intended to accelerate research, ensure research participant safety, and maintain stakeholder confidence in clinical research conducted under the HOPE Act. Notable revisions include the elimination of (i) the transplant program experience requirement of five organ-specific transplants of organs from a donor without HIV in a recipient with HIV conducted over 4 years; (ii) mandated pre-implant biopsies; and (iii) the requirement for HIV independent advocates for living donors with HIV and recipients with HIV. Other organs (including multi visceral organs such as small intestine, stomach, liver, pancreas and colon) and multi organ transplants (*e.g.,* heart-kidney) must comply with the revised Research Criteria for inclusion of any non-kidney or non-liver organs from donors with HIV and subject to IRB approval.

2. Consideration of Public Comment Received on the HOPE Act NPRM

In proposing these changes, NIH has considered the public participation in the HOPE Act rulemaking process through which the Secretary's determination was made. In response to the September 21, 2024, notice of proposed rulemaking that proposed the Secretary's determination with respect to HOPE Act kidney and liver transplants, 89 FR 74174, HHS received multiple comments that were relevant to the NIH Research Criteria, and some comments provided specific suggestions for the content of the revised NIH Research Criteria. All comments relating to the content of the revised Research Criteria were provided to NIH for consideration in the development of the proposed revised Research Criteria that appear later in this document. NIH has considered these comments and proposes changes to the Research Criteria responsive to specific comments received, as described here.

- Several commenters noted that referring to organs ''infected with HIV'' or ''HIV positive organs'' may be stigmatizing, and one commenter requested that references to ''organs with HIV'' be revised to ''organ(s) from donors with HIV.'' The commenters indicated a strong preference for the use of stigma-reducing, and person-first language. In response to these comments, NIH proposes to revise references in the Research Criteria to refer to donors with HIV, recipients with HIV, and organs from donors with HIV. This is consistent with the Centers for Disease Control and Prevention's (CDC) Stigma Language Guide [1] and with language adopted in the final rule.
- Commenters also requested the elimination of the current requirement that a transplant team perform at least five transplants within a four-year period between any donor and a recipient with HIV for all organs, as, in the commenters' estimation, this

[1] Centers for Disease Control and Prevention. Let's Stop HIV Together: Stigma Language Guide. *https://www.cdc.gov/stophivtogether/hiv-stigma/ways-to-stop.html.* Accessed 2/23/2024.

requirement is not necessary for organs from donors with HIV to be used safely. In response to these comments and based on its review of the evidence, NIH proposes to remove this requirement from the proposed revised Research Criteria.

- Commenters suggested that each transplant team should include infectious disease specialists with expertise in HIV care. In response to these comments and based on its review of the evidence, NIH proposes that this requirement of the 2015 NIH Research Criteria be retained in the revised Research Criteria.
- One commenter requested the elimination of the biopsy requirement. In response to this comment and based on its review of the evidence, NIH proposes to eliminate the requirement for a pre-implantation biopsy.
- One commenter noted that, in revising the Research Criteria, NIH should maintain the strong patient safety record for HOPE Act transplants, while actively seeking to reduce burdens that may be slowing the establishment of non-kidney and non-liver HOPE Act transplant programs. In response to this comment and based on its review of the evidence, NIH believes that the proposed revisions to the Research Criteria appropriately strike this balance.

NIH's rationale for these specific proposed revisions to the Research Criteria is provided in more detail in Section III, below.

The Secretary delegated to the Director, NIH, the responsibility to revise the 2015 Research Criteria. The proposed revised Research Criteria proposed below were developed by NIH staff in collaboration with representatives of the Centers for Disease Control and Prevention, the Food and Drug Administration, the Health Resources and Services Administration, and the Office of the Assistant Secretary for Health.

If adopted as proposed, it is anticipated that the revised Research Criteria would expand access to transplantation for recipients with HIV, provide benefits to organ donors; ensure safety of ongoing HOPE Act transplants of organs other than kidneys and livers; and provide for the systematic collection of safety and efficacy data related to transplants of hearts, lungs, and other organs from donors with HIV in recipients with HIV.

3. Other Considerations

(a) Research Results—Heart and Lung Transplants in Recipients With HIV

As the Secretary has decided that HOPE Act transplants of organs other than kidneys and livers should remain subject to the Research Criteria until additional scientific research demonstrates the safety and efficacy of such transplants, NIH wishes to highlight the current state of the science with regard to transplantation of hearts and lungs from donors without HIV in recipients with HIV. The early outcomes data for such transplants may provide a foundation for future HOPE Act thoracic organ transplants (Koval 2018, 2019; Madan 2019). For example, in a retrospective analysis utilizing the OPTN database to compare outcomes of 75 heart transplant recipients with HIV to those of 29,848 heart transplant recipients without HIV, survival rates were similar across the comparator groups, while rejection rates were approximately 2-fold higher in recipients with HIV (38.7% vs. 17.7%, respectively) (Doberne 2021). Similar findings were reported in studies based on the International Society for Heart and Lung Transplantation (ISHLT) and Scientific Registry of Transplant Recipients (SRTR) databases (Wairmu 2021; Storm 2024; Madan 2019). Fewer transplants of lungs from donors without HIV in recipients with HIV have been reported (Koval 2019; Kern 2014; Rouzaud 2022).

NIH recognizes that additional research in this area will advance the state of the relevant science, and the results of such research will increase the evidence basis needed to support any future determination by the Secretary that participation in clinical research is no longer a requirement for transplants of hearts or lungs from donors with HIV in recipients with HIV.

(b) Education Regarding the HOPE Act

While no related proposals are included in the proposed revision to the 2015 Research Criteria, NIH further notes that expanding awareness and continuing education of potential organ donors, transplant centers, organ procurement organizations (OPOs), healthcare providers, and people living with HIV will be important to fully realize the medical and societal benefits envisioned under the HOPE Act. Success in these endeavors will expand the supply of quality donor HIV organs, enhance transplant access, improve quality of life, and increase longevity for potential transplant recipients with HIV. Reducing longstanding stigma and increasing access to organ transplantation will be particularly important for communities disproportionately impacted by HIV (*https://www.hiv.gov/hiv-basics/overview/about-hiv-and-aids/who-is-at-risk-for-hiv*).

(D) Secretary's Review of Research Results

As stated above, the HOPE Act requires that the Secretary, in conjunction with the OPTN, periodically review the results of scientific research to determine whether the results warrant revision to the OPTN standards of quality with respect to organs from donors with HIV and the safety of transplanting an organ from a donor with a particular strain of HIV into a recipient with a different strain of HIV. 42 U.S.C. 274f–5(c)(1). This review allows the Secretary to determine if the safety and efficacy of HOPE Act transplants are comparable to non-HOPE Act transplants and, if warranted, to further determine whether such transplants may be conducted outside of a research setting.

Past procedures for this review are described in detail in the final rule amending the OPTN regulation. Past reviews involved deliberations by bodies that provided recommendations to the Secretary, including the OPTN (which solicited and considered public comments)[2] [3] the HHS Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA)[4] and the HHS Blood, Organ, and Tissue Senior Executive Council (BOTSEC) (an advisory forum for senior leadership from HHS entities involved in blood, organ, and tissue safety and availability. The recommendations of the OPTN, ASBTSA, and BOTSEC, as well as subsequent research results, were considered in the Secretary's decision as to whether participation in clinical research, as a requirement for certain types of transplants of organs from donors with HIV, is no longer warranted.

Although not incorporated into the 2015 Research Criteria or the proposed revised criteria, HHS intends to conduct a regular review of such scientific research to enable evidence-based recommendations, including any changes to the Research Criteria, and any determinations on transitioning additional HOPE Act organ transplants to medical practice and standard-of-care

[2] Organ Procurement and Transplantation Network. Public Comment Proposal: Modify the HOPE Act Variance to Include Other Organs. 2019 Jan 22: *https://optn.transplant.hrsa.gov/media/2800/dtac_publiccomment_20190122.pdf.*

[3] Cooper M. ''OPTN Letter to Secretary Becerra on the HOPE Act.'' 2021 Oct 29. *https://optn.transplant.hrsa.gov/media/ueyjdfnd/hope-act-letter.pdf.*

[4] HHS Advisory Committee on Blood and Tissue Safety and Availability. 2022. Fifty-Sixth ACBTSA Meeting November 17, 2022—Meeting Summary. *https://www.hhs.gov/oidp/advisory-committee/blood-tissue-safety-availability/meeting-summary/2022-11-17/index.html.*

(*i.e.,* removing the clinical research and IRB requirements for such transplants) if appropriate in the future. NIH seeks public comment on this approach, and on the procedures through which this review should be conducted.

II. Instructions for Submitting Comments

Comments are invited on the proposed changes to the 2015 Research Criteria.

Please note that, during the rulemaking process resulting in the HHS final rule published elsewhere in this issue of the **Federal Register**, HHS received and considered public comments regarding whether HOPE Act kidney and liver transplants from donors with HIV should continue to be required to be conducted in accordance with the 2015 Research Criteria. After consideration of public comments received, the Secretary determined that participation in clinical research will no longer be a requirement for HOPE Act kidney and liver transplants from donors with HIV.

Further, in making the determination regarding HOPE Act kidney and liver transplants, the Secretary expressed the view in the notice of proposed rulemaking published on September 12, 2024, 89 FR 74174, that the current research and IRB requirements should be maintained for HOPE Act transplants of all other organs, considering the lack of data on outcomes for HOPE Act organ transplants other than kidney or liver transplants. This decision was affirmed in the HHS final rule published elsewhere in this issue of the **Federal Register**.

Because the Secretary's determination regarding HOPE Act kidney and liver transplants, and the Secretary's decision that other HOPE Act organ transplants should remain subject to the Research Criteria, resulted from full notice and comment rulemaking procedures, NIH views comments concerning the Secretary's determination or decision to be outside the scope of this solicitation and such comments will not be considered. Specifically, related comments will not be considered with respect to these proposed changes to the 2015 Research Criteria: (1) eliminating the requirement that transplants involving kidneys and livers from donors with HIV comply with the NIH Research Criteria; (2) retaining the requirement that transplants involving all other organs (other than kidneys and livers) from donors with HIV comply with the NIH Research Criteria; and (3) removal of criteria specific to the transplantation of kidneys and livers.

Do not include personal information in submitted comments that you do not want to be publicly disclosed.

III. Proposed Revision to the 2015 Research Criteria

The proposed revision to the 2015 Research Criteria is as follows:

Proposed Revised Human Immunodeficiency Virus (HIV) Organ Policy Equity (HOPE) Act Safeguards and Research Criteria for Transplantation of Organs From Donors With HIV

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Abbreviations
Definitions
Proposed Revised Hope Act Safeguards and Research Criteria
Table 1. Revised Final Human Immunodeficiency Virus (HIV) Organ Policy Equity (HOPE) Act Safeguards and Research Criteria for Transplantation of Organs With HIV
REFERENCES

Abbreviations

AIDS	Acquired Immunodeficiency Syndrome.
ART	Antiretroviral Therapy.
CD4	Cluster of Differentiation 4.
D−	Donor Human Immunodeficiency Virus negative.
D+	Donor Human Immunodeficiency Virus positive.
HBV	Hepatitis B virus.
HCT/Ps	Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).
HCV	Hepatitis C virus.
HIV	Human Immunodeficiency Virus.
HIV−	Human Immunodeficiency Virus negative (using serology and/or nucleic acid testing using FDA-licensed, approved or cleared devices).
HIV+	Human Immunodeficiency Virus positive (using serology and/or nucleic acid testing using FDA-licensed, approved or cleared devices).
HOPE Act	HIV Organ Policy Equity Act.
HRSA	Health Resources and Services Administration.
IRB	Institutional review board.
NIH	National Institutes of Health.
NPRM	Notice of proposed rule making.
OI	Opportunistic infection.
OPO	Organ procurement organization.
PML	Progressive multifocal leukoencephalopathy.
R−	Recipient HIV negative.
R+	Recipient HIV positive.
RNA	Ribonucleic acid.
SOPs	Standard operating procedures.

Definitions

Antiretroviral therapy (ART) resistance	When an HIV strain develops drug resistance and/or genetic mutations associated with drug resistance.
HIV superinfection	Systemic HIV superinfection is defined as the detection of HIV viral sequences that phylogenetically cluster with the donor's viral population at two or more time points in circulating blood cells, plasma, or recipient tissues other than the allograft.
Suppressed viral load	HIV RNA below 50 copies per mL with current technology at the time of publication of this research criteria document.

The 2015 Research Criteria are outlined in six broad categories (Donor Eligibility, Recipient Eligibility, Transplant Hospital Criteria, Organ Procurement Organization (OPO) Responsibilities, Prevention of Inadvertent Transmission of HIV, and Study Design/Required Data Elements and Outcome Measures). Table 1 summarizes the proposed new HOPE Act Research Criteria in each category

and compares them to the 2015 NIH Research Criteria.

TABLE 1—PROPOSED REVISED HUMAN IMMUNODEFICIENCY VIRUS (HIV) ORGAN POLICY EQUITY (HOPE) ACT SAFEGUARDS AND RESEARCH CRITERIA FOR TRANSPLANTATION OF ORGANS FROM DONORS WITH HIV [1]

Category	Previous criteria	Proposed revised criteria (No longer pertains to kidney and liver transplants [5])
Donor Eligibility:		
All deceased donors with HIV	No evidence of invasive opportunistic complications of HIV infection.	No evidence of invasive opportunistic complications of HIV infection.
	Pre-implant donor organ biopsy	There is no requirement for a pre-implantation biopsy.*
	Viral load: no requirement	Viral load: no requirement.
Deceased donor with known history of HIV and prior antiretroviral therapy (ART).	The study team must describe the anticipated post-transplant antiretroviral regimen(s) to be prescribed for the recipient and justify its conclusion that the regimen will be safe, tolerable, and effective.	The study team must describe the anticipated post-transplant antiretroviral regimen(s) to be prescribed for the recipient and justify its conclusion that the regimen will be safe, tolerable, and effective.
Living donor with HIV	Well-controlled HIV infection defined as: • Cluster of Differentiation 4 (CD4) + T-cell count ≥500/μL for the 6-month period before donation • HIV–1 ribonucleic acid (RNA) <50 copies/mL • No evidence of invasive opportunistic complications of HIV infection	*Thoracic Organs Exception:* The living donor standards are not relevant for thoracic organ transplant except in the rare instances of living donor lung transplant or ''domino'' heart transplant. In such circumstances, the deceased donor eligibility criteria should be followed.
	Pre-implant donor organ biopsy	*Other Organs:* If a living donor with HIV donates another type or organ (other than kidney and liver), the deceased donor eligibility criteria should be followed.*
Recipient Eligibility:	CD4+ T-cell count ≥200/μL (kidney)	CD4+ T-cell count: no minimum threshold when all other recipient eligibility criteria are met.*
	CD4+ T-cell count ≥100 μL (liver) within 16 weeks prior to transplant and no history of opportunistic infection (OI); or ≥200 μL if history of OI is present.	
	HIV–1 RNA <50 copies/mL and on a stable antiretroviral regimen.	HIV–1 RNA <50 copies/mL and on a stable antiretroviral regimen.
	No evidence of active opportunistic complications of HIV infection.	No evidence of active opportunistic complications of HIV infection.
	No history of primary central nervous system (CNS) lymphoma or progressive multifocal leukoencephalopathy (PML).	No history of primary central nervous system (CNS) lymphoma or progressive multifocal leukoencephalopathy (PML).
Transplant Hospital Criteria	Transplant hospital with established program for care of subjects with HIV.	Transplant hospital with established program for care of patients with HIV.
	HIV program expertise on the transplant team	HIV program expertise on the transplant team.
	Organ-specific experience with transplants of organs from donors without HIV to recipients with HIV (5 D-/R+ transplant cases over 4 years).	There is no longer a center specific case experience requirement with transplants of organs from donors without HIV to recipients with HIV.* Transplant patients with organs from donors with HIV must be managed with a multidisciplinary team before, during, and after transplant. The multidisciplinary team must include transplant surgeons, physicians, HIV specialists, nurses, social workers, and pharmacists capable of therapeutic drug monitoring to minimize drug-drug interactions.
	Standard operating procedures (SOPs) and training for the organ procurement, implanting/operative, and postoperative care teams for handling subjects with HIV, and organs and tissues from individuals with HIV.	Standard operating procedures (SOPs) and training for the organ procurement, implanting/operative, and postoperative care teams for handling HIV-infected subjects with HIV, and organs and tissues from individuals with HIV.
	IRB-approved research protocol for transplantation of organs from donors with HIV in recipients with HIV.	IRB-approved research protocol for transplantation of organs from donors with HIV in recipients with HIV for the applicable organs.*
	Institutional biohazard plan outlining measures to prevent and manage inadvertent exposure to and/or transmission of HIV.	Institutional biohazard plan outlining measures to prevent and manage inadvertent exposure to and/or transmission of HIV.
	Provide each living donor with HIV and recipient with HIV with an ''independent advocate''.	There is no longer a requirement to provide an HIV independent advocate beyond standard site practices.*
	Policies and SOPs governing the necessary knowledge, experience, skills, and training for independent advocates.	Policies and SOPs governing the necessary knowledge, experience, skills, and training for independent advocates.

TABLE 1—PROPOSED REVISED HUMAN IMMUNODEFICIENCY VIRUS (HIV) ORGAN POLICY EQUITY (HOPE) ACT SAFEGUARDS AND RESEARCH CRITERIA FOR TRANSPLANTATION OF ORGANS FROM DONORS WITH HIV [1]—Continued

Category	Previous criteria	Proposed revised criteria (No longer pertains to kidney and liver transplants [5])
OPO Responsibilities	SOPs and staff training procedures for working with deceased donors with HIV and their families in pertinent history taking; medical chart abstraction; the consent process; and handling blood, tissues, organs, and biospecimens.	SOPs and staff training procedures for working with deceased donors with HIV and their families in pertinent history taking; medical chart abstraction; the consent process; and handling blood, tissues, organs, and biospecimens.
	Biohazard plan to prevent and manage HIV exposure and/or transmission.	Biohazard plan to prevent and manage HIV exposure and/or transmission.
Prevention of Inadvertent Transmission of HIV.	Each participating Transplant Program and OPO shall develop an institutional biohazard plan for handling organs from HIV-positive donors that is designed to prevent and/or manage inadvertent transmission or exposure to HIV.	Each participating Transplant Program and OPO shall develop an institutional biohazard plan for handling organs from HIV-positive donors that is designed to prevent and/or manage inadvertent transmission or exposure to HIV.
	Procedures must be in place to ensure that human cells, tissues, and cellular and tissue-based products (HCT/Ps) are not recovered from donors with HIV for implantation, transplantation, infusion, or transfer into a human recipient; however, HCT/Ps from a donor determined to be ineligible may be made available for non-clinical purposes.	Procedures must be in place to ensure that human cells, tissues, and cellular and tissue-based products (HCT/Ps) are not recovered from donors with HIV for implantation, transplantation, infusion, or transfer into a human recipient; however, HCT/Ps from a donor determined to be ineligible may be made available for non-clinical purposes.
Required Data Elements and Outcome Measures **		
Wait List Candidates	HIV status	HIV status.
	CD4+ T-cell counts	CD4+ T-cell counts.
	Co-infection (hepatitis C virus [HCV], hepatitis B virus [HBV]).	Co-infection: • Hepatitis C (HCV RNA). • Hepatitis B (HBV deoxyribonucleic acid, HBV antibody). • Cytomegalovirus (CMV immunoglobulin G [IgG]).*
	HIV viral load	HIV viral load.
	ART resistance	ART resistance.
	Removal from wait list (death or other reason)	Removal from wait list (death or other reason).
	Time on wait list	Time on wait list.
		Renal dysfunction.*
		Liver dysfunction.*
		Indication for transplant.*
		Use of mechanical circulatory devices.*
		Use of extracorporeal membrane oxygenation, intra-aortic balloon pump, ventricular assist device.*
Donors (all)	Type (Living or deceased)	Type Donation after Brain Death vs. Donation after Circulatory Death vs. Living Donor.*
	HIV status (new diagnosis of HIV, or known diagnosis of HIV).	HIV status (new diagnosis of HIV, or known diagnosis of HIV).
	CD4+ T-cell count	CD4+ T-cell count.
	Co-infection (HCV, HBV)	Co-infection (HCV, HBV).
	HIV viral load	HIV viral load.
	ART resistance	ART resistance.
		Ex-vivo perfusion.* • Duration. • Warm and cold ischemia time.
		Normothermic regional perfusion.* • Duration. • Warm and cold ischemia time.
Living Donors	Progression to renal insufficiency in kidney donors Progression to hepatic insufficiency in liver donors	These data elements no longer apply since kidney or liver donation from a living donor with HIV no longer falls under the Research Criteria except that these data elements apply to simultaneous multiple organ transplants.
	Change in ART regimen as a result of organ dysfunction.	Change in ART regimen as a result of organ dysfunction.
	Progression to acquired immunodeficiency syndrome (AIDS).	Progression to AIDS.
	Failure to suppress viral replication (persistent HIV viremia).	Failure to suppress viral replication (persistent HIV viremia).
	Death	Death.
Transplant Recipients	Rejection rate (annual up to 5 years)	Rejection rate (annual through 5 years).
	Progression to AIDS	Progression to AIDS.

TABLE 1—PROPOSED REVISED HUMAN IMMUNODEFICIENCY VIRUS (HIV) ORGAN POLICY EQUITY (HOPE) ACT SAFEGUARDS AND RESEARCH CRITERIA FOR TRANSPLANTATION OF ORGANS FROM DONORS WITH HIV [1]—Continued

Category	Previous criteria	Proposed revised criteria (No longer pertains to kidney and liver transplants [5])
	New OI Failure to suppress viral replication (persistent HIV viremia). HIV-associated organ failure Malignancy Graft failure Mismatched ART resistance versus donor Death	New OI. Failure to suppress viral replication (persistent HIV viremia). HIV-associated organ failure. Malignancy. Graft failure. Mismatched ART resistance versus donor. Death. Type of rejection (antibody mediated versus cellular rejection).* Chronic heart allograft vasculopathy.* Chronic lung allograft dysfunction.* Hospitalized infections.* Estimated glomerular filtration rate.* HIV superinfection.* Re-transplantation.* Simultaneous multiple organ transplants.

* Denotes a revision of the 2015 Research Criteria.
** The previous category of outcome measures (from the original 2015 Research Criteria) is modified to also include data elements.

A summary of the proposed revisions in each category of the Research Criteria is provided below.

Donor Eligibility

The only change proposed by NIH to this category applies to all deceased donors with HIV. NIH proposes removing the requirement for a pre-implantation donor organ biopsy. Although pre-implantation biopsies for kidneys and livers have occurred regularly, pre-implant donor heart and lung biopsies are not routinely performed. Likewise, donor biopsies for other organs are not routine. Given that kidney and liver transplants are no longer subject to the NIH research criteria, NIH proposes removing the requirement for pre-implantation biopsies. Any pre-implant biopsies obtained, as part of future IRB-approved research protocols, should be stored in accordance with local institutional requirements and the federal regulations applicable to slides, tissues, and blocks, if applicable. 42 CFR 493.1105 (*https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493/subpart-J/section-493.1105*).

With respect to living donors with HIV, the 2015 NIH Research Criteria defined a well-controlled HIV infection and required pre-implant donor organ biopsies. The last living lobar lung transplant procedure in the U.S. was performed in 2013. NIH proposes removing this element as not relevant for heart and lung transplantation except in the rare instances of living donor lung transplant or ''domino'' heart transplants. In such circumstances, NIH proposes that the deceased donor eligibility criteria apply. If another type of organ is donated by a living donor with HIV, NIH proposes that the deceased donor eligibility criteria apply.

Recipient Eligibility

The only change proposed in this category concerns CD4+ T-cell counts. The 2015 NIH Research Criteria imposed requirements with respect to the CD4+ T-cell counts specific to livers and kidneys. Given that kidney and liver transplants are no longer required to comply with the research criteria, NIH proposes no minimum threshold CD4+ T-cell counts for other organs when all other eligibility criteria are met.

Transplant Hospital

NIH proposes several changes to this category. The requirement for prior experience with transplantation of organs from donors without HIV in recipients with HIV. The 2015 NIH Research Criteria required experience with five transplants over the four preceding years involving organs from donors without HIV transplanted into recipients with HIV. NIH proposes removing this requirement, which was perceived by many as burdensome and a barrier to entry to transplant hospitals wishing to perform HOPE Act transplants. To maximize favorable outcomes and effectively prevent and manage adverse events, NIH proposes that all patients with transplants involving donors with HIV be managed by multidisciplinary teams before, during, and after transplantation. NIH proposes specific members of this multidisciplinary team.

NIH proposes removing the requirement that each living donor with HIV and each transplant recipient with HIV be provided with an HIV-independent advocate. NIH proposes instead that standard site practices apply. Based on a decade of HOPE Act clinical experience, stakeholder surveys have indicated that a requirement for an independent advocate is widely perceived as a redundant layer of consent and a potential barrier for some HIV patients who would otherwise benefit from an HIV donor transplant. The NIH notes that per current OPTN policy and guidance, all living donors, including those with HIV, have an independent advocate. NIH's proposed change to the 2015 Research Criteria will not alter that.

[5] Consistent with the final rule amending the OPTN regulations, transplants using kidneys and livers from donors with HIV no longer need to comply with the HOPE Act research criteria. When multiple organs from donors with HIV are implanted simultaneously (*e.g.,* dual heart-kidney or dual lung-kidney), the Research Criteria apply to such multiple organ transplants if the transplant of any of the organs are subject to the revised Research Criteria. For example, while a kidney transplant from a donor with HIV no longer is required to be conducted in accordance with the Research Criteria, a dual heart-kidney or dual lung-kidney transplant with organs from donors with HIV is required to be conducted in accordance with the Research Criteria and in accordance with an IRB-approved research protocol. A dual liver-kidney transplant with from donors with HIV is not required to be conducted in accordance with the Research Criteria, as neither liver transplants nor kidney transplants from donors with HIV are required to be conducted as research.

Organ Procurement Organization (OPO) Responsibilities

NIH does not propose changes to this category.

Prevention of Inadvertent Transmission of HIV

NIH does not propose changes to this category.

Required Outcome Measures and Data Elements

The 2015 Research Criteria referenced required outcome measures. NIH proposes using the more precise ''Required Data Elements and Outcome Measures.'' NIH notes that data on these existing and proposed outcome measures is collected by the OPTN as specified by the Secretary. NIH does not intend to propose data collection requirements beyond those collected by the OPTN.

Waitlist Candidates: NIH proposes adding several data elements for waitlist candidates. NIH proposes adding cytomegalovirus (CMV immunoglobulin G [IgG]) as a required outcome measure for co-infection. NIH also proposes adding additional data elements and outcome measures: renal dysfunction, liver dysfunction, indication for transplant, use of mechanical circulatory devices, and use of extracorporeal membrane oxygenation, intra-aortic balloon pump, and ventricular assist device.

Donors (All): First, NIH proposes adding additional elements related to the type of deceased donation: after brain death (DBD) or after circulatory death (DCD) given the increasing use of the latter technique in the U.S. In addition, NIH proposes the following data elements for all donors (if applicable): *ex-vivo* perfusion and normothermic regional perfusion including durations of warm and cold ischemia.

Living Donors: The 2015 NIH Research Criteria included as required outcome measures progression to renal insufficiency in kidney living donors. Because kidney and liver transplants are no longer subject to the research criteria, NIH plans to retain these outcomes only where applicable (*e.g.,* for deceased donor heart-living donor kidney transplants, deceased donor heart-living donor liver transplants, and for other organs subject to the research criteria).

Transplant Recipients: NIH proposes adding several additional data elements and outcome measures to those included for transplant recipients in the 2015 NIH Research Criteria. NIH proposes adding the following outcome measures: type of rejection (antibody-mediated versus cellular rejection), chronic allograft vasculopathy (heart), chronic lung allograft dysfunction (lung), hospital infections, estimated glomerular filtration rate (heart and lung), HIV superinfection, graft failure (heart and lung), re-transplantation, and simultaneous multiple organ transplants.

While not proposed as a requirement of the Research Criteria, NIH proposes to provide the following recommendation regarding patient management: NIH recommends that transplant programs and healthcare providers follow current and updated practice management guidelines. For specific guidance, transplant programs and healthcare providers should consult vaccination guidance (*https://www.cdc.gov/acip-recs/hcp/vaccine-specific/index.html*) and expert guidance for the management of patients with HIV pre-, during-, and post-transplant summarized in: Transplantation in people with HIV (*https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/whats-new*).

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Dated: November 21, 2024.

Lawrence A. Tabak,

Principal Deputy Director, National Institutes of Health.

[FR Doc. 2024–27733 Filed 11–26–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; Comprehensive Partnerships to Advance Cancer Health Equity (CPACHE).

Date: January 16, 2025.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W108, Rockville, Maryland 20850.

Meeting Format: Virtual Meeting.

Contact Person: Clifford W. Schweinfest, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W108, Rockville, Maryland 20850, 240–276–6343, *schweinfestcw@mail.nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; Informatics Technologies for Cancer Research.

Date: January 29, 2025.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W106, Rockville, Maryland 20850.

Meeting Format: Virtual Meeting.

Contact Person: Eduardo Emilio Chufan, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W106, Rockville, Maryland 20850, 240–276–7975, *chufanee@mail.nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Review of Research Projects in Physical Sciences Oncology.

Date: January 31, 2025.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W640, Rockville, Maryland 20850.

Meeting Format: Virtual Meeting.

Contact Person: Saejeong J. Kim, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W640, Rockville, Maryland 20850, 240–276–7684, *saejeong.kim@nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Outstanding Investigator Award (R35).

Date: February 6–7, 2025.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W104, Rockville, Maryland 20850.

Meeting Format: Virtual Meeting.

Contact Person: David G. Ransom, Ph.D., Chief, Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W104, Rockville, Maryland 20850, 240–276–6351, *david.ransom@nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; SEP–3: NCI Clinical and Translational Cancer Research.

Date: February 6–7, 2025.

Time: 9:30 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W612, Rockville, Maryland 20850.

Meeting Format: Virtual Meeting.

Contact Person: Prashant Sharma, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W612, Rockville, Maryland 20850, 240–275–6351, *prashant.sharma@nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; SEP–7: NCI Clinical and Translational Cancer Research.

Date: February 12, 2025.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W640, Rockville, Maryland 20850.

Meeting Format: Virtual Meeting.

Contact Person: Saejeong J. Kim, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W640, Rockville, Maryland 20850, 240–276–7684, *saejeong.kim@nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI IMAT Biospecimen Special Emphasis Panel.

Date: February 13, 2025.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W236, Rockville, Maryland 20850.

Meeting Format: Virtual Meeting.

Contact Person: Shuli Xia, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W236, Rockville, Maryland 20850, 240–276–5256, *shuli.xia@nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; SEP–11: NCI Clinical and Translational Cancer Research.

Date: February 18, 2025.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W606, Rockville, Maryland 20850.

Meeting Format: Virtual Meeting.

Contact Person: Bruce Daniel Hissong, Ph.D., Scientific Review Officer, Resource and Training Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W606, Rockville, Maryland 20850, 240–276–7752, *bruce.hissong@nih.gov*.

Name of Committee: National Cancer Institute, Initial Review Group; Transition to Independence Study Section (I).

Date: February 26–27, 2025.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W602, Rockville, Maryland 20850.

Meeting Format: Virtual Meeting.

Contact Person: Delia Tang, M.D., Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W602, Rockville, Maryland 20850, 240–276–6456, *tangd@mail.nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Research specialist Award (R50).

Date: February 27, 2025.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W242, Rockville, Maryland 20850.

Meeting Format: Virtual Meeting.

Contact Person: Zhiqiang Zou, M.D., Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W242, Rockville, Maryland 20850, 240–276–6372, *zouzhiq@mail.nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; SEP–2: NCI Clinical and Translational Cancer Research.

Date: March 6, 2025.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W242, Rockville, Maryland 20850.

Meeting Format: Virtual Meeting.

Contact Person: Zhiqiang Zou, M.D., Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W242, Rockville, Maryland 20850, 240–276–6372, *zouzhiq@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: November 22, 2024.

Miguelina Perez,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–27877 Filed 11–26–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Environmental Health Sciences Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting can be accessed from the NIEHS Videocast at the following link: *https://www.niehs.nih.gov/news/webcasts/index.cfm.*

The meeting will be closed to the public in accordance with the

provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Environmental Health Sciences Council.

Date: February 18, 2025.

Open: 10:30 a.m. to 3:45 p.m.

Agenda: Discussion of program policies and issues/Council Discussion.

Address: NIEHS/National Institutes of Health Building, 79 T.W. Alexander Drive, Research Triangle Park, NC 27709 Virtual Meeting.

Closed: 4:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: NIEHS/National Institutes of Health Building, 79 T.W. Alexander Drive, Research Triangle Park, NC 27709 Virtual Meeting.

Contact Person: David M. Balshaw, BA, Ph.D., Director Division of Extramural Research and Training National Institute of Environmental Health Sciences, P.O. Box 12233, MD EC–27, Research Triangle Park, NC 27709–2233, 984–287–3234, *balshaw@niehs.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person. In the interest of security, NIH has procedures at *https://www.nih.gov/about-nih/visitor-information/campus-access-security* for entrance into on-campus and off-campus facilities. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus federal facility will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *www.niehs.nih.gov/dert/c-agenda.htm,* where an agenda and any additional information for the meeting will be posted when available. (Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: November 21, 2024.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–27715 Filed 11–26–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Initial Review Group Training and Workforce Development Study Section—D.

Date: February 27–28, 2025.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, National Institute of General Medical Sciences, Natcher Building, 45 Center Drive, Bethesda, Maryland 20892.

Meeting Format: Virtual Meeting.

Contact Person: Marcienne Michele Wright, Scientific Review Officer, Office of Scientific Review, National Institutes of General Medical Sciences, National Institutes of Health, 45 Center Drive, Bethesda, Maryland 20892, 301–827–7635, *marci.wright@nih.gov*

(Catalogue of Federal Domestic Assistance Program No. 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: November 22, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–27873 Filed 11–26–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Neuromodulation and Imaging of Neuronal Circuits II.

Date: December 20, 2024.

Time: 9:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Pablo M Blazquez Gamez, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 435–1042, *pablo.blazquezgamez@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Infectious Diseases and Immunology.

Date: December 20, 2024.

Time: 10:30 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Maria Chiara G Monaco-Kushner, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 555–1212, *monaco@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 22, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–27879 Filed 11–26–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[OMB Control Number 1651–0028]

Agency Information Collection Activities; Extension; Cost Submission (Form 247)

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 30-Day Notice and request for comments.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection (CBP) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and must be submitted no later than December 27, 2024, to be assured of consideration.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Please submit written comments and/or suggestions in English. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177, Telephone number 202–325–0056 or via email *CBP_PRA@cbp.dhs.gov.* Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP website at *https://www.cbp.gov/.*

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This proposed information collection was previously published in the **Federal Register** (89 FR 76864) on September 19, 2024, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: Cost Submission.

OMB Number: 1651–0028.

Form Number: 247.

Current Actions: CBP proposes to extend the expiration date of this information collection. There is no change to the burden hours or to the information collected.

Type of Review: Extension (without change).

Affected Public: Businesses.

Abstract: The information collected on CBP Form 247, Cost Submission, is used by CBP to assist in correctly calculating the duty on imported merchandise. This form includes details on actual costs and helps CBP determine which costs are dutiable and which are not.

This collection of information is provided for by subheadings 9801.00.10, 9802.00.40, 9802.00.50, 9802.00.60 and 9802.00.80 of the Harmonized Tariff Schedule of the United States (HTSUS), and by 19 U.S.C. 1508 through 1509, 19 CFR 10.11–10.24, 19 CFR 141.88 and 19 CFR 152.106.

CBP Form 247 can be found at: http://www.cbp.gov/xp/cgov/toolbox/forms/.

Type of Information Collection: Form 247.

Estimated Number of Respondents: 1,000.

Estimated Number of Annual Responses per Respondent: 1.

Estimated Number of Total Annual Responses: 1,000.

Estimated Time per Response: 50 hours.

Estimated Total Annual Burden Hours: 50,000.

Dated: November 22, 2024.

Seth D Renkema,

Branch Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection.

[FR Doc. 2024–27826 Filed 11–26–24; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[OMB Control Number 1651–0030]

Agency Information Collection Activities; Extension; Declaration of Unaccompanied Articles (CBP Form 255)

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 30-Day notice and request for comments.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection (CBP) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and must be submitted no later than December 27, 2024 to be assured of consideration.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Please submit written comments and/or suggestions in English. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis

Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177, Telephone number 202–325–0056 or via email *CBP_PRA@cbp.dhs.gov.* Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP website at *https://www.cbp.gov/.*

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This proposed information collection was previously published in the **Federal Register** (89 FR 74281) on September 12, 2024, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: Declaration of Unaccompanied Articles (CBP Form 255).

OMB Number: 1651–0030.

Form Number: 255.

Current Actions: This submission will renew the expiration validity, without a change to the information requested or method of collection.

Type of Review: Extension (without change).

Affected Public: Individuals.

Abstract: CBP Form 255, Declaration of Unaccompanied Articles, is completed by travelers arriving in the United States either directly or indirectly from the U.S. Virgin Islands, American Samoa, Guam, and the Commonwealth of the Northern Mariana Islands who are declaring merchandise purchases while visiting these locations which are to be sent from these insular possessions at a later date. It is the only means whereby the CBP officer, when the traveler arrives, can apply the exemptions or 5 percent flat rate of duty to all of the traveler's purchases.

Type of Information Collection: CBP Form 255.

Estimated Number of Respondents: 7,500.

Estimated Number of Annual Responses per Respondent: 2.

Estimated Number of Total Annual Responses: 15,000.

Estimated Time per Response: 5 minutes.

Estimated Total Annual Burden Hours: 1,250.

Dated: November 22, 2024.

Seth D. Renkema,

Branch Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection.

[FR Doc. 2024–27829 Filed 11–26–24; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[OMB Control Number 1651–0058]

Agency Information Collection Activities; Extension; Documents Required Aboard Private Aircraft

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 30-Day Notice and request for comments.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection (CBP) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and must be submitted (no later than December 27, 2024) to be assured of consideration.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Please submit written comments and/or suggestions in English. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177, Telephone number 202–325–0056 or via email *CBP_PRA@cbp.dhs.gov.* Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP website at *https://www.cbp.gov/.*

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This proposed information collection was previously published in the **Federal Register** (89 FR 59921) on July 24, 2024, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting

electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: Documents Required Aboard Private Aircraft.

OMB Number: 1651–0058.

Current Actions: CBP proposes to extend the expiration date of this information collection without a change to the burden hours or information collected.

Type of Review: Extension (without change).

Affected Public: Individuals.

Abstract: In accordance with 19 CFR 122.27(c), a commander of a private aircraft arriving in the U.S. must present several documents to CBP officers for inspection. These documents include: (1) a pilot certificate/license; (2) a medical certificate; and (3) a certificate of registration. CBP officers use the information on these documents as part of the inspection process for private aircraft arriving from a foreign country. This presentation of information is authorized by 19 U.S.C. 1433, as amended by Public Law 99–570.

Type of Information Collection: Documents aboard a private aircraft.

Estimated Number of Respondents: 120,000.

Estimated Number of Annual Responses per Respondent: 1.

Estimated Number of Total Annual Responses: 120,000.

Estimated Time per Response: .0166.

Estimated Total Annual Burden Hours: 1,992.

Dated: November 22, 2024.

Seth D Renkema,

Branch Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection.

[FR Doc. 2024–27832 Filed 11–26–24; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[OMB Control Number 1651–0041]

Agency Information Collection Activities; Extension; Establishment of a Bonded Warehouse (Bonded Warehouse Regulations)

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 30-Day Notice and request for comments.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection (CBP) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and must be submitted no later than December 27, 2024 to be assured of consideration.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Please submit written comments and/or suggestions in English. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177, Telephone number 202–325–0056 or via email *CBP_PRA@cbp.dhs.gov.* Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP website at *https://www.cbp.gov/.*

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This proposed information collection was previously published in the **Federal Register** (89 FR 74281) on September 12, 2024, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: Establishment of a Bonded Warehouse (Bonded Warehouse Regulations).

OMB Number: 1651–0041.

Current Actions: This submission will extend the expiration date validity without a change to the information collected or method of collection.

Type of Review: Extension (w/o change).

Affected Public: Businesses.

Abstract: Owners or lessees desiring to establish a bonded warehouse must make written application to the U.S. Customs and Border Protection (CBP) port director of the port where the warehouse is located. The application must include the warehouse location, a description of the premises, and an indication of the class of bonded warehouse permit desired. Owners or lessees desiring to alter or to relocate a bonded warehouse may submit an application to the CBP port director of the port where the facility is located. The authority to establish and maintain a bonded warehouse is set forth in 19 U.S.C. 1555, and provided for by 19 CFR 19.2, 19 CFR 19.3, 19 CFR 19.6, 19 CFR 19.14, and 19 CFR 19.36.

Type of Information Collection: Bonded Warehouse Application.

Estimated Number of Respondents: 198.

Estimated Number of Annual Responses per Respondent: 47.

Estimated Number of Total Annual Responses: 9,306.

Estimated Time per Response: 32 minutes.

Estimated Total Annual Burden Hours: 4,963.

Dated: November 22, 2024.

Seth D. Renkema

Branch Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection.

[FR Doc. 2024–27827 Filed 11–26–24; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[Docket No. USCBP–2024–0027]

Commercial Customs Operations Advisory Committee

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security (DHS).

ACTION: Committee management; notice of open Federal Advisory Committee meeting.

SUMMARY: The Commercial Customs Operations Advisory Committee (COAC) will hold its quarterly meeting on Wednesday, December 11, 2024, in Washington, DC. The meeting will be open to the public via webinar only.

DATES: The COAC will meet on Wednesday, December 11, 2024, from 1:00 p.m. to 5:00 p.m. Eastern Standard Time (EST). Please note the meeting may close early if the committee has completed its business. Comments must be submitted in writing no later than December 6, 2024.

ADDRESSES: The meeting will be open to the public via webinar only. The webinar link will be posted by 5:00 p.m. EST on November 29, 2024, at *https://www.cbp.gov/trade/stakeholder-engagement/coac/coac-public-meetings.* For information or to request special assistance for the meeting, contact Mrs. Latoria Martin, Office of Trade Relations, U.S. Customs and Border Protection, at (202) 344–1440, as soon as possible.

Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Search for Docket Number USCBP–2024–0027. To submit a comment, click the ''Comment'' button located on the top-left hand side of the docket page.
- *Email: tradeevents@cbp.dhs.gov.* Include Docket Number USCBP–2024–0027 in the subject line of the message.

Comments must be submitted in writing no later than December 6, 2024, and must be identified by Docket No. USCBP–2024–0027. All submissions received must also include the words ''Department of Homeland Security.'' All comments received will be posted without change to *https://www.cbp.gov/trade/stakeholder-engagement/coac/coac-public-meetings* and *www.regulations.gov.* Therefore, please refrain from including any personal information you do not wish to be posted. You may wish to view the Privacy and Security Notice, which is available via a link on *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Mrs. Latoria Martin, Office of Trade Relations, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Room 3.5A, Washington, DC 20229, (202) 344–1440; or Ms. Felicia M. Pullam, Designated Federal Officer, at (202) 344–1440 or via email at *tradeevents@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the authority of the Federal Advisory Committee Act, Title 5 U.S.C., ch. 10. The COAC provides advice to the Secretary of the Department of Homeland Security, the Secretary of the Department of the Treasury, and the Commissioner of U.S. Customs and Border Protection (CBP) on matters pertaining to the commercial operations of CBP and related functions within the Department of Homeland Security and the Department of the Treasury.

The COAC is committed to ensuring all participants have equal access regardless of disability status. If you require a reasonable accommodation due to a disability to fully participate, please contact Mrs. Latoria Martin at (202) 344–1440 as soon as possible.

Please feel free to share this information with other interested members of your organization or association.

To facilitate public participation, we are inviting public comment on the issues the committee will consider prior to the formulation of recommendations as listed in the AGENDA section below.

There will be a public comment period after each subcommittee update during the meeting on December 11, 2024. During the meeting, comments may be submitted via the trade events mailbox at *tradeevents@cbp.dhs.gov* or through the Microsoft Teams chat feature. Please note the public comment period for speakers may end before the time indicated on the schedule that is posted on the CBP web page: *http://www.cbp.gov/trade/stakeholder-engagement/coac.*

Agenda

The COAC will hear from the current subcommittees on the topics listed below:

1. The Intelligent Enforcement Subcommittee will provide updates on the work completed and topics discussed in its working groups as well as present proposed recommendations for the COAC's consideration. The Antidumping/Countervailing Duty (AD/CVD) Working Group will provide updates regarding its work and discussions on importer compliance with AD/CVD and other trade remedy measures and requirements. The Intellectual Property Rights (IPR) Process Modernization Working Group anticipates providing updates concerning progress associated with its proposed recommendations specific to IPR enforcement and facilitation. The Forced Labor Working Group (FLWG) will provide updates on continued discussions regarding trade outreach, clarification of requirements, and proposed recommendations. The FLWG reports that it will continue to provide CBP with input as CBP rolls out a case management portal. The Bond Working Group remained on hiatus status since the last public meeting.

2. The Next Generation Facilitation Subcommittee will provide updates on all its existing working groups. The Automated Commercial Environment (ACE) 2.0 Working Group was focused on completing discussions on the Concept of Operations document regarding scenarios for Electronic Export Manifests (EEM) and a portal for infrequent importers, along with the status of previous recommendations proposed earlier this term. The Broker Modernization Working Group (BMWG) remains dedicated to the enhancement of the end user experience and improving the administration of the Customs Broker Licensing Exam (CBLE). This quarter, the Modernized Entry Processes Working Group (MEPWG) continues its National Customs Automation Program (NCAP) discussions and will provide updates on its efforts concerning the reconciliation test. The remaining working group, the Customs Interagency Industry Working Group (CIIWG), was not active this past quarter but will provide a report on topics that the working group will focus on in the coming quarter.

3. The Secure Trade Lanes Subcommittee will provide updates on its seven active working groups: the Centers Working Group, the Cross-Border Recognition Working Group, the De Minimis Working Group, the Export Modernization Working Group, the FTZ/Warehouse Working Group, the Pipeline Working Group, and the Trade Partnership and Engagement Working Group. The Centers Working Group consolidated its review of the Centers' communications functions into the Structure Sub-Working Group and the

Operations Sub-Working Group. The Centers Working Group as a whole, through these two sub-working groups, continues to evaluate the structure and operations of the Centers to enhance their effectiveness, increase transparency, and build stronger communities within CBP and with the Trade. The Cross-Border Recognition Working Group is evaluating whether all deliverables outlined in the Statement of Work have been achieved to determine next steps. CBP has formed a Task Force to assist the De Minimis Working Group regarding the timeframe for submitting de minimis shipments. The De Minimis Working Group, via the Task Force, intends to present proposed recommendations at the December quarterly COAC meeting. The Export Modernization Working Group has continued its work on the Electronic Export Manifest Pilot Program and the effects of progressive filing by the shipper to continuously update export information on successive dates, rather than on a specific date. The Export Modernization Working Group is also working on previous proposed recommendations to determine if new proposed recommendations need to be made and is reviewing the status of proposed recommendations that have not been finalized. The Drawback Task Force, within the Export Modernization Working Group, has continued discussions around COAC-approved recommendations that are in the process of being implemented from last quarter. They are also conducting an analysis of program statistics in the areas of streamlining drawback ruling processes, reviewing compliance issues, and examining areas to maximize resources. The FTZ/Warehouse Working Group continues to review 19 CFR part 146, explore areas in which the Customs-Trade Partnership Against Terrorism (CTPAT) program can be expanded, and consider how to modernize ACE functionality for Foreign Trade Zones (FTZs), and it anticipates presenting proposed recommendations for the COAC's consideration at the December public meeting. The Pipeline Working Group has continued discussing the most appropriate commodities for and potential users of Distributed Ledger Technology to engage in the contemplated pilot for tracking pipeline-borne goods. The Global Interoperability Standard (GIS) Information Collection **Federal Register** Notice (FRN) was published on September 3, 2024 (89 FR 71381), and comments were accepted through November 4, 2024. The Pipeline Working Group has no proposed recommendations for this quarter.

Meeting materials will be available on December 2, 2024, at: *http://www.cbp.gov/trade/stakeholder-engagement/coac/coac-public-meetings.*

Felicia M. Pullam,

Executive Director, Office of Trade Relations.

[FR Doc. 2024–27805 Filed 11–26–24; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[OMB Control Number 1651–0006]

Agency Information Collection Activities; Extension; Application and Approval To Manipulate, Examine, Sample or Transfer Goods (CBP Form 3499)

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 30-Day notice and request for comments.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection (CBP) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and must be submitted no later than December 27, 2024 to be assured of consideration.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Please submit written comments and/or suggestions in English. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177, Telephone number 202–325–0056 or via email *CBP_PRA@cbp.dhs.gov.* Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP website at *https://www.cbp.gov/.*

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This proposed information collection was previously published in the **Federal Register** (89 FR 76866) on September 19, 2024, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: Application and Approval to Manipulate, Examine, Sample or Transfer Goods (CBP Form 3499).

OMB Number: 1651–0006.

Form Number: 3499.

Current Actions: This submission will renew the expiration date while updating the burden hours to reflect current usage. No change to information collected or method of collection.

Type of Review: Extension (with change).

Affected Public: Businesses.

Abstract: CBP Form 3499, ''Application and Approval to

Manipulate, Examine, Sample or Transfer Goods,'' is used as an application to perform various operations on merchandise located at a Customs and Border Protection (CBP) approved bonded facility. This form is filed by importers, bonded warehouse proprietors, consignees, transferees, or owners of merchandise, and is subject to approval by the port director. The data requested on the form identifies the merchandise for which action is being sought and specifies the operation that is to be performed. The form may also be approved as a blanket application to manipulate goods for a period of up to one year for continuous or repetitive manipulation. CBP Form 3499 is provided for by 19 U.S.C. 1562, and 19 CFR 158.43, 19.8, 19.11 and is accessible at: *https://www.cbp.gov/newsroom/publications/forms?title=3499&=Apply.*

Type of Information Collection: Form 3499.

Estimated Number of Respondents: 4,200.

Estimated Number of Annual Responses per Respondent: 60.

Estimated Number of Total Annual Responses: 252,000.

Estimated Time per Response: 6 minutes.

Estimated Total Annual Burden Hours: 25,200.

Dated: November 22, 2024.

Seth D. Renkema,

Branch Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection.

[FR Doc. 2024–27830 Filed 11–26–24; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[OMB Control Number 1651–0036]

Agency Information Collection Activities; Extension; Declaration of Ultimate Consignee That Articles Were Exported for Temporary Scientific or Educational Purposes

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 30-Day notice and request for comments.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection (CBP) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and must be submitted (no later than December 27, 2024) to be assured of consideration.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain* . Please submit written comments and/or suggestions in English. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177, Telephone number 202–325–0056 or via email *CBP_PRA@cbp.dhs.gov.* Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP website at *https://www.cbp.gov/.*

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This proposed information collection was previously published in the **Federal Register** (89 FR 78325) on September 25, 2024, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: Declaration of Ultimate Consignee That Articles Were Exported for Temporary Scientific or Educational Purposes.

OMB Number: 1651–0036.

Form Number: N/A.

Current Actions: CBP proposes to extend the expiration date of this information collection with no change to the burden hours or to the information collected.

Type of Review: Extension (without change).

Affected Public: Businesses.

Abstract: The Declaration of the Ultimate Consignee that Articles were Exported for Temporary Scientific or Educational Purposes is used to document duty free entry under conditions when articles are temporarily exported solely for scientific or educational purposes. This declaration is provided for under 19 U.S.C. 1202, HTSUS Subheading 9801.00.40, and 19 CFR 10.67(a)(3) which requires a declaration from the ultimate consignee stating that the articles were sent from the United States solely for temporary scientific or educational use and for no other use abroad than for exhibition, examination, or experimentation; and that the articles are being returned without having been changed in condition in any manner, except by reason of their bona fide use as described in the declaration. This declaration is submitted to CBP by the importer or the agent of the importer and is used by CBP to determine whether the imported articles should be free of duty.

Type of Information Collection: Declaration that Articles were Exported for Temporary Scientific or Educational Purposes.

Estimated Number of Respondents: 55.

Estimated Number of Annual Responses per Respondent: 3.

Estimated Number of Total Annual Responses: 165.

Estimated Time per Response: 10 minutes.

Estimated Total Annual Burden Hours: 27.

Dated: November 22, 2024.

Seth D Renkema,

Branch Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection.

[FR Doc. 2024–27828 Filed 11–26–24; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2024–0002]

Final Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: Flood hazard determinations, which may include additions or modifications of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or regulatory floodways on the Flood Insurance Rate Maps (FIRMs) and where applicable, in the supporting Flood Insurance Study (FIS) reports have been made final for the communities listed in the table below. The FIRM and FIS report are the basis of the floodplain management measures that a community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the Federal Emergency Management Agency's (FEMA's) National Flood Insurance Program (NFIP).

DATES: The date of March 25, 2025 has been established for the FIRM and, where applicable, the supporting FIS report showing the new or modified flood hazard information for each community.

ADDRESSES: The FIRM, and if applicable, the FIS report containing the final flood hazard information for each community is available for inspection at the respective Community Map Repository address listed in the tables below and will be available online through the FEMA Map Service Center at *https://msc.fema.gov* by the date indicated above.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the new or modified flood hazard information for each community listed. Notification of these changes has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Insurance and Mitigation has resolved any appeals resulting from this notification.

This final notice is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the new or revised FIRM and FIS report available at the address cited below for each community or online through the FEMA Map Service Center at *https://msc.fema.gov.*

The flood hazard determinations are made final in the watersheds and/or communities listed in the table below.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Nicholas A. Shufro,

Assistant Administrator (Acting) for Risk Management, Federal Emergency Management Agency, Department of Homeland Security.

Community	Community map repository address
Barber County, Kansas and Incorporated Areas Docket No.: FEMA–B–2378	
City of Hardtner	City Hall, 104 East Woodworth Avenue, Hardtner, KS 67057.
City of Hazelton	City Hall, 404 West Main Street, Hazelton, KS 67061.
City of Isabel	Barber County Courthouse, 120 East Washington Avenue, Medicine Lodge, KS 67104.
City of Kiowa	Barber County Courthouse, 120 East Washington Avenue, Medicine Lodge, KS 67104.
City of Medicine Lodge	City Hall, 114 West First Avenue, Medicine Lodge, KS 67104.
City of Sharon	Barber County Courthouse, 120 East Washington Avenue, Medicine Lodge, KS 67104.
City of Sun City	Barber County Courthouse, 120 East Washington Avenue, Medicine Lodge, KS 67104.
Unincorporated Areas of Barber County	Barber County Courthouse, 120 East Washington Avenue, Medicine Lodge, KS 67104.
Harper County, Kansas and Incorporated Areas Docket No.: FEMA–B–2374	
City of Anthony	Harper County Courthouse, 201 North Jennings Avenue, Anthony, KS 67003.
City of Attica	Harper County Courthouse, 201 North Jennings Avenue, Anthony, KS 67003.
City of Bluff City	Harper County Courthouse, 201 North Jennings Avenue, Anthony, KS 67003.
City of Danville	Harper County Courthouse, 201 North Jennings Avenue, Anthony, KS 67003.
City of Harper	Harper County Courthouse, 201 North Jennings Avenue, Anthony, KS 67003.
City of Waldron	Harper County Courthouse, 201 North Jennings Avenue, Anthony, KS 67003.

Community	Community map repository address
Unincorporated Areas of Harper County	Harper County Courthouse, 201 North Jennings Avenue, Anthony, KS 67003.
St. Louis County, Minnesota and Incorporated Areas Docket No.: FEMA–B–2360	
City of Aurora	City Hall, 16 West 2nd Avenue N, Aurora, MN 55705.
City of Babbitt	City Hall, 71 South Drive, Babbitt, MN 55706.
City of Biwabik	City Offices, 321 North Main Street, Biwabik, MN 55708.
City of Brookston	City Hall, 8757 1st Street S, Brookston, MN 55711.
City of Cook	City Hall, 127 South River Street, Cook, MN 55723.
City of Duluth	City Hall, 411 West 1st Street, Duluth, MN 55802.
City of Ely	City Hall, 209 East Chapman Street, Ely, MN 55731.
City of Floodwood	City Hall, 111 West 8th Avenue, Floodwood, MN 55736.
City of Hermantown	City Hall, 5105 Maple Grove Road, Hermantown, MN 55811.
City of Hibbing	City Hall, 401 East 21st Street, Hibbing, MN 55746.
City of Hoyt Lakes	Municipal Building, 206 Kennedy Memorial Drive, Hoyt Lakes, MN 55750.
City of Iron Junction	City Offices, 4141 Merrit Avenue, Iron Junction, MN 55751.
City of Meadowlands	Community Center, 7758 Western Avenue, Meadowlands, MN 55765.
City of Mountain Iron	City Hall, 8586 Enterprise Drive South, Mountain Iron, MN 55768.
City of Orr	City Hall, 4429 Highway 53, Orr, MN 55771.
City of Proctor	City Hall, 100 Pionk Drive, Proctor, MN 55810.
City of Rice Lake	Rice Lake City Hall, 4107 West Beyer Road, Duluth, MN 55803.
City of Tower	City Hall, 602 Main Street, Tower, MN 55790.
City of Virginia	City Hall, 327 South First Street, Virginia, MN 55792.
City of Winton	Community Center, 102 North Main Street, Winton, MN 55796.
Bois Forte Band of Chippewa	Boise Forte Band of Chippewa Tribal Government and Community Services Building, 5344 Lakeshore Drive, Nett Lake, MN 55772.
Fond du Lac Band of Lake Superior Chippewa	Fond du Lac Band of Lake Superior Chippewa Tribal Center, 1720 Big Lake Road, Cloquet, MN 55720.
Township of Gnesen	Gnesen Community Center, 6356 Howard Gnesen Road, Duluth, MN 55803.
Township of Lakewood	Lakewood Town Hall, 3110 Strand Road, Duluth, MN 55803.
Township of Midway	Midway Town Hall, 3230 Midway Road, Duluth, MN 55810.
Unincorporated Areas of St. Louis County	St. Louis County Courthouse, 100 North 5th Avenue W, Duluth, MN 55802.
Douglas County, Nebraska and Incorporated Areas Docket No.: FEMA–B–2261	
City of Bennington	City Hall, 15505 Warehouse Street, Bennington, NE 68007.
City of Omaha	Omaha-Douglas Civic Center, 1819 Farnam Street, Omaha, NE 68183.
City of Ralston	City Hall, 5500 South 77th Street, Ralston, NE 68127.
City of Valley	City Hall, 203 North Spruce Street, Valley, NE 68064.
Unincorporated Areas of Douglas County	Douglas County Environmental Services, 15335 West Maple Road, Suite 201, Omaha, NE 68116.
Village of Boys Town	Village Clerk, 14100 Crawford Street, Boys Town, NE 68010.
Village of Waterloo	Village Office, 509 South Front Street, Waterloo, NE 68069.
McIntosh County, North Dakota and Incorporated Areas Docket No.: FEMA–B–2222 and FEMA–B–2362	
City of Ashley	McIntosh County Courthouse, 112 1st Street NE, Ashley, ND 54813.
City of Lehr	McIntosh County Courthouse, 112 1st Street NE, Ashley, ND 54813.
City of Venturia	McIntosh County Courthouse, 112 1st Street NE, Ashley, ND 54813.
City of Wishek	McIntosh County Courthouse, 112 1st Street NE, Ashley, ND 54813.
City of Zeeland	McIntosh County Courthouse, 112 1st Street NE, Ashley, ND 54813.
Unincorporated Areas of McIntosh County	McIntosh County Courthouse, 112 1st Street NE, Ashley, ND 54813.
Chesterfield County, South Carolina and Incorporated Areas Docket No.: FEMA–B–2371	
Town of Cheraw	Town Hall, 200 Market Street, Cheraw, SC 29520.
Town of Chesterfield	Town Hall, 112 Main Street, Chesterfield, SC 29709.
Unincorporated Areas of Chesterfield County	Chesterfield County Administration Office, 178 Mill Street, Chesterfield, SC 29709.
Darlington County, South Carolina and Incorporated Areas Docket No.: FEMA–B–2371	
City of Darlington	City Hall, 400 Pearl Street, Darlington, SC 29532.
Unincorporated Areas of Darlington County	Darlington County Courthouse, 1 Public Square, Room 303, Darlington, SC 29532.

Community	Community map repository address
Florence County, South Carolina and Incorporated Areas Docket No.: FEMA–B–2371	
City of Florence	City Center, 324 West Evans Street, Florence, SC 29501.
Unincorporated Areas of Florence County	Florence County Planning and Building, 518 South Irby Street, Florence, SC 29501.
Spink County, South Dakota and Incorporated Areas Docket No.: FEMA–B–2380	
City of Ashton	City Hall, 14 Main Street, Ashton, SD 57424.
City of Conde	City Hall, 343 Broadway Street, Conde, SD 57434.
City of Doland	City Hall, 106 North 2nd Street, Doland, SD 57436.
City of Frankfort	City Hall, 404 Maple Street, Frankfort, SD 57440.
City of Redfield	City Hall, 626 Main Street, Redfield, SD 57469.
Town of Northville	Town Hall, 402 Thayer Street, Northville, SD 57465.
Town of Tulare	Community Hall, 112 Main Street, Tulare, SD 57476.
Town of Turton	Farmers State Bank, 123 East Center Street, Turton, SD 57477.
Unincorporated Areas of Spink County	Spink County Courthouse, 210 East 7th Avenue, Redfield, SD 57469.
Buckingham County, Virginia and Incorporated Areas Docket No.: FEMA–B–2375	
Unincorporated Areas of Buckingham County	Buckingham County Administration Building, 13380 West James Anderson Highway, Buckingham, VA 23921.

[FR Doc. 2024–27725 Filed 11–26–24; 8:45 am]
BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Immigration and Customs Enforcement

[Docket No. ICEB–2024–0010]

RIN 1653–ZA54

Employment Authorization for Lebanese F–1 Nonimmigrant Students Experiencing Severe Economic Hardship as a Direct Result of the Current Crisis in Lebanon

AGENCY: U.S. Immigration and Customs Enforcement; Department of Homeland Security.

ACTION: Notice.

SUMMARY: The Department of Homeland Security (DHS) is suspending certain regulatory requirements for F–1 nonimmigrant students from Lebanon who are experiencing severe economic hardship as a direct result of the current crisis in Lebanon. The Secretary is providing relief to these students who are in lawful F–1 nonimmigrant status, so the students may request employment authorization, work an increased number of hours while school is in session, and reduce their course load while continuing to maintain their F–1 nonimmigrant status.

DATES: This action covers eligible Lebanese F–1 nonimmigrant students beginning on November 27, 2024, and ending on May 27, 2026.

FOR FURTHER INFORMATION CONTACT: Sharon Snyder, Unit Chief, Policy and Response Unit, Student and Exchange Visitor Program, MS 5600, U.S. Immigration and Customs Enforcement, 500 12th Street SW, Washington, DC 20536–5600; email: *sevp@ice.dhs.gov,* telephone: (703) 603–3400. This is not a toll-free number. Program information can be found at *https://www.ice.gov/sevis/.*

SUPPLEMENTARY INFORMATION:

What action is DHS taking under this notice?

The Secretary is exercising authority under 8 CFR 214.2(f)(9) to temporarily suspend the applicability of certain requirements governing on-campus and off-campus employment for F–1 nonimmigrant students whose country of citizenship is Lebanon regardless of country of birth (or individuals having no nationality who last habitually resided in Lebanon), who are present in the United States in lawful F–1 nonimmigrant student status on the date of publication of this notice, and who are experiencing severe economic hardship as a direct result of the current crisis in Lebanon. Previously, DHS issued a notice which applied to F–1 nonimmigrant students from Lebanon who met certain criteria, including having been lawfully present in the United States in F–1 nonimmigrant status on July 26, 2024, that was effective through January 25, 2026. *See* 89 FR 83897 (Oct. 18, 2024). While DHS's prior notice remains effective for eligible F–1 nonimmigrant students, effective with this publication, suspension of the employment limitations is also available through May 27, 2026, for those who are in lawful F–1 nonimmigrant status on the date of publication of this notice. DHS will deem an F–1 nonimmigrant student granted employment authorization through this Notice to be engaged in a ''full course of study'' for the duration of the employment authorization, if the student satisfies the minimum course load set forth in this notice.[1] *See* 8 CFR 214.2(f)(6)(i)(F).

Who is covered by this notice?

This notice applies exclusively to F–1 nonimmigrant students who meet all of the following conditions:

(1) Are a citizen of Lebanon regardless of country of birth (or an individual having no nationality who last habitually resided in Lebanon);

(2) Were lawfully present in the United States on November 27, 2024, in F–1 nonimmigrant status under section 101(a)(15)(F)(i) of the Immigration and Nationality Act (INA), 8 U.S.C. 1101(a)(15)(F)(i);

(3) Are enrolled in an academic institution that is Student and Exchange Visitor Program (SEVP)-certified for

[1] Because the suspension of requirements under this notice applies throughout an academic term during which the suspension is in effect, DHS considers an F–1 nonimmigrant student who engages in a reduced course load or employment (or both) after this notice is effective to be engaging in a ''full course of study,'' *see* 8 CFR 214.2(f)(6), and eligible for employment authorization, through the end of any academic term for which such student is matriculated as of May 27, 2026, provided the student satisfies the minimum course load requirements in this notice.

enrollment for F–1 nonimmigrant students;

(4) Are currently maintaining F–1 nonimmigrant status; and

(5) Are experiencing severe economic hardship as a direct result of the current crisis in Lebanon.

This notice applies to F–1 nonimmigrant students in an approved private school in kindergarten through grade 12, public school grades 9 through 12, and undergraduate and graduate education. An F–1 nonimmigrant student covered by this notice who transfers to another SEVP-certified academic institution remains eligible for the relief provided by means of this notice.

Why is DHS taking this action?

DHS is taking action to provide relief to Lebanese F–1 nonimmigrant students experiencing severe economic hardship due to the current crisis in Lebanon. Based on its review of country conditions in Lebanon and input received from the U.S. Department of State (DOS), DHS is taking action to allow eligible F–1 nonimmigrant students from Lebanon to request employment authorization, work an increased number of hours while school is in session, and reduce their course load while continuing to maintain F–1 nonimmigrant student status.

Lebanon faces multiple and competing security threats, including political instability, civil unrest and violence, spill-over from the Syrian civil war, and increased border tension between Hezbollah [2] and Israel.[3] Additionally, the deteriorating economic situation has led to alarming levels of poverty, food insecurity, and crumbling infrastructure.[4]

Security Concerns

Since October 7, 2023, there has been an escalation of hostilities across the Lebanon-Israel border between Israeli forces and Hezbollah.[5] As of early October 2024, the conflict between Israel and Hezbollah escalated significantly.[6] Increased Israeli airstrikes in Lebanon, including urban regions in and around Beirut, have resulted in civilian casualties and displacement.[7] According to Lebanese authorities, more than 2,300 people have been killed since October 2023 and 1.2 million people have been forced to flee their homes.[8] On September 30, 2024, Israel launched a ground invasion into southern Lebanon days after an Israeli air strike killed Hassan Nasrallah, the leader of Hezbollah.[9] Rising tensions between Israel and Hezbollah have resulted in the evacuation of both Israeli and Lebanese residents in communities along both sides of the shared border.[10]

Economic Crisis

The recent intensification of military conflict and population displacement has exacerbated an existing economic crisis in Lebanon. In 2021, the International Monetary Fund (IMF) estimated that Lebanon's economic collapse may be the third worst economic crisis in the world since the mid-nineteenth century.[11] Four years after the collapse, in September 2023, the IMF warned that ''the small nation is still facing 'enormous economic challenges,' with a collapsed banking sector, eroding public services, deteriorating infrastructure, inflation, and worsening poverty.'' [12]

Poverty in Lebanon has more than tripled over the past decade reaching 44 percent of the total population in 2022.[13] Families in Lebanon are described as multidimensionally poor, with ''rising deprivation in the areas of health care, medicines, services, education employment, housing and assets.'' [14] Protective food subsidies have ended and living costs have risen dramatically, preventing families from accessing enough food and other basic needs each day.[15]

This economic crisis has caused Lebanon's Gross Domestic Product to ''decrease from $54.9 billion in 2018 to $17.94 billion in 2023.'' [16] Additionally, Lebanon is grappling with hyperinflation, which is eroding the purchasing power of much of the Lebanese population.[17] Data from June 2023 indicates ''that 59 percent of Lebanese households (and of these 86 percent of female headed households), excluding refugees, faced substantial challenges in meeting their needs, primarily driven by disrupted livelihoods.'' [18]

Political Crisis

Since 2021, reports have implicated current and former Lebanese prime ministers in corruption cases.[19] More

[2] Hezbollah (also spelled ''Hizballah'') was designated as a foreign terrorist organization in 1997. *See* U.S. Dep't of State, Country Reports on Terrorism 2022, 276, Nov. 30, 2023, available at *https://www.state.gov/wp-content/uploads/2023/11/Country_Reports_on_Terrorism_2022-v3.pdf* (accessed Nov. 8, 2024).

[3] Instability in Lebanon, Global Conflict Tracker, Center for Preventive Action, Council on Foreign Relations, Oct. 28, 2024, available at *https://www.cfr.org/global-conflict-tracker/conflict/political-instability-lebanon* (last visited Nov. 5, 2024).

[4] Famine Early Warning System, Escalating conflict leads to rising population in need of food assistance, Sept. 2024, available at *https://fews.net/middle-east-and-asia/lebanon/key-message-update/september-2024* (last visited Nov. 5, 2024); Mass displacement in Lebanon war revives spectre of sectarian strife, Reuters, Oct. 15, 2024, available at *https://www.reuters.com/world/middle-east/mass-displacement-lebanon-war-revives-spectre-sectarian-strife-2024-10-15* (last visited Nov. 5, 2024).

[5] Instability in Lebanon, Global Conflict Tracker, Center for Preventive Action, Council on Foreign Relations, Oct. 28, 2024, available at *https://www.cfr.org/global-conflict-tracker/conflict/political-instability-lebanon* (last visited Nov. 5, 2024).

[6] ReliefWeb, Statement by the Humanitarian Coordinator for Lebanon, Imran Riza, on the One-Year Mark of Escalations in Lebanon, Oct. 9, 2024, available at *https://reliefweb.int/report/lebanon/statement-humanitarian-coordinator-lebanon-imran-riza-one-year-mark-escalations-lebanon-9-october-2024-enar* (last visited Nov. 5, 2024).

[7] Melanie Lidman, Bassam Hatoum, and Bassem Mroue, Israel expands its bombardment in Lebanon as thousands flee widening war, AP, Oct. 5, 2024, available at *https://apnews.com/article/mideast-wars-lebanon-hezbollah-hamas-5-october-2024-a8b70daeccc57a86fc6d939c604f2caf* (last visited Nov. 5, 2024).

[8] BBC, Israel-Hezbollah conflict in maps: Where is fighting happening in Lebanon, Oct. 17, 2024, available at *https://www.bbc.com/news/articles/c9vp7dg3ml1o* (last visited Nov. 5, 2024).

[9] *Id.*

[10] NPR, Israel begins ground offensive in Lebanon, Oct. 1, 2024, available at *https://www.npr.org/2024/10/01/g-s1-25657/israel-ground-offensive-lebanon* (last visited Nov. 5, 2024).

[11] The World Bank, Lebanon Economic Monitor, Spring 2021: Lebanon Sinking (to the Top 3), available at *https://www.worldbank.org/en/country/lebanon/publication/lebanon-economic-monitor-spring-2021-lebanon-sinking-to-the-top-3* (last visited Nov. 5, 2024).

[12] Bassem Mroue, IMF warns Lebanon that the country is still facing enormous challenges, years after a meltdown began, Reuters, Sept. 15, 2023, available at *https://apnews.com/article/lebanon-imf-central-bank-sayrafa-banks-meltdown-0d56ddea8dc9510d110959f794a06ed9* (last visited Nov. 5, 2024).

[13] World Bank, Lebanon Poverty and Equity Assessment 2024: Weathering a Protracted Crisis (English). Washington, D.C: World Bank Group, May 23, 2024, available at *http://documents.worldbank.org/curated/en/099052224104516741/P1766511325da10a71ab6b1ae97816dd20c* (last visited Nov. 5, 2024).

[14] United Nations Economic and Social Commission for Western Asia (ESCWA), Multidimensional poverty in Lebanon (2019–2021), available at *https://www.unescwa.org/sites/default/files/news/docs/21-00634-_multidimentional_poverty_in_lebanon_-policy_brief_-_en.pdf* (last visited Nov. 5, 2024).

[15] United Nations, Around 2 million facing food insecurity across Lebanon, Jan. 19, 2023, available at *https://news.un.org/en/story/2023/01/1132642* (last visited Nov. 5, 2024).

[16] Flash Appeal: Lebanon, October—December 2024, OCHA, October 2024, available at *https://www.unocha.org/publications/report/lebanon/flash-appeal-lebanon-october-december-2024-october-2024* (last visited Nov. 5, 2024).

[17] *Id.*

[18] *Id.*

[19] The Washington Post, Pandora Papers: Leaks prompt investigations in some countries—and denial in others, Oct. 9, 2021, available at: *https://www.washingtonpost.com/world/2021/10/09/russia-ukraine-jordan-lebanon-pandora-papers/* (last visited Nov. 5, 2024).

crucially, Lebanon has not had a President since 2022, when Michel Aoun stepped down a day before his presidential term expired.[20] The country's affairs are run by an unelected caretaker government; [21] with no elected president, passage of new legislation and much needed economic reform is not occurring.[22] Moreover, since the hostilities increased between Israel and Hezbollah, tensions have also increased between Hezbollah and Sunni and Maronite factions in the government, making political agreements unlikely in the near-term.[23]

The inability to effectively govern in Lebanon has resulted in financial insolvency, crumbling infrastructure, and the inability to provide basic services including access to electricity and fuel.[24] Human Rights Watch reported that, ''[o]n August 17, 2024, Lebanon's only operational power plant shut down after the state-run electricity company . . . ran out of fuel, resulting in a complete nationwide power outage.'' [25] This outage left residents of Lebanon and key state services like ''the airport, water pump stations, sewage systems, and prisons, without state-provided electricity for more than 24 hours, and reliant on costly and highly polluting private diesel generators.'' [26] The Lebanese state is unable to provide the vast majority of residents with more than one to three hours of electricity per day.[27] This lack of access to electricity has adversely impacted Lebanese residents' access to education, health, water, sanitation, and a healthy environment.[28]

Humanitarian Concerns

The economic crisis, government failings, and increasingly escalating conflict have worsened an already fragile humanitarian situation in Lebanon.[29] Access to sufficient food, water, sanitation, hygiene, shelter, income, essential commodities, and healthcare have decreased.[30] Humanitarian needs continue to increase amid the escalating hostilities in Lebanon, exacerbated by the damage to vital infrastructure and the scale of internal and external displacement from conflict-affected areas of the country.[31] As of October 21, 2024, over 800,000 individuals were internally displaced in Lebanon.[32] More than 191,000 individuals have sought shelter in over 1,000 collective shelters, the vast majority of which are operating at full capacity.[33] Furthermore, the United Nations High Commissioner for Refugees estimates that approximately 425,000 people, including Syrians and Lebanese, have crossed from Lebanon into Syria since September, while more than 16,000 Lebanese have arrived in Iraq from Lebanon.[34] On October 4, 2024, the U.S. committed to providing nearly $157 million in new humanitarian assistance to support populations affected by conflict in Lebanon and the region.[35]

Access to health care had been drastically reduced due to financial barriers and lack of medicine in Lebanon.[36] The current hostilities have aggravated the issues, with services struggling to respond to the needs of the displaced and conflict-affected,[37] and health care facilities have been either destroyed or closed due to the conflict.[38]

Access to food and potable water continue to be limited. As of October 2024, ''at least 25 water facilities [were] damaged affecting more than 300,000 people.'' [39] According to the World Food Programme, 2.5 million people of the 5.3 million population need food assistance and 2.5 million, 47.5 percent, of people in Lebanon (including Lebanese nationals and refugees) are food insecure.[40]

Moreover, increasing levels of internal displacement are exacerbating the challenges facing Lebanon, including those related to hosting the substantial Syrian refugee population.[41] Children have also been impacted by the conflict. The start of the new school year has been postponed until November 4, 2024, as 75 percent of the country's public schools have been converted into shelters to accommodate the influx of internally displaced persons that have departed conflict-affected areas of

[20] Lebanon's president leaves with no replacement amid political, economic crisis, PBS News Hour, Oct. 30, 2022, available at *https://www.pbs.org/newshour/world/lebanons-president-leaves-with-no-replacement-amid-political-economic-crisis* (last visited Nov. 5, 2024); Matt Bradley, Analysis: As was rages, some in Lebanon see opportunity in a weakened Hezbollah, NBC News, Oct. 4, 2024, available at *https://www.nbcnews.com/news/world/israel-hezbollah-war-nasrallah-airstrikes-hamas-gaza-assassinations-rcna173851* (last visited Nov. 5, 2024).

[21] Key Developments in 2023: Lebanon, Freedom House, 2023, available at *https://freedomhouse.org/country/lebanon/freedom-world/2024* (last visited Nov. 5, 2024).

[22] Matt Bradley, Analysis: As war rages, some in Lebanon see opportunity in a weakened Hezbollah, NBC News, Oct. 4, 2024, available at *https://www.nbcnews.com/news/world/israel-hezbollah-war-nasrallah-airstrikes-hamas-gaza-assassinations-rcna173851* (last visited Nov. 5, 2024).

[23] Instability in Lebanon, Global Conflict Tracker, Center for Preventive Action, Council on Foreign Relations, Oct. 28, 2024, available at *https://www.cfr.org/global-conflict-tracker/conflict/political-instability-lebanon* (last visited Nov. 5, 2024).

[24] International Organization for Migration, Lebanon Crisis Response Plan 2024, available at *https://crisisresponse.iom.int/response/lebanon-crisis-response-plan-2024* (last visited Nov. 5, 2024).

[25] Human Rights Watch, Lebanon: Nationwide Electricity Blackout, Aug. 29, 2024, available at *https://www.hrw.org/news/2024/08/29/lebanon-nationwide-electricity-blackout* (last visited Nov. 5, 2024).

[26] *Id.*

[27] Human Rights Watch, ''Cut Off From Life Itself'' Lebanon's Failure on the Right to Electricity, Mar. 9, 2023, available at *https://www.hrw.org/report/2023/03/09/cut-life-itself/lebanons-failure-right-electricity* (last visited Nov. 5, 2024).

[28] *Id.*

[29] United Nations Office for the Coordination of Humanitarian Affairs (OCHA), Today's top news: Israel and Occupied Palestinian Territory, Lebanon, Sudan, Oct. 7, 2024, available at *https://www.unocha.org/news/todays-top-news-israel-and-occupied-palestinian-territory-lebanon-sudan* (last visited Nov. 5, 2024).

[30] *Id;* World Food Programme, Lebanon, available at *https://www.wfp.org/countries/lebanon* (last visited Nov. 5, 2024).

[31] *Id.*

[32] OCHA, Lebanon Flash Update #37, Oct. 23, 2024, available at *https://reliefweb.int/report/lebanon/lebanon-flash-update-37-escalation-hostilities-lebanon-21-october-2024* (last visited Nov. 5, 2024)

[33] OCHA, Lebanon Flash Update #37, Oct. 23, 2024, available at *https://reliefweb.int/report/lebanon/lebanon-flash-update-37-escalation-hostilities-lebanon-21-october-2024* (last visited Nov. 5, 2024)

[34] The United Nations High Commissioner for Human Rights Syria Flash Update #17, Sept. 24–Oct 20, 2024, available at *https://reporting.unhcr.org/syrian-arab-republic-response-displacement-lebanon-flash-update-17* (last visited Nov. 5, 2024); OCHA, Lebanon Flash Update #37, Oct. 23, 2024, available at *https://reliefweb.int/report/lebanon/lebanon-flash-update-37-escalation-hostilities-lebanon-21-october-2024* (last visited Nov. 5, 2024); OCHA, Iraq Flash Update #14: Update on Displacement from Lebanon, Oct. 20, 2024, available at *https://reliefweb.int/report/iraq/iraq-flash-update-14-update-displacement-lebanon-20-october-2024* (last visited Nov. 5, 2024).

[35] U.S. Dep't of State, United States Provides Humanitarian Assistance in Response to the Escalating Crisis in Lebanon, Oct. 4, 2024, available at *https://www.state.gov/united-states-provides-humanitarian-assistance-in-response-to-the-escalating-crisis-in-lebanon/* (last visited Nov. 5, 2024).

[36] European Commission, Lebanon, available at *https://civil-protection-humanitarian-aid.ec.europa.eu/where/middle-east-and-northern-africa/lebanon_en* (last visited Nov. 5, 2024).

[37] *Id.*

[38] OCHA, Today's top news: Israel and Occupied Palestinian Territory, Lebanon, Sudan, Oct. 7, 2024, available at *https://www.unocha.org/news/todays-top-news-israel-and-occupied-palestinian-territory-lebanon-sudan* (last visited Nov. 5, 2024).

[39] OCHA, Today's top news: Israel and Occupied Palestinian Territory, Lebanon, Sudan, Oct. 7, 2024, available at *https://www.unocha.org/news/todays-top-news-israel-and-occupied-palestinian-territory-lebanon-sudan* (last visited Nov. 5, 2024).

[40] World Food Programme, Lebanon, available at *https://www.wfp.org/countries/lebanon* (last visited Nov. 5, 2024).

[41] Flash Appeal: Lebanon, October–December 2024, OCHA, October 2024, available at *https://www.unocha.org/publications/report/lebanon/flash-appeal-lebanon-october-december-2024-october-2024* (last visited Nov. 5, 2024).

Lebanon since the recent escalation.[42] According to the European Commission, ''[m]ore than 10 percent of the 1.2 million school-aged Lebanese children are out of school, mainly due to economic vulnerabilities.'' [43]

As of November 7, 2024, 1,760 F–1 nonimmigrant students from Lebanon are enrolled at SEVP-certified academic institutions in the United States. Given the extent of the current crisis exacerbated by recent escalating violence, conflict and displacement in Lebanon, affected students whose primary means of financial support comes from Lebanon may need to be exempt from the normal student employment requirements to continue their studies in the United States. The current crisis has made it unfeasible for many students to safely return to Lebanon for the foreseeable future. Without employment authorization, these students may lack the means to meet basic living expenses.

What is the minimum course load requirement to maintain valid F–1 nonimmigrant status under this notice?

Undergraduate F–1 nonimmigrant students who receive on-campus or off-campus employment authorization under this notice must remain registered for a minimum of six semester or quarter hours of instruction per academic term. Undergraduate F–1 nonimmigrant students enrolled in a term of different duration must register for at least one half of the credit hours normally required under a ''full course of study.'' *See* 8 CFR 214.2(f)(6)(i)(B) and (F). A graduate-level F–1 nonimmigrant student who receives on-campus or off-campus employment authorization under this notice must remain registered for a minimum of three semester or quarter hours of instruction per academic term. *See* 8 CFR 214.2(f)(5)(v). Nothing in this notice affects the applicability of other minimum course load requirements set by the academic institution.

In addition, an F–1 nonimmigrant student (either undergraduate or graduate) granted on-campus or off-campus employment authorization under this notice may count up to the equivalent of one class or three credits per session, term, semester, trimester, or quarter of online or distance education toward satisfying this minimum course load requirement, unless their course of study is in an English language study program. *See* 8 CFR 214.2(f)(6)(i)(G). An F–1 nonimmigrant student attending an approved private school in kindergarten through grade 12 or public school in grades 9 through 12 must maintain ''class attendance for not less than the minimum number of hours a week prescribed by the school for normal progress toward graduation,'' as required under 8 CFR 214.2(f)(6)(i)(E). Nothing in this notice affects the applicability of federal and state labor laws limiting the employment of minors.

May an eligible F–1 nonimmigrant student who already has on-campus or off-campus employment authorization benefit from the suspension of regulatory requirements under this notice?

Yes. An F–1 nonimmigrant student who is a Lebanon citizen, regardless of country of birth (or an individual having no nationality who last habitually resided in Lebanon), who already has on-campus or off-campus employment authorization and is otherwise eligible may benefit under this notice, which suspends certain regulatory requirements relating to the minimum course load requirement under 8 CFR 214.2(f)(6)(i) and certain employment eligibility requirements under 8 CFR 214.2(f)(9). Such an eligible F–1 nonimmigrant student may benefit without having to apply for a new Form I–766, Employment Authorization Document (EAD). To benefit from this notice, the F–1 nonimmigrant student must request that their designated school official (DSO) enter the following statement in the remarks field of the student's Student and Exchange Visitor Information System (SEVIS) record, which the student's Form I–20, Certificate of Eligibility for Nonimmigrant (F–1) Student Status, will reflect:

Approved for more than 20 hours per week of [DSO must insert ''on-campus'' or ''off-campus,'' depending upon the type of employment authorization the student already has] employment authorization and reduced course load under the Special Student Relief authorization from [DSO must insert the beginning date of the notice or the beginning date of the student's employment, whichever date is later] until [DSO must insert either the student's program end date, the current EAD expiration date (if the student is currently authorized for off-campus employment), or the end date of this notice, whichever date comes first].[44]

Must the F–1 nonimmigrant student apply for reinstatement after expiration of this special employment authorization if the student reduces his or her ''full course of study''?

No. DHS will deem an F–1 nonimmigrant student who receives and comports with the employment authorization permitted under this notice to be engaged in a ''full course of study'' [45] for the duration of the student's employment authorization, provided that a qualifying undergraduate level F–1 nonimmigrant student remains registered for a minimum of six semester or quarter hours of instruction per academic term, and a qualifying graduate level F–1 nonimmigrant student remains registered for a minimum of three semester or quarter hours of instruction per academic term. *See* 8 CFR 214.2(f)(5)(v) and (f)(6)(i)(F). Undergraduate F–1 nonimmigrant students enrolled in a term of different duration must register for at least one half of the credit hours normally required under a ''full course of study.'' *See* 8 CFR 214.2(f)(6)(i)(B) and (F). DHS will not require such students to apply for reinstatement under 8 CFR 214.2(f)(16) if they are otherwise maintaining F–1 nonimmigrant status.

Will an F–2 dependent (spouse or minor child) of an F–1 nonimmigrant student covered by this notice be eligible for employment authorization?

No. An F–2 spouse or minor child of an F–1 nonimmigrant student is not authorized to work in the United States and, therefore, may not accept employment while in F–2 nonimmigrant status, consistent with 8CFR 214.2(f)(15)(i).

Will the suspension of the applicability of the standard student employment requirements apply to an individual who receives an initial F–1 visa and makes an initial entry into the United States after the effective date of this notice in the Federal Register?

No. The suspension of the applicability of the standard regulatory

[42] ReliefWeb, Statement by the Humanitarian Coordinator for Lebanon, Imran Riza, on the One-Year Mark of Escalations in Lebanon, Oct. 9, 2024, available at *https://reliefweb.int/report/lebanon/statement-humanitarian-coordinator-lebanon-imran-riza-one-year-mark-escalations-lebanon-9-october-2024-enar* (last visited Nov. 5, 2024).

[43] European Commission, Lebanon, available at *https://civil-protection-humanitarian-aid.ec.europa.eu/where/middle-east-and-northern-africa/lebanon_en* (last visited Nov. 5, 2024).

[44] Because the suspension of requirements under this notice applies throughout an academic term during which the suspension is in effect, DHS considers an F–1 nonimmigrant student who engages in a reduced course load or employment (or both) after this notice is effective to be engaging in a ''full course of study,'' *see* 8 CFR 214.2(f)(6), and eligible for employment authorization, through the end of any academic term for which such student is matriculated as of May 27, 2026, provided the student satisfies the minimum course load requirements in this notice.

[45] *See* 8 CFR 214.2(f)(6).

requirements only applies to certain F–1 nonimmigrant students who meet the following conditions:

(1) Are a citizen of Lebanon regardless of country of birth (or an individual having no nationality who last habitually resided in Lebanon);

(2) Were lawfully present in the United States on November 27, 2024, in F–1 nonimmigrant status, under section 101(a)(15)(F)(i) of the INA, 8 U.S.C. 1101(a)(15)(F)(i);

(3) Are enrolled in an academic institution that is SEVP-certified for enrollment of F–1 nonimmigrant students;

(4) Are maintaining F–1 nonimmigrant status; and

(5) Are experiencing severe economic hardship as a direct result of the current crisis in Lebanon.

An F–1 nonimmigrant student who does not meet all these requirements is ineligible for the suspension of the applicability of the standard regulatory requirements (even if experiencing severe economic hardship as a direct result of the current crisis in Lebanon).

Does this notice apply to a continuing F–1 nonimmigrant student who departs the United States after the effective date of this notice in the Federal Register and who needs to obtain a new F–1 visa before returning to the United States to continue an educational program?

Yes. This notice applies to such an F–1 nonimmigrant student, but only if the DSO has properly notated the student's SEVIS record, which will then appear on the student's Form I–20. The normal rules for visa issuance remain applicable to a nonimmigrant who needs to apply for a new F–1 visa to continue an educational program in the United States.

Does this notice apply to elementary school, middle school, and high school students in F–1 status?

Yes. However, this notice does not by itself reduce the required course load for F–1 nonimmigrant students from Lebanon enrolled in kindergarten through grade 12 at a private school, or grades 9 through 12 at a public high school. Such students must maintain the minimum number of hours of class attendance per week prescribed by the academic institution for normal progress toward graduation, as required under 8CFR214.2(f)(6)(i)(E). The suspension of certain regulatory requirements related to employment through this notice is applicable to all eligible F–1 nonimmigrant students regardless of educational level. Eligible F–1 nonimmigrant students from Lebanon enrolled in an elementary school, middle school, or high school may benefit from the suspension of the requirement in 8 CFR 214.2(f)(9)(i) that limits on-campus employment to 20 hours per week while school is in session.

On-Campus Employment Authorization

Will an F–1 nonimmigrant student who receives on-campus employment authorization under this notice be authorized to work more than 20 hours per week while school is in session?

Yes. For an F–1 nonimmigrant student covered in this notice, the Secretary is suspending the applicability of the requirement in 8 CFR 214.2(f)(9)(i) that limits an F–1 nonimmigrant student's on-campus employment to 20 hours per week while school is in session. An eligible F–1 nonimmigrant student has authorization to work more than 20 hours per week while school is in session if the DSO has entered the following statement in the remarks field of the student's SEVIS record, which will be reflected on the student's Form I–20:

> Approved for more than 20 hours per week of on-campus employment and reduced course load, under the Special Student Relief authorization from [DSO must insert the beginning date of this notice or the beginning date of the student's employment, whichever date is later] until [DSO must insert the student's program end date or the end date of this notice, whichever date comes first].[46]

To obtain on-campus employment authorization, the F–1 nonimmigrant student must demonstrate to the DSO that the employment is necessary to avoid severe economic hardship directly resulting from the current crisis in Lebanon. An F–1 nonimmigrant student authorized by the DSO to engage in on-campus employment by means of this notice does not need to file any applications with U.S. Citizenship and Immigration Services (USCIS). The standard rules permitting full-time on-campus employment when school is not in session or during school vacations apply, as described in 8 CFR 214.2(f)(9)(i).

Will an F–1 nonimmigrant student who receives on-campus employment authorization under this notice have authorization to reduce the normal course load and still maintain his or her F–1 nonimmigrant student status?

Yes. DHS will deem an F–1 nonimmigrant student who receives on-campus employment authorization under this notice to be engaged in a ''full course of study'' [47] for the purpose of maintaining their F–1 nonimmigrant student status for the duration of the on-campus employment, if the student satisfies the minimum course load requirement described in this notice, consistent with 8 CFR 214.2(f)(6)(i)(F). However, the authorization to reduce the normal course load is solely for DHS purposes of determining valid F–1 nonimmigrant student status. Nothing in this notice mandates that school officials allow an F–1 nonimmigrant student to take a reduced course load if the reduction would not meet the academic institution's minimum course load requirement for continued enrollment.[48]

Off-Campus Employment Authorization

What regulatory requirements does this notice temporarily suspend relating to off-campus employment?

For an F–1 nonimmigrant student covered by this notice, as provided under 8 CFR 214.2(f)(9)(ii)(A), the Secretary is suspending the following regulatory requirements relating to off-campus employment:

(a) The requirement that a student must have been in F–1 nonimmigrant student status for one full academic year to be eligible for off-campus employment;

(b) The requirement that an F–1 nonimmigrant student must demonstrate that acceptance of employment will not interfere with the student's carrying a full course of study;

(c) The requirement that limits an F–1 nonimmigrant student's employment authorization to no more than 20 hours per week of off-campus employment while the school is in session; and

(d) The requirement that the student demonstrate that employment under 8 CFR 214.2(f)(9)(i) is unavailable or otherwise insufficient to meet the needs that have arisen as a result of the unforeseen circumstances.

[46] Because the suspension of requirements under this notice applies throughout an academic term during which the suspension is in effect, DHS considers an F–1 nonimmigrant student who engages in a reduced course load or employment (or both) after this notice is effective to be engaging in a ''full course of study,'' *see* 8 CFR 214.2(f)(6), and eligible for employment authorization, through the end of any academic term for which such student is matriculated as of May 27, 2026, provided the student satisfies the minimum course load requirements in this notice.

[47] *See* 8 CFR 214.2(f)(6).

[48] Minimum course load requirement for enrollment in a school must be established in a publicly available document (*e.g.,* catalog, website, or operating procedure), and it must be a standard applicable to all students (U.S. citizens and foreign students) enrolled at the school.

Will an F–1 nonimmigrant student who receives off-campus employment authorization under this notice have authorization to reduce the normal course load and still maintain F–1 nonimmigrant status?

Yes. DHS will deem an F–1 nonimmigrant student who receives off-campus employment authorization by means of this notice to be engaged in a ''full course of study'' [49] for the purpose of maintaining F–1 nonimmigrant student status for the duration of the student's employment authorization if the student satisfies the minimum course load requirement described in this notice, consistent with 8 CFR 214.2(f)(6)(i)(F). The authorization for a reduced course load is solely for DHS purposes of determining valid F–1 nonimmigrant student status. Nothing in this notice mandates that school officials allow an F–1 nonimmigrant student to take a reduced course load if such reduced course load would not meet the school's minimum course load requirement.[50]

How may an eligible F–1 nonimmigrant student obtain employment authorization for off-campus employment with a reduced course load under this notice?

An F–1 nonimmigrant student must file a Form I–765, Application for Employment Authorization, with USCIS to apply for off-campus employment authorization based on severe economic hardship directly resulting from the current crisis in Lebanon.[51] Filing instructions are located at *https://www.uscis.gov/i-765*.

Fee considerations. Submission of a Form I–765 currently requires payment of a $520 fee. An applicant who is unable to pay the fee may submit a completed Form I–912, Request for Fee Waiver, along with the Form I–765, Application for Employment Authorization. *See https://www.uscis.gov/i-912*. The submission must include an explanation about why USCIS should grant the fee waiver and the reason(s) for the inability to pay, and any evidence to support the reason(s). *See* 8 CFR 106.2 and 106.3.

Supporting documentation. An F–1 nonimmigrant student seeking off-campus employment authorization due to severe economic hardship must demonstrate the following to their DSO:

(1) This employment is necessary to avoid severe economic hardship; and

(2) The hardship is a direct result of the current crisis in Lebanon.

If the DSO agrees that the F–1 nonimmigrant student is entitled to receive such employment authorization, the DSO must recommend application approval to USCIS by entering the following statement in the remarks field of the student's SEVIS record, which will then appear on that student's Form I–20:

> Recommended for off-campus employment authorization in excess of 20 hours per week and reduced course load under the Special Student Relief authorization from the date of the USCIS authorization noted on Form I–766 until [DSO must insert the program end date or the end date of this notice, whichever date comes first].[52]

The F–1 nonimmigrant student must then file the properly endorsed Form I–20 and Form I–765 according to the instructions for the Form I–765. The F–1 nonimmigrant student may begin working off campus only upon receipt of the EAD from USCIS.

DSO recommendation. In making a recommendation that an F–1 nonimmigrant student be approved for Special Student Relief, the DSO certifies that:

(a) The F–1 nonimmigrant student is in good academic standing and is carrying a ''full course of study'' [53] at the time of the request for employment authorization;

(b) The F–1 nonimmigrant student is a citizen of Lebanon, regardless of country of birth (or an individual having no nationality who last habitually resided in Lebanon), and is experiencing severe economic hardship as a direct result of the current crisis in Lebanon, as documented on the Form I–20;

(c) The F–1 nonimmigrant student has confirmed that the student will comply with the reduced course load requirements of this notice and register for the duration of the authorized employment for a minimum of six semester or quarter hours of instruction per academic term if at the undergraduate level, or for a minimum of three semester or quarter hours of instruction per academic term if the student is at the graduate level; [54] and

(d) The off-campus employment is necessary to alleviate severe economic hardship to the individual as a direct result of the current crisis in Lebanon.

Processing. To facilitate prompt adjudication of the student's application for off-campus employment authorization under 8 CFR 214.2(f)(9)(ii)(C), the F–1 nonimmigrant student should do both of the following:

(a) Ensure that the application package includes the following documents:

(1) A completed Form I–765 with all applicable supporting evidence;

(2) The required fee or properly documented fee waiver request as defined in 8 CFR 106.2 and 106.3; and

(3) A signed and dated copy of the student's Form I–20 with the appropriate DSO recommendation, as previously described in this notice; and

(b) Send the application in an envelope which is clearly marked on the front of the envelope, bottom right-hand side, with the phrase ''SPECIAL STUDENT RELIEF.'' [55] Failure to include this notation may result in significant processing delays.

If USCIS approves the student's Form I–765, USCIS will send the student a Form I–766 EAD as evidence of employment authorization. The EAD will contain an expiration date that does not exceed the end of the granted temporary relief.

Temporary Protected Status (TPS) Considerations

Can an F–1 nonimmigrant student apply for TPS and for benefits under this notice at the same time?

Yes. An F–1 nonimmigrant student who has not yet applied for TPS or for other relief that reduces the student's course load per term and permits an increased number of work hours per week, such as Special Student Relief,[56] under this notice has two options.

Under the first option, the F–1 nonimmigrant student may apply for TPS according to the instructions in the USCIS notice designating Lebanon for TPS elsewhere in this issue of the **Federal Register**. All TPS applicants must file a Form I–821, Application for

[49] *See* 8 CFR 214.2(f)(6).

[50] Minimum course load requirement for enrollment in a school must be established in a publicly available document (*e.g.,* catalog, website, or operating procedure), and it must be a standard applicable to all students (U.S. citizens and foreign students) enrolled at the school.

[51] *See* 8 CFR 274a.12(c)(3)(iii).

[52] Because the suspension of requirements under this notice applies throughout an academic term during which the suspension is in effect, DHS considers an F–1 nonimmigrant student who engages in a reduced course load or employment (or both) after this notice is effective to be engaging in a ''full course of study,'' *see* 8 CFR 214.2(f)(6), and eligible for employment authorization, through the end of any academic term for which such student is matriculated as of May 27, 2026, provided the student satisfies the minimum course load requirements in this notice.

[53] *See* 8 CFR 214.2(f)(6).

[54] 8 CFR 214.2(f)(5)(v).

[55] Students who wish to apply for a Special Student Relief-related EAD under this notice should use the mailing address specifically designated for (C)(3)(iii) filings. The direct filing address is available at *https://www.uscis.gov/i-765-addresses* (last visited Sept. 12, 2024).

[56] *See* DHS Study in the States, Special Student Relief, available at *https://studyinthestates.dhs.gov/students/special-student-relief* (last visited Feb. 28, 2024).

Temporary Protected Status, with the appropriate fee (or request a fee waiver). Although not required to do so, if F–1 nonimmigrant students want to obtain a new TPS-related EAD that is valid through May 27, 2026, and to be eligible for automatic EAD extensions that may be available to certain EADs with an A–12 or C–19 category code, they must file Form I–765 and pay the Form I–765 fee (or request a fee waiver). After receiving the TPS-related EAD, an F–1 nonimmigrant student may request that their DSO make the required entry in SEVIS and issue an updated Form I–20, which notates that the nonimmigrant student has been authorized to carry a reduced course load, as described in this notice. As long as the F–1 nonimmigrant student maintains the minimum course load described in this notice, does not otherwise violate their nonimmigrant status, including as provided under 8 CFR 214.1(g), and maintains TPS, then the student maintains F–1 status and TPS concurrently.

Under the second option, the F–1 nonimmigrant student may apply for an EAD under Special Student Relief by filing Form I–765 with the location specified in the filing instructions. At the same time, the F–1 nonimmigrant student may file a separate TPS application but must submit the Form I–821 according to the instructions provided in the **Federal Register** notice designating Lebanon for TPS. If the F–1 nonimmigrant student has already applied for employment authorization under Special Student Relief, they are not required to submit the Form I–765 as part of the TPS application. However, some nonimmigrant students may wish to obtain a TPS-related EAD in light of certain extensions that may be available to EADs with an A–12 or C–19 category code that are not available to the C–3 category under which Special Student Relief falls. The F–1 nonimmigrant student should check the appropriate box when filling out Form I–821 to indicate whether a TPS-related EAD is being requested. Again, as long as the F–1 nonimmigrant student maintains the minimum course load described in this notice and does not otherwise violate the student's nonimmigrant status, included as provided under 8 CFR 214.1(g), the nonimmigrant will be able to maintain compliance requirements for F–1 nonimmigrant student status while having TPS.

When a student applies simultaneously for TPS and benefits under this notice, what is the minimum course load requirement while an application for employment authorization is pending?

The F–1 nonimmigrant student must maintain normal course load requirements for a ''full course of study'' [57] unless or until the nonimmigrant student receives employment authorization under this notice. TPS-related employment authorization, by itself, does not authorize a nonimmigrant student to drop below twelve credit hours, or otherwise applicable minimum requirements (*e.g.,* clock hours for non-traditional academic programs). Once approved for a TPS-related EAD and Special Student Relief employment authorization, as indicated by the DSO's required entry in SEVIS and issuance of an updated Form I–20, the F–1 nonimmigrant student may drop below twelve credit hours, or otherwise applicable minimum requirements (with a minimum of six semester or quarter hours of instruction per academic term if at the undergraduate level, or for a minimum of three semester or quarter hours of instruction per academic term if at the graduate level). *See* 8 CFR 214.2(f)(5)(v), (f)(6), and (f)(9)(i) and (ii).

How does a student who has received a TPS-related EAD then apply for authorization to take a reduced course load under this notice?

There is no further application process with USCIS if a student has been approved for a TPS-related EAD. The F–1 nonimmigrant student must demonstrate and provide documentation to the DSO of the direct economic hardship resulting from the current crisis in Lebanon. The DSO will then verify and update the student's record in SEVIS to enable the F–1 nonimmigrant student with TPS to reduce the course load without any further action or application. No other EAD needs to be issued for the F–1 nonimmigrant student to have employment authorization.

Can a noncitizen who has been granted TPS apply for reinstatement of F–1 nonimmigrant student status after the noncitizen's F–1 nonimmigrant student status has lapsed?

Yes. Regulations permit certain students who fall out of F–1 nonimmigrant student status to apply for reinstatement. *See* 8 CFR 214.2(f)(16). This provision may apply to students who worked on a TPS-related EAD or dropped their course load before publication of this notice, and therefore fell out of student status. These students must satisfy the criteria set forth in the F–1 nonimmigrant student status reinstatement regulations.

Deferred Enforced Departure (DED) Considerations

Can an F–1 nonimmigrant student apply for a DED-related EAD and for benefits under this notice at the same time?

Yes. Although they are not required to apply for a DED-related EAD, an F–1 nonimmigrant student who meets the eligibility requirements under the applicable DED notice and wants to obtain such an EAD must file Form I–765 and pay the related fee (or request a fee waiver). The eligible F–1 student may also apply for Special Student Relief under this notice by requesting that the DSO notate on their Form I–20 in SEVIS that the student has been authorized to carry a reduced course load and is permitted to work an increased number of hours under Special Student Relief while school is in session. The DSO should also notate on the Form I–20 that the student is working pursuant to a DED-related EAD. As long as the F–1 nonimmigrant student maintains the minimum course load described in this notice, does not otherwise violate the student's nonimmigrant status, including as provided under 8 CFR 214.1(g), and remains covered under DED, then the student maintains F–1 nonimmigrant status and DED concurrently.

When a student applies simultaneously for a DED-related EAD and benefits under this notice, what is the minimum course load requirement while an application for employment authorization is pending?

The F–1 nonimmigrant student must maintain normal course load requirements for a ''full course of study'' [58] unless or until the F–1 nonimmigrant student is granted employment authorization under this notice. DED-related employment authorization, by itself, does not authorize a nonimmigrant student to drop below twelve credit hours, or otherwise applicable minimum requirements (*e.g.,* clock hours for non-traditional academic programs). Once approved for a DED-related EAD and Special Student Relief employment authorization, as indicated by the DSO's required entry in SEVIS and issuance of an updated Form I–20, the F–1 nonimmigrant student may drop below

[57] *See* 8 CFR 214.2(f)(6).

[58] *See* 8 CFR 214.2(f)(6).

twelve credit hours, or otherwise applicable minimum requirements (with a minimum of six semester or quarter hours of instruction per academic term if the student is at the undergraduate level, or a minimum of three semester or quarter hours of instruction per academic term if the student is at the graduate level). *See* 8 CFR 214.2(f)(5)(v), 214.2(f)(6), 214.2(f)(9)(i) and (ii).

How does an F–1 student who has received a DED-related EAD then apply for authorization to take a reduced course load under this notice?

There is no further application process with USCIS if a student has been approved for a DED-related EAD. However, the F–1 nonimmigrant student must demonstrate and provide documentation to the DSO of severe economic hardship as a direct result of the current humanitarian crisis in Lebanon. The DSO will then verify and update the student's SEVIS record to enable the F–1 nonimmigrant student with DED to reduce their course load without any further action or application. No other EAD needs to be issued for the F–1 nonimmigrant student to have employment authorization.

Can a noncitizen who has been granted a DED-related EAD apply for reinstatement to F–1 nonimmigrant student status after the noncitizen's F–1 nonimmigrant student status has lapsed?

Yes. Current regulations permit certain students who fall out of F–1 nonimmigrant student status to apply for reinstatement. *See* 8 CFR 214.2(f)(16). This provision might apply to students who worked on a DED-related EAD or dropped their course load before July 26, 2024, and therefore fell out of F–1 nonimmigrant status. The student must satisfy the criteria set forth in the F–1 nonimmigrant student status reinstatement regulations.

How long will this notice remain in effect?

This notice grants temporary relief until May 27, 2026,[59] to eligible F–1 nonimmigrant students. DHS will continue to monitor the situation in Lebanon. Should the special provisions authorized by this notice need modification or extension, DHS will announce such changes in the **Federal Register**.

Paperwork Reduction Act (PRA)

An F–1 nonimmigrant student seeking off-campus employment authorization due to severe economic hardship resulting from the current crisis in Lebanon must demonstrate to the DSO that this employment is necessary to avoid severe economic hardship. A DSO who agrees that a nonimmigrant student should receive such employment authorization must recommend an application approval to USCIS by entering information in the remarks field of the student's SEVIS record. The authority to collect this information is in the SEVIS collection of information currently approved by the Office of Management and Budget (OMB) under OMB Control Number 1653–0038.

This notice also allows an eligible F–1 nonimmigrant student to request employment authorization, work an increased number of hours while the academic institution is in session, and reduce their course load while continuing to maintain F–1 nonimmigrant student status.

To apply for employment authorization, certain F–1 nonimmigrant students must complete and submit a currently approved Form I–765 according to the instructions on the form. OMB has previously approved the collection of information contained on the current Form I–765, consistent with the PRA (OMB Control Number 1615–0040). Although there will be a slight increase in the number of Form I–765 filings because of this notice, the number of filings currently contained in the OMB annual inventory for Form I–765 is sufficient to cover the additional filings. Accordingly, there is no further action required under the PRA.

Alejandro Mayorkas,

Secretary, U.S. Department of Homeland Security.

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[59] Because the suspension of requirements under this notice applies throughout an academic term during which the suspension is in effect, DHS considers an F–1 nonimmigrant student who engages in a reduced course load or employment (or both) after this notice is effective to be engaging in a ''full course of study,'' *see* 8 CFR 214.2(f)(6), and eligible for employment authorization, through the end of any academic term for which such student is matriculated as of May 27, 2026, provided the student satisfies the minimum course load requirements in this notice.

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[CIS No. 2789–25; DHS Docket No. USCIS–2024–0015]

RIN 1615–ZC11

Designation of Lebanon for Temporary Protected Status

AGENCY: U.S. Citizenship and Immigration Services (USCIS), Department of Homeland Security (DHS).

ACTION: Notice of Temporary Protected Status (TPS) designation.

SUMMARY: Through this notice, the Department of Homeland Security (DHS) announces that the Secretary of Homeland Security (Secretary) is designating Lebanon for Temporary Protected Status (TPS) for 18 months, beginning on November 27, 2024, and ending on May 27, 2026. This designation allows Lebanese nationals (and individuals having no nationality who last habitually resided in Lebanon) who have continuously resided in the United States since October 16, 2024, and who have been continuously physically present in the United States since November 27, 2024, to apply for TPS.

DATES: *Designation of Lebanon for TPS* begins on November 27, 2024, and will remain in effect for 18 months. For registration instructions, see the Registration Information section below.

FOR FURTHER INFORMATION CONTACT:

- You may contact René Cutlip-Mason, Chief, Humanitarian Affairs Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security, by mail at 5900 Capital Gateway Drive, Camp Springs, MD 20746, or by phone at 240–721–3000.
- For further information on TPS, including guidance on the registration process and additional information on eligibility, please visit the USCIS TPS web page at *https://uscis.gov/tps.* You can find specific information about Lebanon's TPS designation by selecting ''Lebanon'' from the menu on the left side of the TPS web page.
- If you have additional questions about TPS, please visit *https://uscis.gov/tools.* Our online virtual assistant, Emma, can answer many of your questions and point you to additional information on our website. If you cannot find your answers there, you may also call our USCIS Contact Center at 800–375–5283 (TTY 800–767–1833).

• Applicants seeking information about the status of their individual cases may check Case Status Online, available on the USCIS website at *uscis.gov*, or visit the USCIS Contact Center at *https://uscis.gov/contactcenter.*

• You can also find more information at local USCIS offices after this notice is published.

SUPPLEMENTARY INFORMATION:

Table of Abbreviations

BIA—Board of Immigration Appeals
CFR—Code of Federal Regulations
DHS—U.S. Department of Homeland Security
DoS—U.S. Department of State
EAD—Employment Authorization Document
FNC—Final Nonconfirmation
Form I–131—Application for Travel Documents, Parole Documents, and Arrival/Departure Records
Form I–765—Application for Employment Authorization
Form I–797—Notice of Action (Approval Notice)
Form I–797C—Notice of Action (Receipt Notice)
Form I–821—Application for Temporary Protected Status
Form I–9—Employment Eligibility Verification
Form I–912—Request for Fee Waiver
Form I–94—Arrival/Departure Record
FR—Federal Register
Government—U.S. Government
IER—U.S. Department of Justice, Civil Rights Division, Immigrant and Employee Rights Section
IJ—Immigration Judge
INA—Immigration and Nationality Act
PDF—Portable Document Format
SAVE—USCIS Systematic Alien Verification for Entitlements Program
Secretary—Secretary of Homeland Security
TPS—Temporary Protected Status
TTY—Text Telephone
USCIS—U.S. Citizenship and Immigration Services
U.S.C.—United States Code

Registration Information

Registration: The registration period for individuals to apply for TPS begins on November 27, 2024, and will remain in effect through May 27, 2026.

Purpose of This Action (TPS)

Through this notice, DHS sets forth procedures necessary for nationals of Lebanon (or individuals having no nationality who last habitually resided in Lebanon) to submit an initial registration application under the designation of Lebanon for TPS and apply for an Employment Authorization Document (EAD). Under the designation, individuals must submit an initial Application for Temporary Protected Status (Form I–821) for Lebanon, and they may also submit an Application for Employment Authorization (Form I–765), during the 18-month initial registration period that runs from November 27, 2024, through May 27, 2026. In addition to demonstrating continuous residence in the United States since October 16, 2024,[1] and meeting other eligibility criteria, initial applicants for TPS under this designation must demonstrate that they have been continuously physically present in the United States since November 27, 2024, the effective date of this designation of Lebanon, before USCIS may grant them TPS. DHS estimates that approximately 11,000 individuals are eligible to apply for TPS under the designation of Lebanon.

What is Temporary Protected Status (TPS)?

• TPS is a temporary immigration status granted to eligible nationals of a foreign state designated for TPS under the INA, or to eligible individuals without nationality who last habitually resided in the designated foreign state, regardless of their country of birth.

• During the TPS designation period, TPS beneficiaries are eligible to remain in the United States, may not be removed, are authorized to work, and may obtain EADs if they continue to meet the requirements of TPS.

• TPS beneficiaries may also apply for and be granted travel authorization as a matter of DHS discretion.

• To qualify for TPS, beneficiaries must meet the eligibility standards at INA section 244(c)(1)–(2), 8 U.S.C. 1254a(c)(1)–(2).

• When the Secretary terminates a foreign state's TPS designation, beneficiaries return to one of the following:

○ The same immigration status or category that they maintained before TPS, if any (unless that status or category has since expired or terminated); or

○ Any other lawfully obtained immigration status or category they received while registered for TPS, as long as it is still valid beyond the date TPS terminates.

What authority does the Secretary have to designate Lebanon for TPS?

Section 244(b)(1) of the INA, 8 U.S.C. 1254a(b)(1), authorizes the Secretary, after consultation with appropriate agencies of the U.S. Government, to designate a foreign state (or part thereof) for TPS if the Secretary determines that certain country conditions exist.[2] The Secretary may designate a country (or part of a country) for TPS on the basis of an ''ongoing armed conflict'' in the country if, due to such conflict, requiring the return of that country's nationals ''would pose a serious threat to their personal safety.'' [3] The Secretary also may designate a country (or part thereof) for TPS if the Secretary finds ''that there exist extraordinary and temporary conditions'' in the country that prevent that country's nationals ''from returning to the [country] in safety,'' unless the Secretary finds that permitting such nationals ''to remain temporarily in the United States is contrary to the national interest of the United States.'' [4]

The decision to designate any foreign state (or part thereof) is a discretionary decision, and there is no judicial review of any determination with respect to the designation, termination, or extension of a designation. *See* INA sec. 244(b)(5)(A), 8 U.S.C. 1254a(b)(5)(A). The Secretary, at their discretion, may then grant TPS to eligible nationals of that foreign state (or individuals having no nationality who last habitually resided in the designated foreign state). *See* INA sec. 244(a)(1)(A), 8 U.S.C. 1254a(a)(1)(A).

At least 60 days before the expiration of a foreign state's TPS designation or extension, the Secretary, after consultation with appropriate U.S. Government agencies, must review the conditions in the foreign state designated for TPS to determine whether they continue to meet the conditions for the TPS designation. *See* INA sec. 244(b)(3)(A), 8 U.S.C. 1254a(b)(3)(A). If the Secretary determines that the conditions in the foreign state continue to meet the conditions for TPS designation, the designation will be extended for an additional period of six months or, in the Secretary's discretion, 12 or 18 months. *See* INA sec. 244(b)(3)(A), (C), 8 U.S.C. 1254a(b)(3)(A), (C). If the Secretary determines that the foreign

[1] The ''continuous residence date'' (CR) is any date established by the Secretary when a country is designated (or sometimes redesignated) for TPS. The ''continuous physical presence date'' (CPP) is the effective date of the most recent TPS designation of the country, which is either the publication date of the designation announcement in the **Federal Register** or a later date established by the Secretary. *See* INA sec. 244(b)(2)(A) (effective date of designation), (c)(1)(A)(i)–(ii) (discussing CR and CPP date requirements); 8 U.S.C. 1254a(b)(2)(A), (c)(1)(A)(i)–(ii).

[2] Although INA section 244(b)(1) ascribes this power to the Attorney General, Congress transferred this authority from the Attorney General to the Secretary of Homeland Security. *See* Homeland Security Act of 2002, Pub. L. 107–296, 116 Stat. 2135 (2002); *see also* 8 U.S.C. 1103(a); 6 U.S.C. 557.

[3] INA sec. 244(b)(1)(A), 8 U.S.C. 1254a(b)(1)(A).

[4] INA sec. 244(b)(1)(C), 8 U.S.C. 1254a(b)(1)(C). In addition, the Secretary may designate a country (or part thereof) for TPS based on an environmental disaster if the country has officially requested such designation and certain other statutory requirements are met. INA sec. 244(b)(1)(B), 8 U.S.C. 1254a(b)(1)(B).

state no longer meets the conditions for TPS designation, the Secretary must terminate the designation. *See* INA sec. 244(b)(3)(B), 8 U.S.C. 1254a(b)(3)(B).

Why was Lebanon designated for TPS?

DHS has reviewed conditions in Lebanon. Based on this review, including input received from the Department of State (DoS) and other U.S. Government agencies, the Secretary has determined that an 18-month TPS designation is warranted because of armed conflict and extraordinary and temporary conditions described below.[5]

Overview

Long-standing humanitarian needs in Lebanon have been exacerbated by an escalation of armed conflict in the country, resulting in civilian casualties and massive numbers of displaced individuals. Lebanon was already grappling with profound socioeconomic and political crises, and the destruction and casualties caused by the ongoing armed conflict further threaten the safety of people in Lebanon and have significantly intensified the impact of the crises on people in Lebanon.

Armed Conflict

Since October 7, 2023, there has been an escalation of hostilities across the Lebanon-Israel border between Hezbollah [6] and the Israel Defense Forces. By September 2024, the conflict between Israel and Hezbollah had significantly escalated, with Israel launching a ground invasion of southern Lebanon on September 30, 2024.[7] Israeli airstrikes targeting Hezbollah strongholds, including in urban regions in and around Beirut, caused civilian casualties and displacement.[8]

Since October 2023, more than 2,000 people in Lebanon have been killed and almost 10,000 injured, with approximately 1,100 people in Lebanon killed and 7,000 injured between September 17, 2024, and October 7, 2024 alone.[9] Approximately one million people have been impacted by the conflict, with estimates of between 541,000 and one million people being displaced in Lebanon, and over 200,000 people have fled to Syria.[10] The armed conflict has resulted in one of the deadliest periods in Lebanon's recent history.[11]

Economic Crisis

Lebanon has been experiencing an economic crisis since 2019.[12] In October 2019, the Lebanese pound collapsed due to the nation's ''unstable fixed exchange rate, large external and fiscal deficits, and mounting losses in the banking sector, which led to an abrupt reduction of capital inflows.'' [13] In March 2020, Lebanon defaulted on its government debt for the first time in its history.[14] Since the onset of the financial crisis in 2019, the Lebanese pound has lost more than 98% of its value.[15] In 2021, the International Monetary Fund (IMF) estimated that Lebanon's economic collapse may be the third worst economic crisis in the world since the mid-nineteenth century.[16] Almost four years after the collapse, in December 2023, the IMF warned that ''the small nation is still facing 'enormous economic challenges,' with a collapsed banking sector, eroding public services, deteriorating infrastructure and worsening poverty.'' [17]

Poverty in Lebanon has more than tripled over the past decade reaching 44% of the total population.[18] Families in Lebanon are described as multidimensionally poor, with ''rising deprivation in the areas of health care, medicines, services, education employment, housing and assets.'' [19]

[5] This TPS designation for Lebanon is separate and apart from the President's July 26, 2024 memorandum providing for deferred enforced departure (DED) for certain Lebanese nationals in the United States. *See Deferred Enforced Departure for Certain Lebanese Nationals,* 89 FR 61341 (July 26, 2024); *see also Implementation of Employment Authorization for Individuals Covered by Deferred Enforced Departure for Lebanon,* 89 FR 83901 (Oct. 18, 2024).

[6] Hezbollah (also spelled ''Hizballah'') was designated as a foreign terrorist organization in 1997. *See* U.S. Dep't of State, Country Reports on Terrorism 2022, 276, Nov. 30, 2023, available at *https://www.state.gov/wp-content/uploads/2023/11/Country_Reports_on_Terrorism_2022-v3.pdf* (accessed Oct. 15, 2024).

[7] Israel-Hezbollah conflict in maps: Where is fighting happening in Lebanon, BBC, Oct. 9, 2024, available at: *https://www.bbc.com/news/articles/c9vp7dg3ml1o* (last visited Oct. 31, 2024); ReliefWeb, Statement By the Humanitarian Coordinator for Lebanon, Imran Riza, on the One-Year Mark of Escalations in Lebanon, 9 October 2024, available at: *https://reliefweb.int/report/lebanon/statement-humanitarian-coordinator-lebanon-imran-riza-one-year-mark-escalations-lebanon-9-october-2024-enar* (accessed Oct. 31, 2024).

[8] Melanie Lidman, Bassam Hatoum, and Bassem Mroue, Israel expands its bombardment in Lebanon as thousands flee widening war, AP, October 5, 2024, available at: *https://apnews.com/article/mideast-wars-lebanon-hezbollah-hamas-5-october-2024-a8b70daeccc57a86fc6d939c604f2caf* (accessed Oct. 31, 2024).

[9] 9 Lebanon: Flash Update #33—Escalation of hostilities in Lebanon, United Nations Office for the Coordination of Humanitarian Affairs (OCHA), Oct. 9, 2024, available at: *https://reliefweb.int/report/lebanon/lebanon-flash-update-33-escalation-hostilities-lebanon-7-october-2024* (last visited Oct. 31, 2024); Lebanon: At a Glance—Escalation of hostilities in Lebanon, as of 07 October 2024, United Nations Office for the Coordination of Humanitarian Affairs (OCHA), Oct. 7, 2024, available at: *https://reliefweb.int/report/lebanon/lebanon-glance-escalation-hostilities-lebanon-07-october-2024-assistance-provided-27-september-2024* (last visited Oct. 31, 2024).

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Continued

Protective food subsidies have ended and living costs have risen dramatically, preventing families from accessing enough food and other basic needs each day.[20]

Political Crisis

Since 2022, reports have implicated current and former Lebanese prime ministers in corruption cases.[21] More crucially, Lebanon has not had a President since 2022, when Michel Aoun stepped down a day before his presidential term expired.[22] The country's affairs are run by an unelected caretaker government; with no elected president, passage of new legislation and much needed economic reform is not occurring.[23] Moreover, since the hostilities increased between Israel and Hezbollah, tensions have also increased between Hezbollah and Sunni and Maronite factions, making political agreements unlikely in the near-term.[24]

The inability to effectively govern in Lebanon has resulted in financial insolvency, crumbling infrastructure, and the inability to provide basic services including access to electricity and fuel.[25] Problems with the electric utility are particularly severe, leading to shortages, including in August of this year when ''Lebanon's only operational power plant shut down after the state-run electricity company . . . ran out of fuel, resulting in a complete nationwide power outage.'' [26] The blackout ''left residents and key state institutions, such as the airport, water pump stations, sewage systems, and prisons, without state-provided electricity for more than 24 hours, and reliant on costly and highly polluting private diesel generators.'' [27] The Lebanese state is unable to provide the vast majority of citizens with more than one to three hours of electricity per day.[28] This lack of access to electricity has adversely impacted access to education, health, water, sanitation, and a healthy environment.[29]

Humanitarian Crisis

The economic crisis, government failings, and recent escalating conflict have worsened an already fragile humanitarian situation in Lebanon.[30] According to the United Nations Office for the Coordination of Humanitarian Affairs, ''one year on from the escalation of hostilities across the country's southern border, Lebanon's humanitarian crisis is deteriorating at an alarming rate,'' with Israeli airstrikes expanding beyond the border into civilian areas and greatly impacting vulnerable populations in Lebanon.[31] Access to sufficient food, water, and healthcare has decreased.[32] Humanitarian needs continue to increase amid the escalating hostilities in Lebanon, exacerbated by the damage to vital infrastructure.[33]

Financial barriers and lack of medicine have significantly reduced access to health care in Lebanon.[34] The ongoing hostilities have aggravated these issues, with services struggling to respond to the needs of the displaced and conflict-affected,[35] and health care facilities have been either destroyed or closed due to the conflict.[36] Access to food and potable water continue to be limited, as ''[w]ater infrastructure is also affected with to date, at least 25 water facilities damaged affecting more than 300,000 people.'' [37] According to the World Food Programme, 2.5 million people of the 5.3 million population need food assistance and 47.5 percent of people in Lebanon (including Lebanese nationals and refugees) are food insecure.[38]

Moreover, increasing levels of internal displacement are exacerbating the challenges facing Lebanon, including those related to hosting the substantial Syrian refugee population.[39] Children have also been impacted by the conflict. The start of the new school year has been postponed until November 4th as 75 percent of the country's public schools have been converted into shelters.[40] ''More than 10% of the 1.2

Multidimensional poverty in Lebanon (2019–2021), available at: *https://www.unescwa.org/sites/default/files/news/docs/21-00634-_multidimentional_poverty_in_lebanon_-policy_brief_-_en.pdf* (accessed Oct. 31, 2024).

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[29] *Id.*

[30] OCHA, Today's top news: Israel and Occupied Palestinian Territory, Lebanon, Sudan, Oct. 7, 2024, available at: *https://www.unocha.org/news/todays-top-news-israel-and-occupied-palestinian-territory-lebanon-sudan* (accessed Oct. 31, 2024).

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[32] OCHA, Today's top news: Israel and Occupied Palestinian Territory, Lebanon, Sudan, Oct. 7, 2024, available at: *https://www.unocha.org/news/todays-top-news-israel-and-occupied-palestinian-territory-lebanon-sudan* (accessed Oct. 31, 2024); World Food Programme, Lebanon, available at: *https://www.wfp.org/countries/lebanon* (accessed Oct. 31, 2024).

[33] OCHA, Today's top news: Israel and Occupied Palestinian Territory, Lebanon, Sudan, Oct. 7, 2024, available at: *https://www.unocha.org/news/todays-top-news-israel-and-occupied-palestinian-territory-lebanon-sudan* (accessed Oct. 31, 2024).

[34] European Commission, Lebanon, available at: *https://civil-protection-humanitarian-aid.ec.europa.eu/where/middle-east-and-northern-africa/lebanon_en#:~:text=People%20in%20Lebanon%2C%20including%20refugees,are%20dramatically%20exacerbating%20these%20vulnerabilities* (accessed Oct. 31, 2024).

[35] *Id.*

[36] OCHA, Today's top news: Israel and Occupied Palestinian Territory, Lebanon, Sudan, Oct. 7, 2024, available at: *https://www.unocha.org/news/todays-top-news-israel-and-occupied-palestinian-territory-lebanon-sudan* (accessed Oct. 31, 2024).

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[38] World Food Programme, Lebanon, available at: *https://www.wfp.org/countries/lebanon* (accessed Oct. 31, 2024).

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[40] ReliefWeb, Statement by the Humanitarian Coordinator for Lebanon, Imran Riza, on the One-Year Mark of Escalations in Lebanon, 9 October 2024, available at: *https://reliefweb.int/report/lebanon/statement-humanitarian-coordinator-*

million school-aged Lebanese children are out of school, mainly due to economic vulnerabilities. Additionally, 54% of the 715,000 Syrian refugee children are out of formal education, with only 47,000 of them accessing some form of non-formal education.'' [41]

In summary, based on the escalation of armed conflict and its resulting impacts on critical infrastructure, pre-existing economic and political crises, and further deteriorating humanitarian conditions, Lebanese nationals are unable to return safely to their homes.

Notice of the Designation of Lebanon for TPS

By the authority vested in me as Secretary under INA section 244, 8 U.S.C. 1254a, I have determined, after consultation with the appropriate U.S. Government agencies, the statutory conditions supporting Lebanon's designation for TPS on the basis of armed conflict and extraordinary and temporary conditions are met, and it is not contrary to the national interest of the United States to permit TPS Lebanon beneficiaries to remain in the United States temporarily. *See* INA sec. 244(b)(1)(A) and (C), 8 U.S.C. 1254a(b)(1)(A) and (C). I estimate approximately 11,000 individuals may be eligible for TPS under the designation of Lebanon. On the basis of this determination, I am designating Lebanon for TPS for 18 months, beginning on November 27, 2024, and ending on May 27, 2026. *See* INA sec. 244(b)(1) and (b)(2); 8 U.S.C. 1254a(b)(1), and (b)(2).

Alejandro N. Mayorkas

Secretary, U.S. Department of Homeland Security.

Eligibility and Employment Authorization for TPS

Required Application Forms and Application Fees To Register for TPS

To register for TPS based on the designation of Lebanon, you must submit a Form I–821 and pay the filing fee (or request a fee waiver, which you may submit on Form I–912). You also need to pay a biometric services fee. If you cannot pay the biometric services fee, you may ask USCIS to waive the fee. Please see additional information under the ''Biometric Services Fee'' section of this notice.

TPS beneficiaries are eligible for an EAD, which proves they are authorized to work in the United States. You do not need to submit Form I–765 or have an EAD to be granted TPS, but if you want an EAD to use as proof that you can work in the United States, see below for more information.

For more information on the application forms and fees for TPS, please visit the USCIS TPS web page at *https://www.uscis.gov/tps*. Fees for the Form I–821, the Form I–765, and biometric services are also described in 8 CFR 106.2 and the fee waiver-related regulations in 8 CFR 106.3. In addition, USCIS Form G–1055, Fee Schedule, provides the current fees required for the Form I–821 and Form I–765 for TPS applicants.

How can TPS beneficiaries obtain an Employment Authorization Document (EAD)?

Everyone must provide their employer with documentation showing that they have the legal right to work in the United States. TPS beneficiaries are eligible to obtain an EAD, which proves their legal right to work. If you want to obtain an EAD, you must file Form I–765 and pay the Form I–765 fee (or request a fee waiver, which you may submit on Form I–912). TPS applicants may file this form along with their TPS application, or at a later date, if their TPS application is still pending or has been approved.

Refiling an Initial TPS Registration Application After Receiving a Denial of a fee Waiver Request

If USCIS denies your fee waiver request, you can resubmit your TPS application. The fee waiver denial notice will contain specific instructions about resubmitting your application.

Filing Information

USCIS offers the option to applicants for TPS under Lebanon's designation to file Form I–821 and related requests for EADs online or by mail. However, if you file Form I–912, Request for Fee Waiver or a written fee waiver request for your Form I–821 or any applications filed together with your Form I–821, you must submit your applications by mail. When filing a TPS application, you can also request an EAD by submitting a completed Form I–765 with your Form I–821. Under certain circumstances, you may also upload a completed Form I–765 with a fee or fee waiver request, in Portable Document Format (PDF) through your USCIS online account. More information about filing your Form I–765 and fee waiver request through a PDF upload is available at *https://www.uscis.gov/newsroom/stakeholder-messages/uscis-launches-online-pdf-filing-option*.

Online filing: Form I–821 and Form I–765 are available for concurrent filing online.[42] To file these forms online, you must first create a USCIS online account.[43]

PDF upload: Form I–765, if applicable, and Form I–912, if applicable, are available for PDF upload. To upload these documents, you must first create a USCIS online account.[44]

Mail filing: Mail your completed Form I–821; Form I–765, if applicable; Form I–912, if applicable; and supporting documentation to the proper address in Table 1—Mailing Addresses.

TABLE 1—MAILING ADDRESSES

If you send your paper application via:	Then, mail your application to:
U.S. Postal Service USPS:	USCIS Attn: TPS Lebanon, P.O. Box 6943, Chicago, IL 60680–6943.
FedEx, UPS, or DHL deliveries:	USCIS Attn: TPS Lebanon (Box 6943), 131 S. Dearborn St. 3rd Floor, Chicago, IL 60603–5517.

If you were granted TPS by an immigration judge (IJ) or the Board of Immigration Appeals (BIA) and you want to request an EAD, you may submit Form I–765 one of three ways: online, mail your Form I–765 to the appropriate address in table 1, or upload a completed PDF through your USCIS online account. If you file online, you must include the fee. If you file by mail, you must include the fee or fee waiver request. If you file by PDF upload, you must include the fee or a fee waiver request. When you request an EAD based on an IJ or BIA grant of TPS, include with your application a copy of the order from the IJ or BIA granting you TPS. This will help us verify your grant of TPS and process your application.

Supporting Documents

The filing instructions for Form I–821 list all the documents you need to establish eligibility for TPS. You may

lebanon-imran-riza-one-year-mark-escalations-lebanon-9-october-2024-enar (accessed Oct. 31, 2024).

[41] European Commission, Lebanon, available at: *https://civil-protection-humanitarian-aid.ec.europa.eu/where/middle-east-and-northern-africa/lebanon_en#:~:text=People%20in%20Lebanon%2C%20including%20refugees,are%20dramatically%20exacerbating%20these%20vulnerabilities* (accessed Oct. 31, 2024).

[42] Find information about online filing at ''Forms Available to File Online,'' *https://www.uscis.gov/file-online/forms-available-to-file-online.*

[43] *https://myaccount.uscis.gov/users/sign_up.*

[44] *https://www.uscis.gov/newsroom/stakeholder-messages/uscis-launches-online-pdf-filing-option.* Sign up to create a new USCIS online account at *https://myaccount.uscis.gov/users/sign_up.*

also find information on the acceptable documentation and other requirements for applying (also called registering) for TPS on the USCIS website at *https://uscis.gov/tps* under ''Lebanon.''

Travel

TPS beneficiaries and TPS applicants with pending Form I–821 applications may also apply for travel authorization, which USCIS may grant as a matter of discretion. You must file for travel authorization if you wish to travel outside of the United States. If USCIS grants travel authorization, it gives you permission to leave the United States and return during a specific period. To request travel authorization, you must file Form I–131, available at *https://www.uscis.gov/i-131.* You may file Form I–131 together with your Form I–821 or separately.

When you file Form I–131, a TPS beneficiary must:

- Select Item Number 4 in Part 1 on the Form I–131; and
- Submit the fee for Form I–131, or request a fee waiver, which you may submit on Form I–912.

When you file Form I–131, a TPS applicant with a pending Form I–821 must:

- Select Item Number 5C in Part 1 on the Form I–131; and
- Submit the fee for Form I–131, or request a fee waiver, which you may submit on Form I–912.

If you are filing Form I–131 together with Form I–821, send your forms to the address listed in table 1. If you are filing Form I–131 separately based on a pending or approved Form I–821, send your form to the address listed in table 2 and include a copy of Form I–797, Notice of Action, or Form I–797C, Notice of Action, indicating either approval or receipt of Form I–821. Form I–131 may not be filed by PDF upload.

TABLE 2—MAILING ADDRESSES

If you are . . .	Mail to . . .
Filing Form I–131 together with a Form I–821	The address provided in table 1.
Filing Form I–131 based on a pending or approved Form I–821, and you are using the U.S. Postal Service (USPS): You must include a copy of the Notice of Action (Form I–797C or I–797) showing USCIS received or approved your Form I–821.	USCIS, Attn: I–131 TPS, P.O. Box 660167, Dallas, TX 75266–0867.
Filing Form I–131 based on a pending or approved Form I–821, and you are using FedEx, UPS, or DHL: You must include a copy of the Notice of Action (Form I–797C or Form I–797) showing USCIS received or approved your Form I–821.	USCIS, Attn: I–131 TPS, 2501 S. State Hwy. 121 Business, Ste. 400, Lewisville, TX 75067.

Biometric Services Fee for TPS

Biometrics (such as fingerprints) are required for all applicants, in addition to a biometric services fee. As previously stated, if you cannot pay the biometric services fee, you may request a fee waiver, which you may submit on Form I–912. For more information on the application forms and fees for TPS, please visit the USCIS TPS web page at *https://uscis.gov/tps.* USCIS may require you to visit an Application Support Center to have your biometrics collected. For additional information on the USCIS biometric screening process, please see the USCIS Customer Profile Management Service Privacy Impact Assessment, available at *https://www.dhs.gov/publication/dhsuscispia-060-customer-profile-management-service-cpms.*

General Employment-Related Information for TPS Applicants and Their Employers

How can I obtain information on the status of my TPS application and EAD request?

To get case status information about your TPS application, as well as the status of your TPS-based EAD request, you can check Case Status Online at uscis.gov or visit the USCIS Contact Center at *https://uscis.gov/contactcenter.* If you still need assistance, you may ask a question about your case online at *https://egov.uscis.gov/e-request/Intro.do* or call the USCIS Contact Center at 800–375–5283 (TTY 800–767–1833).

When hired, what documentation may I show my employer as evidence of identity and employment authorization to complete Form I–9?

You can find the Lists of Acceptable Documents on Form I–9, Employment Eligibility Verification, as well as on the Acceptable Documents web page at *https://uscis.gov/i-9-central/acceptable-documents.* Employers must complete Form I–9 to verify the identity and employment authorization of all new employees. Within three business days of hire, employees must present acceptable documents to their employers as evidence of identity and employment authorization to satisfy Form I–9 requirements.

You may present one selection from List A (which provides evidence of both identity and employment authorization) or one selection from List B (which provides evidence of your identity) together with one selection from List C (which provides evidence of employment authorization), or you may present an acceptable receipt as described in these lists. Employers may not reject a document based on a future expiration date. You can find additional information about Form I–9 on the I–9 Central web page at *https://www.uscis.gov/I-9Central.* An EAD is an acceptable document under List A.

If I have an EAD based on another immigration status, can I obtain a new TPS-based EAD?

Yes, if you are eligible for TPS, you can obtain a new TPS-based EAD, even if you already have an EAD or work authorization based on another immigration status. If you want to obtain a new TPS-based EAD valid through May 27, 2026, you must file Form I–765 and pay the associated fee (unless USCIS grants your fee waiver request).

Can my employer require that I provide any other documentation to complete Form I–9, such as evidence of my status, proof of my Lebanese citizenship, or a Form I–797 showing that I registered for TPS?

No. When completing Form I–9, employers must accept any documentation you choose to present from the Form I–9 Lists of Acceptable Documents that reasonably appears to be genuine and that relates to you, or an acceptable List A, List B, or List C receipt. Employers may not request proof of Lebanese citizenship or proof of registration for TPS when completing Form I–9 for new hires or reverifying the employment authorization of current employees. Refer to the ''Note to Employees'' section of this **Federal**

Register notice for important information about your rights if your employer rejects lawful documentation, requires additional documentation, or otherwise discriminates against you based on your citizenship or immigration status, or your national origin.

Note to All Employers

Employers are reminded that the laws requiring proper employment eligibility verification and prohibiting unfair immigration-related employment practices remain in full force. This **Federal Register** notice does not supersede or in any way limit applicable employment verification rules and policy guidance, including those rules setting forth reverification requirements. For general questions about the employment eligibility verification process, employers may call USCIS at 888–464–4218 (TTY 877–875–6028) or email USCIS at *I9Central@uscis.dhs.gov.* USCIS accepts calls and emails in English, Spanish and many other languages. For questions about avoiding discrimination during the employment eligibility verification process (Form I–9 and E-Verify), employers may call the U.S. Department of Justice, Civil Rights Division, Immigrant and Employee Rights Section (IER) Employer Hotline at 800–255–8155 (TTY 800–237–2515). IER offers language interpretation in many languages. Employers may also email IER at *IER@usdoj.gov* or get more information online at *https://www.justice.gov/ier.*

Note to Employees

For general questions about the employment eligibility verification process, employees may call USCIS at 888–897–7781 (TTY 877–875–6028) or email USCIS at *I-9Central@uscis.dhs.gov.* USCIS accepts calls and emails in English, Spanish and many other languages. Employees or job applicants may also call the U.S. Department of Justice, Civil Rights Division, Immigrant and Employee Rights Section (IER) Worker Hotline at 800–255–7688 (TTY 800–237–2515) for information regarding employment discrimination based on citizenship, immigration status, or national origin, including discrimination related to Form I–9 and E-Verify. The IER Worker Hotline provides language interpretation in many languages.

To comply with the law, employers must accept any document or combination of documents from the Lists of Acceptable Documents if the documentation reasonably appears to be genuine and to relate to the employee, or an acceptable List A, List B, or List C receipt as described in these lists. Employers may not require extra or additional documentation beyond what is required for Form I–9 completion. Further, employers participating in E-Verify who receive an E-Verify case result of ''Tentative Nonconfirmation'' (mismatch) must promptly inform employees of the mismatch and give such employees an opportunity to take action to contest the mismatch. A mismatch means that the information entered into E-Verify from Form I–9 differs from records available to DHS.

Employers may not terminate, suspend, delay training, withhold or lower pay, or take any adverse action against an employee because of a mismatch while the case is still pending with E-Verify. A Final Nonconfirmation (FNC) case result occurs if E-Verify cannot confirm an employee's employment eligibility. An employer may terminate employment based on a case result of FNC. Work-authorized employees who receive an FNC may call USCIS for assistance at 888–897–7781 (TTY 877–875–6028). For more information about E-Verify-related discrimination or to report an employer for discrimination in the E-Verify process based on citizenship, immigration status, or national origin, contact IER's Worker Hotline at 800–255–7688 (TTY 800–237–2515). Additional information about proper nondiscriminatory Form I–9 and E-Verify procedures is available on the IER website at *https://www.justice.gov/ier* and the USCIS and E-Verify websites at *https://www.uscis.gov/i-9-central* and *https://www.e-verify.gov.*

Note Regarding Federal, State, and Local Government Agencies (Such as Departments of Motor Vehicles)

For Federal purposes, individuals approved for TPS may show their Form I–797, Notice of Action, indicating approval of their Form I–821 application, or may show their EAD with category code of A12 or C19 to prove that they have TPS. However, while Federal Government agencies must follow the guidelines laid out by the Federal Government, State and local government agencies establish their own rules and guidelines when granting certain benefits. Each state may have different laws, requirements, and determinations about what documents you need to provide to prove eligibility for certain benefits. Whether you are applying for a Federal, State, or local government benefit, you may need to provide the government agency with documents that show you are a TPS beneficiary or applicant, show you are authorized to work based on TPS or other status, or that may be used by DHS to determine if you have TPS or another immigration status. Examples of such documents are:

- Your new EAD with a TPS category code of A12 or C19, even if your country of birth noted on the EAD does not reflect the TPS-designated country of Lebanon;
- Your Form I–94, Arrival/Departure Record;
- Your Form I–797, Notice of Action, reflecting approval of your Form I–765; or
- Your Form I–797 or Form I–797C, Notice of Action, reflecting approval or receipt of a current Form I–821, if you received one from USCIS.

Check with the government agency requesting documentation about which documents the agency will accept.

Some state and local government agencies use SAVE, *https://www.uscis.gov/save,* to confirm the current immigration status of applicants for public benefits. SAVE can verify when an individual has TPS or a pending TPS application based on the documents above. In most cases, SAVE provides an automated electronic response to benefit-granting agencies within seconds, but occasionally verification can be delayed.

You can check the status of your SAVE verification by using CaseCheck at *https://www.uscis.gov/save/save-casecheck.* CaseCheck is a free service that lets you follow the progress of your SAVE verification case using your date of birth and one immigration identifier number (such as your A-Number, USCIS number, or Form I–94 number) or Verification Case Number. If an agency has denied your application based solely or in part on a SAVE response, the agency must allow you to appeal the decision in accordance with the agency's procedures. If the agency has received and acted on or will act on a SAVE verification and you do not believe the SAVE response is correct, the SAVE website, *https://www.uscis.gov/save/for-benefit-applicants,* has detailed information on how to correct or update your immigration record, make an appointment, or submit a written request to correct records.

[FR Doc. 2024–27788 Filed 11–26–24; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7090–N–09]

60-Day Notice of Proposed Information Collection: Manufactured Housing Survey; OMB Control No.: 2528–0229

AGENCY: Office of Policy Development and Research, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: Comments Due Date: January 27, 2025.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal.

Written comments and recommendations for the proposed information collection can be submitted within 60 days of publication of this notice to *www.regulations.gov.* Interested persons are also invited to submit comments regarding this proposal by name and/or OMB Control Number and can be sent to: Anna Guido, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410–5000 or email at *PaperworkReductionActOffice@hud.gov.*

FOR FURTHER INFORMATION CONTACT: Anna Guido, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email; *Anna.P.Guido@hud.gov;* telephone (202) 402–5535 (this is not a toll-free number). HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

Copies of available documents submitted to OMB may be obtained from Ms. Guido.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Manufactured Housing Survey.

OMB Approval Number: 2528–0029.

Type of Request: Revision of a currently approved collection.

Form Number: C–MH–9A.

Description of the need for the information and proposed use: The Manufactured Housing Survey collects data on the characteristics of newly manufactured homes placed for residential use. Key data collected includes sales price and the number of units placed and sold within 4 months of shipment. Other selected housing characteristics collected include size, location, and titling. HUD is authorized to collect these statistics under the ''Housing and Community Development Act of 1980,'' Title 42 U.S.C. 5424 note (see Attachment 3), which provides the Secretary discretion to take necessary actions to ensure the public is aware of the distinctions between the types of factory-built housing. This allows HUD to collect and report manufactured home sales price information for the nation, Census Regions, States, and selected metropolitan statistical areas, and to monitor whether new manufactured homes are being placed on owned rather than rented lots. HUD also used these data to monitor total housing production and its affordability.

Furthermore, the Manufactured Housing Survey serves as a basis for HUD's mandated indexing of loan limits. Section 2145 (b) of the Housing and Economic Recovery Act (HERA) of 2008 requires HUD to develop a method of indexing to annually adjust Title I manufactured home loan limits. This index is partially based on manufactured housing price data collected by this survey. Section 2145 of the HERA of 2008 also amends the maximum loan limits for manufactured home loans insured under Title I. The Final Rule, entitled Indexing Methodology for Title I Manufactured Home Loan Limits, was published in the **Federal Register** on February 28, 2024. This Rule established separate indexing methodologies to annually calculate future loan limits for Manufactured Homes Loans, Manufactured Lot Loans and Manufactured Home and Lot Combination Loans for the Title I Manufactured Home Loan Program. Single- and double-section price data from this survey are used to determine maximum loan amounts for Title I Manufactured Home Loans. HUD implemented the revised loan limits, as shown below, for all manufactured home loans for which applications are received on or after March 29, 2024.

Loan type	Purpose	Old loan limit	New loan limit
MANUFACTURED HOME IMPROVEMENT LOAN.	For financing alterations, repairs and improvements upon or in connection with existing manufactured homes.	$25,090	$25,090.
MANUFACTURED HOME UNIT(S)	To purchase or refinance a Manufactured Home unit (s).	69,678	Single-section: $105,532. Multi-section: $193,719.
LOT LOAN	To purchase and develop a lot on which to place a manufactured home unit.	23,226	$43,377.
COMBINATION LOAN FOR LOT AND HOME	To purchase or refinance a manufactured home and lot on which to place the home.	92,904	Single-section: $148,909. Multi-section: $237,096.

Method of Collection

The methodology for collecting information on new manufactured homes involves contacting dealers from a monthly sample of new manufactured homes shipped by manufacturers. The units are sampled from lists obtained from the Institute for Building Technology and Safety. Dealers that take shipment of the selected homes are mailed a survey form four months after shipment for recording the status of the manufactured home.

Respondents: Business firms or other for-profit institutions.

Respondent's Obligation: Voluntary.

Estimated Number of Respondents: 4,860.

Frequency of Response: Once.

Average Hours per Response: 20 minutes per response (.33 hour).

Estimated Total Annual Burden Hours: 1,620.

Estimated Total Annual Cost: $58,547. (We do not expect respondents to incur any costs other than that of their time to respond. The estimated hourly cost per response is $36.14, which is the hourly rate for typical

respondent: Occupational code 41–4010: Sales Representatives, Wholesale and Manufacturing. The estimate total annual cost burden to respondents is $58,547, which is not a direct financial cost of respondents' time, but rather the associated cost burden of the respondents' voluntary responses.)

TOTAL ESTIMATED BURDENS

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
Manufactured Housing Survey	4,860	1	4,860	0.33	1,620	$36.14	$58,547

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected, and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comments in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507.

Todd M. Richardson,

General Deputy Assistant Secretary for Policy Development and Research

[FR Doc. 2024–27789 Filed 11–26–24; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BLM_AK_FRN_MO4500183278; AA–8489–A]

Alaska Native Claims Selection

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of decision approving lands for conveyance.

SUMMARY: The Bureau of Land Management (BLM) hereby provides constructive notice that it will issue an appealable decision approving conveyance of the surface estate in certain lands to Chickaloon Moose Creek Native Association, Inc. for the Native village of Chickaloon, pursuant to the Alaska Native Claims Settlement Act of 1971 (ANCSA). The subsurface estate in the same lands will be conveyed to Cook Inlet Region, Inc. when the surface estate is conveyed to Chickaloon Moose Creek Native Association, Inc.

DATES: Any party claiming a property interest in the lands affected by the decision may appeal the decision in accordance with the requirements of 43 CFR part 4 within the time limits set out in the **SUPPLEMENTARY INFORMATION** section.

ADDRESSES: You may obtain a copy of the decision from the Bureau of Land Management, Alaska State Office, 222 West Seventh Avenue, #13, Anchorage, AK 99513–7504.

FOR FURTHER INFORMATION CONTACT: Matthew R. Lux, Land Transfer Resolution Specialist, BLM Alaska State Office, 907–271–3176, or *mlux@blm.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point of contact in the United States.

SUPPLEMENTARY INFORMATION: As required by 43 CFR 2650.7(d), notice is hereby given that the BLM will issue an appealable decision to Chickaloon Moose Creek Native Association, Inc. The decision approves conveyance of the surface estate in certain lands pursuant to ANCSA (43 U.S.C. 1601, *et seq.*). As provided by ANCSA, the subsurface estate in the same lands will be conveyed to Cook Inlet Region, Inc. when the surface estate is conveyed to Chickaloon Moose Creek Native Association, Inc. The lands are located in the vicinity of Chickaloon, Alaska, and are described as:

Seward Meridian, Alaska

T. 19 N., R. 3 E.,
Secs. 25, 26, and 27;
Secs. 32 to 36, inclusive.
Containing approximately 2,691 acres.
T. 19 N., R. 4 E.,
Secs. 12 and 19.
Containing 113.28 acres.
T. 20 N., R. 5 E.,
Tract A.
Containing 4,414.29 acres.
T. 21 N., R. 5 E.,
Sec. 3;
Secs. 9 and 10;
Secs. 16 and 17;
Secs. 19 and 20;
Secs. 30, and 31.
Containing 5,735.68 acres.
T. 22 N., R. 5 E.,
Secs. 25 and 26;
Secs. 34, 35, and 36.
Containing 3,200 acres.
T. 21 N., R. 6 E.,
Secs. 2 and 3;
Secs. 10 and 11;
Secs. 14 and 15;
Secs. 21 and 22;
Secs. 28 and 29;
Secs. 31, 32, and 33.
Containing 8,323.92 acres.
T. 22 N., R. 6 E.,
Sec. 1;
Secs. 11 to 14, inclusive;
Sec. 23;
Sec. 26;
Secs. 30 and 31;
Sec. 35.
Containing 5,894.64 acres.
Aggregating approximately 30,373 acres.

The decision addresses public access easements, if any, to be reserved to the United States pursuant to sec. 17(b) of ANCSA (43 U.S.C. 1616(b)), in the lands described above.

The BLM will also publish notice of the decision once a week for four consecutive weeks in the Anchorage Daily News newspaper.

Any party claiming a property interest in the lands affected by the decision may appeal the decision in accordance with the requirements of 43 CFR part 4 within the following time limits:

1. Unknown parties, parties unable to be located after reasonable efforts have been expended to locate, parties who fail or refuse to sign their return receipt, and parties who receive a copy of the decision by regular mail which is not certified, return receipt requested, shall have until December 27, 2024 to file an appeal.

2. Parties receiving service of the decision by certified mail shall have 30 days from the date of receipt to file an appeal.

Parties who do not file an appeal in accordance with the requirements of 43 CFR part 4 shall be deemed to have waived their rights. Notices of appeal transmitted by facsimile will not be accepted as timely filed.

Matthew R. Lux,

Land Transfer Resolution Specialist, Resolution Group.

[FR Doc. 2024–27785 Filed 11–26–24; 8:45 am]

BILLING CODE 4331–10–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BLM_WY_FRN_MO4500183156]

Notice of Availability of the Record of Decision and Approved Resource Management Plan Amendment for the Buffalo Field Office, Wyoming

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: The Bureau of Land Management (BLM) announces the availability of the Record of Decision (ROD) for the Approved Resource Management Plan (RMP) Amendment for the Buffalo Field Office located in Buffalo, Wyoming. The BLM Director signed the ROD on November 20, 2024, which constitutes the decision of the BLM and makes the Approved RMP Amendment effective immediately.

DATES: The BLM Director signed the ROD/Approved RMP Amendment on November 20, 2024.

ADDRESSES: The ROD/Approved RMP Amendment is available online at: *https://eplanning.blm.gov/eplanning-ui/project/2021239/510.* Printed copies of the ROD/Approved RMP Amendment are available for public inspection at the Buffalo Field Office or can be provided upon request by contacting Tom Bills, Project Manager, telephone (307) 684–1133; or at the address BLM Buffalo Field Office, 1425 Fort Street, Buffalo, WY 82834; email *tbills@blm.gov.*

A copy of the Protest Resolution Report is available at: *https://www.blm.gov/programs/planning-and-nepa/public-participation/protest-resolution-reports.*

FOR FURTHER INFORMATION CONTACT: Thomas Bills, Project Manager, telephone (307) 684–1133; or at the address BLM Buffalo Field Office, 1425 Fort Street, Buffalo, WY 82834; email *tbills@blm.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The Approved RMP Amendment addresses a United States District Court for the District of Montana order (*Western Organization of Resource Councils, et al.* v. *BLM*; CV 00076–GF–BMM; 8/3/2022). The Approved RMP Amendment changes the existing 2015 Buffalo Approved RMP.

The RMP Amendment approved by the ROD includes land use allocations of areas acceptable for further consideration for coal leasing and those that are not. The Approved RMP Amendment is Alternative A (No Leasing) from the Final Supplemental Environmental Impact State (EIS), making no BLM administered coal acceptable and 413,250 acres unavailable for further consideration for coal leasing within the Buffalo Field Office planning area. The Approved RMP Amendment does not affect the area with coal development potential or the area determined to be suitable for surface coal mining. The Approved RMP Amendment includes the updated coal screens (43 CFR 3420.1–4(e)) using current data and evaluated the issues identified through internal and public scoping. Application of coal screen 1 (development potential) identified approximately 413,250 acres of BLM-administered coal as having development potential. The Approved RMP Amendment also addresses the NEPA deficiencies identified by the court order associated with the application of the multiple-use screen. Specifically, the application of a multiple-use climate change criterion that uses greenhouse gas emissions as a proxy for climate change. Reducing availability of BLM-administered coal for leasing consideration reduces the contribution of greenhouse gas emissions from the development and combustion of BLM-administered coal from the planning area.

The BLM determined that additional leasing of BLM-administered coal is not necessary based on the current analysis in the Final Supplemental EIS. The analysis indicates that operating mines in the planning area collectively have existing leases with sufficient coal reserves to maintain projected mine production levels into 2041.

The BLM published a notice of availability for the Draft Supplemental EIS and Potential RMP Amendment in the **Federal Register** on May 8, 2023, which initiated a 90-day comment period (88 FR 29691). On May 31, 2023, the BLM hosted a public meeting in Gillette, Wyoming, to present the Draft Supplemental EIS/RMP Amendment to the public and solicit comments. The BLM also hosted an on-line public meeting on June 5, 2023. During the public comment period, the BLM received 25 unique written submissions containing 147 substantive comments. The Draft Supplemental EIS comments helped the BLM refine the Final Supplemental EIS and guided the development of the Proposed RMP Amendment.

The BLM provided the Proposed RMP Amendment for public protest on May 17, 2024 (89 FR 43431), for a 30-day protest period, and received five valid protests. The BLM Assistant Director for Planning and Resources resolved all protests. Responses to protest issues were compiled and documented in a Protest Resolution Report (see **ADDRESSES**). No changes were made to the Approved RMP Amendment as a result of protest resolution.

The BLM provided the Proposed RMP Amendment to the Governor of Wyoming for a 60-day Governor's consistency review. The State Director made no changes to the Proposed RMP Amendment as a result of the Governor's review. On September 13, 2024, the Governor submitted an appeal to the BLM Director on the State Director's response to the Governor's consistency review. In accordance with planning regulations (1610.3–2), the Director notified the Governor on November 6, 2024, of the reasons for the determination to reject the Governor's recommendations.

(Authority: 40 CFR 1506.6; 43 CFR 1610.5–1)

Tracy Stone-Manning,

BLM Director.

[FR Doc. 2024–27677 Filed 11–26–24; 8:45 am]

BILLING CODE 4331–26–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BLM_MT_FRN_MO4500182720]

Notice of Availability of the Record of Decision and Approved Resource Management Plan Amendment for the Miles City Field Office, Montana

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: The Bureau of Land Management (BLM) announces the availability of the Record of Decision (ROD) for the Approved Resource Management Plan (RMP) Amendment for the Miles City Field Office located in Miles City, Montana. The BLM Director signed the ROD on November 20, 2024, which constitutes the decision of the BLM and makes the Approved RMP Amendment effective immediately.

DATES: The BLM Director signed the ROD/Approved RMP Amendment on November 20, 2024.

ADDRESSES: The ROD/Approved RMP Amendment is available online *https://eplanning.blm.gov/eplanning-ui/project/2021155/510.* Printed copies of the ROD/Approved RMP Amendment are available for public inspection at the Miles City Field Office or can be provided upon request by contacting Irma Nansel, Project Manager, telephone (406) 233–3653; or at the address BLM Miles City Field Office, 111 Garryowen Road, Miles City, MT 59301; email *inansel@blm.gov.*

A copy of the Protest Resolution Report is available at: *https://www.blm.gov/programs/planning-and-nepa/public-participation/protest-resolution-reports.*

FOR FURTHER INFORMATION CONTACT: Irma Nansel, Project Manager, telephone (406) 233–3653; or at the address BLM Miles City Field Office, 111 Garryowen Road, Miles City, MT 59301; email *inansel@blm.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The Approved RMP Amendment addresses a United States District Court for the District of Montana order (*Western Organization of Resource Councils, et al.* v. *BLM*; CV 00076–GF–BMM; 8/3/2022). The Approved RMP Amendment changes the existing 2015 Miles City Approved RMP.

The RMP Amendment approved by the ROD includes land use allocations of areas acceptable for further consideration for coal leasing and those that are not. The Approved RMP Amendment is Alternative D from the Final Supplemental EIS, which allocates zero acres of BLM administered coal as available, and 1,745,040 acres unavailable for further consideration for coal leasing within the Miles City Field Office planning area. The Approved RMP Amendment does not affect the area with coal development potential or the area determined to be suitable for surface coal mining.

The Approved RMP Amendment includes the updated coal screens (43 CFR 3420.1–4(e)) using current data and evaluated the issues identified through internal and public scoping. Application of coal screen 1 (development potential) identified approximately 1,745,000 acres of BLM-administered coal as having development potential. The Approved RMP Amendment also addresses the NEPA deficiencies identified by the court order associated with the application of the multiple-use screen. Specifically, the application of a multiple-use climate change criterion that uses greenhouse gas emissions as a proxy for climate change. Reducing availability of BLM-administered coal for leasing consideration reduces the contribution of greenhouse gas emissions from the development and combustion of BLM-administered coal from the planning area.

The BLM determined that additional leasing of BLM-administered coal is not necessary based on the current analysis in the Final Supplemental EIS. The analysis indicates that operating mines in the planning area have existing leases with sufficient coal reserves to maintain existing mine production levels until 2035 for Spring Creek Mine and 2060 for Rosebud Mine.

The BLM published a notice of availability for the Draft Supplemental EIS and Potential RMP Amendment in the **Federal Register** on May 8, 2023, which initiated a 90-day comment period (88 FR 29689). On June 6th, the BLM hosted a public meeting at the BLM Miles City Field Office in Miles City, Montana, to present the Draft Supplemental EIS and RMP Amendment to the public and solicit comments. The BLM also hosted an on-line public meeting on June 7, 2023. Eight members of the public attended the on-line meeting. During the public comment period, the BLM received 14 unique written submissions containing 167 substantive comments. The Draft Supplemental EIS comments helped the BLM refine the Final Supplemental EIS and guided the development of the Proposed RMP Amendment.

The BLM provided the Proposed RMP Amendment for public protest on May 17, 2024 (89 FR 43432), for a 30-day protest period, and received seven valid protests. The BLM Assistant Director for Planning and Resources resolved all protests. Responses to protest issues were compiled and documented in a Protest Resolution Report (see **ADDRESSES**). No changes were made to the Approved RMP Amendment as a result of protest resolution.

The BLM provided the Proposed RMP Amendment to the Governor of Montana for a 60-day Governor's consistency review. There were no inconsistencies with State or local plans, policies, or programs identified during the Governor's consistency review of the Proposed RMP Amendment. The State Director made no changes to the Proposed RMP Amendment as a result of the Governor's review. On September 18, 2024, the Governor submitted an appeal to the BLM Director on the State Director's response to the Governor's consistency review. In accordance with planning regulations (1610.3–2), the Director notified the Governor on November 6, 2024, of the reasons for the determination to reject the Governor's recommendations.

(Authority: 40 CFR 1506.6; 43 CFR 1610.5–1)

Tracy Stone-Manning,

BLM Director.

[FR Doc. 2024–27678 Filed 11–26–24; 8:45 am]

BILLING CODE 4331–20–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–748–749 and 731–TA–1726–1727 (Preliminary)]

Float Glass Products From China and Malaysia; Institution of Antidumping and Countervailing Duty Investigations and Scheduling of Preliminary Phase Investigations

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the institution of investigations and commencement of preliminary phase antidumping and countervailing duty investigation Nos. 701–TA–748–749 and 731–TA–1726–1727 (Preliminary) pursuant to the Tariff Act of 1930 (''the Act'') to determine whether there is a reasonable indication that an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports of float glass products from China and Malaysia, described in statistical reporting numbers 7005.10.8000, 7005.21.1010, 7005.21.1030, 7005.21.2000,

7005.29.1810, 7005.29.1850, 7005.29.2500, 7007.29.0000, 7008.00.0000, 7009.91.5010, 7009.91.5095, 7009.92.5010, 7006.00.4010, 7006.00.4050, and 7007.19.0000 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value and alleged to be subsidized by the Governments of China and Malaysia. Unless the Department of Commerce (''Commerce'') extends the time for initiation, the Commission must reach a preliminary determination in antidumping and countervailing duty investigations in 45 days, or in this case by January 6, 2025. The Commission's views must be transmitted to Commerce within five business days thereafter, or by January 13, 2025.

DATES: November 21, 2024.

FOR FURTHER INFORMATION CONTACT: Kristina Lara (202–205–3386), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for these investigations may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov*.

SUPPLEMENTARY INFORMATION:

Background.—These investigations are being instituted, pursuant to sections 703(a) and 733(a) of the Tariff Act of 1930 (19 U.S.C. 1671b(a) and 1673b(a)), in response to petitions filed on November 21, 2024, by Vitro Flat Glass, LLC, Cheswick, Pennsylvania, and Vitro Meadville Flat Glass, LLC, Cochranton, Pennsylvania.

For further information concerning the conduct of these investigations and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and B (19 CFR part 207).

Participation in the investigations and public service list.—Persons (other than petitioners) wishing to participate in the investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in §§ 201.11 and 207.10 of the Commission's rules, not later than seven days after publication of this notice in the **Federal Register**. Industrial users and (if the merchandise under investigation is sold at the retail level) representative consumer organizations have the right to appear as parties in Commission antidumping duty and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to these investigations upon the expiration of the period for filing entries of appearance.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to § 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in these investigations available to authorized applicants representing interested parties (as defined in 19 U.S.C. 1677(9)) who are parties to the investigations under the APO issued in the investigations, provided that the application is made not later than seven days after the publication of this notice in the **Federal Register**. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Conference.—The Office of Investigations will hold a staff conference in connection with the preliminary phase of these investigations beginning at 9:30 a.m. on Thursday, December 12, 2024. Requests to appear at the conference should be emailed to *preliminaryconferences@usitc.gov* (DO NOT FILE ON EDIS) on or before Tuesday, December 10, 2024. Please provide an email address for each conference participant in the email. Information on conference procedures, format, and participation, including guidance for requests to appear as a witness via videoconference, will be available on the Commission's Public Calendar (Calendar (USITC) √ United States International Trade Commission). A nonparty who has testimony that may aid the Commission's deliberations may request permission to participate by submitting a short statement.

Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Written submissions.—As provided in §§ 201.8 and 207.15 of the Commission's rules, any person may submit to the Commission on or before 5:15 p.m. on December 17, 2024, a written brief containing information and arguments pertinent to the subject matter of the investigations. Parties shall file written testimony and supplementary material in connection with their presentation at the conference no later than 4:00 p.m. on December 11, 2024. All written submissions must conform with the provisions of § 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

In accordance with §§ 201.16(c) and 207.3 of the rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Certification.—Pursuant to § 207.3 of the Commission's rules, any person submitting information to the Commission in connection with these investigations must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will acknowledge that any information that it submits to the Commission during these investigations may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of these or related investigations or reviews, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. appendix 3; or (ii) by U.S. Government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.12 of the Commission's rules.

By order of the Commission.

Issued: November 21, 2024.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2024–27739 Filed 11–26–24; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1118 (Remand)]

Certain Movable Barrier Operator Systems and Components Thereof; Notice of a Final Determination Finding a Violation of Section 337 and Issuing a Limited Exclusion Order and Cease and Desist Orders; Termination of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (''Commission'') has determined that respondents Nortek Security & Control, LLC of Carlsbad, California (presently doing business as Nice North America LLC); Nortek, Inc. of Providence, Rhode Island; and GTO Access Systems, LLC of Tallahassee, Florida (collectively, ''Nortek'') have violated section 337 of the Tariff Act of 1930, as amended, by importing, selling for importation, or selling in the United States after importation certain movable barrier operators (including garage door operators) and components thereof that infringe claim 11 of U.S. Patent No. 8,587,404 (''the '404 patent''). The Commission has determined that the appropriate remedies are a limited exclusion order (''LEO'') and cease and desist orders (''CDOs'') against Nortek. The Commission has also determined to set a bond in the amount of zero percent (0%) of the entered value of the excluded products imported during the period of Presidential review. This investigation is hereby terminated.

FOR FURTHER INFORMATION CONTACT: Carl P. Bretscher, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2382. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket system (''EDIS'') at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal, telephone (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on June 11, 2018, based on a complaint, as supplemented, filed by The Chamberlain Group, Inc. (''Chamberlain'') of Oak Brook, Illinois. 83 FR 27020–21 (June 11, 2018). The complaint accuses Nortek of violating section 337 of the Tariff Act, as amended, 19 U.S.C. 1337 (''section 337'') by importing, selling for importation, or selling in the United States after importation certain movable barrier operator systems that infringe one or more of the asserted claims of the '404 patent and U.S. Patent Nos. 7,755,223 (''the '223 patent'') and 6,741,052 (''the '052 patent''). *Id.* The complaint also alleges the existence of a domestic industry. The Office of Unfair Import Investigations is not a party to the investigation.

On November 25, 2019, the presiding administrative law judge (''ALJ'') issued two initial determinations (''IDs''). First, the ALJ issued Order No. 38, granting Chamberlain's motion for summary determination that it satisfied the economic prong of the domestic industry requirement (''DI economic prong''). Order No. 38 (Nov. 25, 2019). Second, the ALJ issued a final ID on violation, as well as a recommended determination (''RD'') on remedy and bond. The final ID finds no violation of section 337 because: (i) Nortek did not infringe claim 11 of the '404 patent; (ii) Nortek did not infringe the '223 patent and Chamberlain did not satisfy the technical prong of the domestic industry requirement (''DI technical prong'') for that patent; and (iii) asserted claim 1 of the '052 patent is invalid as obvious. The RD recommends issuing an LEO and CDOs against Nortek and setting the bond of 100 percent during the period of Presidential review.

On April 22, 2020, the Commission determined to review and, on review, to adopt the final ID's no-violation finding for the '404 patent, which was based on a narrow construction of the limitation ''movable barrier operator'' that excluded the wall station. Comm'n Notice at 3 (Apr. 22, 2020). The Commission took no position on the final ID's finding that Nortek failed to prove that claim 11 of the '404 patent is patent ineligible under 35 U.S.C. 101. The Commission also adopted the final ID's finding that there was no violation with respect to the '052 patent because the asserted claim is obvious. At the same time, the Commission vacated Order No. 38 and remanded the economic prong issue to the ALJ for further proceedings with respect to the '223 patent. *Id.;* Order Vacating and Remanding Order No. 38 (Apr. 22, 2020) (''First Remand Order'').

The ALJ, after re-analyzing the domestic industry per the Commission's instructions, issued a Remand Initial Determination (''First RID'') on July 10, 2020. The First RID finds that Chamberlain made significant investments in plant and equipment as well as labor and capital, which satisfied the DI economic prong for the '223 patent under sections 337(a)(3)(A) and (B), respectively.

On September 9, 2020, the Commission determined to review the First RID and requested additional briefing by the parties on issues relating to the DI economic prong and remedy, bond, and the public interest. 85 FR 57249–50 (Sept. 14, 2020).

On December 3, 2020, the Commission determined to adopt the First RID's findings that Chamberlain had satisfied the DI economic prong under subsections 337(a)(3)(A) and (B). 85 FR 79217–18 (Dec. 9, 2020). The Commission reversed the final ID's non-infringement finding for the '223 patent, finding instead that Nortek violated section 337 by infringing the '223 patent. *Id.* Finding that the public interest did not preclude relief, the Commission issued an LEO and CDOs against Nortek and set the bond at 100 percent of entered value. Comm'n Op. at 34–39, 41.

On June 16, 2020, Chamberlain appealed the Commission's no-violation determinations for the '404 patent and '052 patent (which expired while the appeal was pending). On April 1, 2021, Nortek cross-appealed the Commission's violation determination for the '223 patent.

On April 27, 2023, the Federal Circuit issued its decision, in which it: (i) affirmed the Commission's violation determination for the '223 patent; (ii) for the '404 patent, reversed the Commission's construction of the term ''movable barrier operator,'' vacated its non-infringement, waiver, and no-violation determinations, and remanded with instructions to the Commission to re-evaluate infringement of the '404 patent using a proper claim construction; and (iii) vacated the Commission's determinations for the expired '052 patent and remanded with instructions to dismiss the infringement claim as moot. The *Chamberlain Group, Inc.* v. *ITC,* Appeal Nos. 20–1965, 21–1829, 2023 WL 3115579 at *1, *4–7 (Fed. Cir. Apr. 27, 2023).

On August 4, 2023, the Commission issued a notice asking the parties which issues needed to be resolved in view of the Federal Circuit's remand and whether additional proceedings were necessary. Comm'n Notice (Aug. 4, 2023). The parties filed responses identifying infringement of the '404 patent, patent-ineligibility of claim 11 of the '404 patent under section 101, and

the economic prong of domestic industry with respect to the '404 patent as the violation issues that needed to be resolved. The parties agreed there was no need to reopen the evidentiary record, as it has already been fully developed.

On October 4, 2023, the Commission issued a second notice directing the parties to brief: (i) which, if any, of the accused products infringe claim 11 of the '404 patent under the Court's new construction of ''movable barrier operator'' and (ii) whether the ID properly finds that claim 11 is not patent-ineligible under 35 U.S.C. 101. Comm'n Notice at 3 (Oct. 4, 2023). The Commission determined not to reopen the evidentiary record. The Commission also remanded the investigation to the ALJ for the sole purpose of determining whether Chamberlain satisfied the DI economic prong for the '404 patent. *See* Remand Order (Oct. 4, 2023) (''Second Remand Order'').

On January 11, 2024, the presiding ALJ issued Order No. 46 directing the parties to provide supplemental information regarding the covered products allegedly protected by the '404 patent, the extent to which domestic investments relating to products covered by the '223 patent were applicable to products covered by the '404 patent, the domestic inventories of products covered by the '404 patent, and other issues relating to the DI economic prong analysis. *See* Order No. 46 (Jan. 11, 2024).

On May 8, 2024, the ALJ issued the Recommended [*sic,* Remand] Initial Determination on Second Remand Order (''Second RID'') presently at issue. Order No. 50 (May 8, 2024). The Second RID finds that Chamberlain has satisfied the DI economic prong for the '404 patent under subsections 337(a)(3)(A), (B), and (C). The Second RID also makes subsidiary findings regarding infringement and the accused Nortek products. The Second RID also notes that the Commission previously found that Chamberlain's domestic industry products (the ''404 DI Products'') practice the '404 patent and Chamberlain thus satisfied the DI technical prong.

On May 20, 2024, Nortek filed a petition for review of the Second RID. On May 28, 2024, Chamberlain filed its opposition to Nortek's petition for review.

On June 28, 2024, the Commission determined to review the Second RID. 89 FR 54038 (June 28, 2024). The Commission also requested briefing on remedy, bond, and the public interest. *Id.*

Upon review of the final ID, the Second RID, the Federal Circuit's decision on appeal, the parties' submissions, and the evidence of record, the Commission finds that Nortek has violated section 337 by importing into the United States, selling for importation, or selling in the United States after importation certain movable barrier operators and components thereof that infringe claim 11 of the '404 patent. As set forth in the accompanying Opinion, the Commission finds that Nortek has infringed claim 11 of the '404 patent, and that claim 11 is not abstract or patent-ineligible under 35 U.S.C. 101. The Commission also finds that Chamberlain has satisfied the DI economic prong per 19 U.S.C. 1337(a)(3)(A), (B), but takes no position on whether it has also satisfied the DI economic prong under section 337(a)(3)(C).

The Commission has determined that the appropriate remedy is: (i) an LEO prohibiting the importation of certain movable barrier operator systems, including garage door operators, and components thereof that infringe claim 11 of the '404 patent; and (ii) a CDO against each Nortek respondents. The Commission has determined that the public interest factors do not preclude issuance of a remedy. The Commission has determined to set a bond in the amount of zero percent (0%) of the entered value of the infringing products imported during the period of Presidential review (19 U.S.C. 1337(j)).

The Commission issues its opinion herewith setting forth its determinations on certain issues. This investigation is hereby terminated.

The Commission's orders and opinion were delivered to the President and United States Trade Representative on the day of their issuance.

The Commission vote for this determination took place on November 21, 2024.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: November 21, 2024.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2024–27783 Filed 11–26–24; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

[OMB 1140–0062]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Identification of Imported Explosives Materials

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 30 days until December 27, 2024.

FOR FURTHER INFORMATION CONTACT: If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact: Michael O'Lena, Explosives Industry Programs Branch, by email at *eipb-informationcollection@atf.gov* or *michael.olena@atf.gov,* or telephone at (202) 648–7120.

SUPPLEMENTARY INFORMATION: The proposed information collection was previously published in the **Federal Register**, volume 89 page 80933, on Friday, October 4, 2024, allowing a 60-day comment period. Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Enhance the quality, utility, and clarity of the information to be collected; and/or

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms

of information technology, *e.g.,* permitting electronic submission of responses.

Written comments and recommendations for this information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the information collection or the OMB Control Number 1140–0062. This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view Department of Justice, information collections currently under review by OMB.

DOJ seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOJ notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Overview of This Information Collection

1. *Type of Information Collection:* Extension of a previously approved collection.

2. *Title of the Form/Collection:* Identification of Imported Explosives Materials.

3. *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* None.

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract: Affected Public:* Private Sector-for or not for profit institutions.

5. *Obligation to Respond:* The obligation to respond is mandatory per 27 CFR part 555.

6. *Total Estimated Number of Respondents:* 51.

7. *Estimated Time per Respondent:* 1 hour.

8. *Frequency:* 3 times annually.

9. *Total Estimated Annual Time Burden:* 51 hours.

10. *Total Estimated Annual Other Costs Burden:* $0.

If additional information is required, contact: Darwin Arceo, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, United States Department of Justice, Two Constitution Square, 145 N Street NE, 4W–218, Washington, DC 20530.

Dated: November 24, 2024.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2024–27860 Filed 11–26–24; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

[OMB 1140–0031]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Records of Acquisition and Disposition, Registered Importers of Arms, Ammunition & Defense Articles on the U.S. Munitions Import List

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 30 days until December 27, 2024.

FOR FURTHER INFORMATION CONTACT: If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact: Victoria Kenney, FESD/FEIB, by email at *Victoria.Kenney@atf.gov,* or telephone at 304–616–3376.

SUPPLEMENTARY INFORMATION: The proposed information collection was previously published in the **Federal Register**, volume 89 page 80931, on Friday, October 4, 2024, allowing a 60-day comment period. Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Enhance the quality, utility, and clarity of the information to be collected; and/or

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Written comments and recommendations for this information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the information collection or the OMB Control Number 1140–0101. This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view Department of Justice, information collections currently under review by OMB.

DOJ seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOJ notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Overview of This Information Collection

1. *Type of Information Collection:* Revision of a previously approved collection.

2. *Title of the Form/Collection:* Records of Acquisition and Disposition, Registered Importers of Arms, Ammunition & Defense Articles on the U.S. Munitions Import List.

3. *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* None.

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Affected Public: Private Sector-for or not for profit institutions.

Abstract: The records associated with this collection are defense articles other than firearms and ammunition enumerated on the U.S. Munitions Import List. Information Collection (IC) OMB 1140–0031 is being revised to

change the title from 'Records of Acquisition and Disposition, Registered Importers of Arms, Ammunition & Implements of War on the U.S. Munitions Import List' to 'Records of Acquisition and Disposition, Registered Importers of Arms, Ammunition & Defense Articles on the U.S. Munitions Import List' to reflect a change in terminology.

5. *Obligation to Respond:* Mandatory. The statutory requirements are implemented in per aw 22 U.S.C. 2778 and regulations 27 CFR 447.54.

6. *Total Estimated Number of Respondents:* 50 respondents.

7. *Estimated Time per Respondent:* 5 hours.

8. *Frequency:* Once annually.

9. *Total Estimated Annual Time Burden:* 250 hours.

10. *Total Estimated Annual Other Costs Burden:* $0.

If additional information is required, contact: Darwin Arceo, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, United States Department of Justice, Two Constitution Square, 145 N Street NE, 4W–218 Washington, DC 20530.

Dated: November 22, 2024.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2024–27820 Filed 11–26–24; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

[CPCLO Order No. 007–2024

Privacy Act of 1974; System of Records

AGENCY: Office of Justice Programs, United States Department of Justice.

ACTION: Notice of a new system of records.

SUMMARY: Pursuant to the Privacy Act of 1974, Office of Management and Budget (OMB) Circular No. A–108, and Federal law, notice is hereby given that the DOJ's Office of Justice Programs (OJP) proposes a new system of records notice titled the Peer Review Management System (PRMS), JUSTICE/OJP–020. The DOJ uses the PRMS, a web-based tool, to manage the planning, selection, and assignment of peer reviewers as part of the merit review of DOJ's funding opportunities.

DATES: In accordance with 5 U.S.C. 552a(e)(4) and (11), this system of records is effective upon publication, subject to a 30-day period in which to comment on the routine uses described below. Please submit any comments by December 27, 2024.

ADDRESSES: The public, OMB, and Congress are invited to submit any comments by mail to the United States Department of Justice, Office of Privacy and Civil Liberties, ATTN: Privacy Analyst, 145 N St. NE, Suite 8W, Washington, DC 20002; by facsimile at 202–307–0693; or by email at *privacy.compliance@usdoj.gov.* To ensure proper handling, please reference the above CPCLO Order No. on your correspondence.

FOR FURTHER INFORMATION CONTACT: Bryce Mitchell, Division Director; Enterprise Application Development Division, Office of the Chief Information Officer, Office of Justice Programs; 999 North Capitol Street NE, Washington, DC 20002, *Bryce.Mitchell@usdoj.gov,* (202) 598–9418.

Jennifer Tyson, Deputy Director, Grants Management Division, Audit, Assessment, and Management, Office of Justice Programs; 999 North Capitol Street NE, Washington, DC 20002, *Jennifer.Tyson@usdoj.gov,* (202) 307–0750.

SUPPLEMENTARY INFORMATION:

Potential peer reviewers, who may be members of the public or Federal Government personnel, use the PRMS online tool to enter their records via enrollment applications (*i.e.,* profiles) to be considered for peer review assignments. Authorized DOJ users (*i.e.* DOJ program office and contract staff) can search these profiles to nominate and invite a peer reviewer to review and score DOJ funding opportunity applications. Authorized users (*i.e.,* those members of the public or Federal Government personnel invited by a DOJ program office staff to serve as peer reviewer) may log into PRMS to review their profiles and obtain access to assigned peer review tasks.

In accordance with 5 U.S.C. 552a(r), the DOJ has provided a report to OMB and Congress on this new system of records.

Dated: November 19, 2024

Peter A. Winn,

Acting Chief Privacy and Civil Liberties Officer, United States Department of Justice.

JUSTICE/OJP—020

**SYSTEM NAME AND NUMBER: **

Peer Review Management System (PRMS), JUSTICE/OJP—020

SECURITY CLASSIFICATION:

The system is unclassified.

SYSTEM LOCATION:

Records in this system are maintained at the following locations: Office of Justice Programs (OJP); 999 North Capitol Street NE, Washington, DC 20002; and cloud service providers at AWS GovCloud; 1200 12th Avenue; South Seattle, WA 98144. The cloud computing service providers and their location may change from time to time, and this document may not reflect the most current information available. To confirm information about the current cloud computing service provider, please contact OJP through the OJP service desk at email address *OJP.ITservicedesk@ojp.usdoj.gov.*

SYSTEM MANAGER(S):

Bryce Mitchell, Division Director, Enterprise Application Development Division, Office of the Chief Information Officer, Office of Justice Programs, 999 North Capitol Street NE, Washington, DC 20002, *Bryce.Mitchell@usdoj.gov,* (202) 514–2412.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

28 U.S.C. 530C, Authority to use available funds; 34 U.S.C. 10226(b), Personnel and Administrative Authority

PURPOSE(S) OF THE SYSTEM:

The Peer Review Management System (PRMS) supports DOJ's overall grantmaking and research efforts toward fair, equitable, and objective funding decisions by providing a centralized directory for DOJ staff to obtain peer reviewers. DOJ peer reviewers consist of Federal Government staff or members of the public, who offer their expertise in merit reviewing and scoring OJP funding opportunities. The system achieves this purpose through its two main components, the Peer Reviewer Database (PRD) and the Peer Review Support System (PRSS).

The PRD maintains and disseminates records of peer reviewers and potential peer reviewers, including their electronic enrollment information. This component collects records about potential peer reviewers who voluntarily complete a multi-step online application process to be assigned peer review as needed by DOJ. The PRD allows authorized DOJ users (DOJ program and contractor staff) to nominate and invite a potential peer reviewer for a peer review assignment. Authorized DOJ users can also review and evaluate work performed once a peer reviewer completes an assignment.

The PRSS maintains details of the peer review process necessary for authorized DOJ users to manage the peer review process, including application review criteria from funding opportunities, application data, and peer reviewer assignments. The PRSS also converts raw peer review scores into normalized scores or tiers, which are uploaded into OJP's grants

management system for programmatic review.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals applying to serve as peer reviewers and individuals selected by DOJ to serve as peer reviewers (including members of the public or Federal Government personnel); and DOJ personnel and DOJ contractors who have access to the system as permitted and authorized by the DOJ.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records in the PRMS include an individual's name, mailing address, personal email address, telephone number, work-related information (*e.g.,* current occupation, job title, work address, email address, work address, and work history), areas of expertise, and information on any relevant lived justice-involved experience. In addition, information regarding potential peer reviewers' education level, race, cultural or ethnic identity, education, sex or gender identity, Tribal affiliation, and former incarceration (as self-reported by the potential peer reviewers) may be provided.

RECORD SOURCE CATEGORIES:

The records in the system may obtained from, among other sources, individuals applying to serve as peer reviewers, individuals selected by DOJ to serve as peer reviewers, and OJP's grants management system, which provides grant application data.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b), all or a portion of the records contained in this system of records may be disclosed as a routine use pursuant to 5 U.S.C. 552a(b)(3) under the circumstances or for the purposes described below, to the extent such disclosures are compatible with the purposes for which the information was collected:

1. Where a record, either alone or in conjunction with other information, may be relevant to investigating a violation or potential violation of law—criminal, civil, or regulatory in nature—the relevant records may be referred to the appropriate Federal, State, local, territorial, Tribal, or foreign law enforcement authority or other appropriate entity charged with the responsibility for investigating or prosecuting such violation or charged with enforcing or implementing such law.

2. To appropriate officials and employees of a Federal agency or entity to the extent necessary for making decisions about peer review assignments, such as but not limited to knowledge and skills needed to evaluate DOJ funding opportunities.

3. To any person or entity that the DOJ has reason to believe possesses knowledge regarding matters pertaining to DOJ programs and activities, to the extent deemed to be necessary by the DOJ to elicit information about the potential peer reviewer for use in conferring the DOJ peer reviewer assignments.

4. To any person or entity that the DOJ has reason to believe possesses information regarding a matter within the jurisdiction of the DOJ, to the extent deemed to be necessary by the DOJ to elicit such information or cooperation from the recipient for use in the performance of an authorized activity.

5. In an appropriate proceeding before a court, grand jury, or administrative or adjudicative body, when the DOJ determines that the records are arguably relevant to the proceeding; or in an appropriate proceeding before an administrative or adjudicative body when the adjudicator determines the records to be relevant to the proceeding.

6. To the news media and the public, including but not limited to disclosures pursuant to 28 CFR 50.2, unless it is determined that release of the specific information in the context of a particular case or matter would constitute an unwarranted invasion of personal privacy. While disclosures under 28 CFR 50.2 are in connection with a civil or criminal proceeding, disclosures under this routine use may also pertain to administrative proceedings as well as investigations of Federal employee misconduct prejudicial to the interests of members of the public.

7. To contractors, recipients, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for the Federal Government, when necessary to accomplish an agency function related to this system of records.

8. To a former employee of the DOJ for official purposes where the DOJ requires information and/or consultation assistance from the former employee regarding a matter within that person's former area of responsibility.

9. To a Member of Congress or staff acting upon the Member's behalf when the Member or staff requests the information on behalf of, and at the request of, the individual who is the subject of the record.

10. To the National Archives and Records Administration for purposes of records management inspections conducted under the authority of 44 U.S.C. 2904 and 2906.

11. To appropriate agencies, entities, and persons when (1) the DOJ suspects or has confirmed that there has been a breach of the system of records; (2) the DOJ has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the DOJ (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the DOJ's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

12. To another Federal agency or Federal entity, when the DOJ determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach, or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

13. To any agency, organization, or individual for the purpose of performing authorized audit or oversight operations of DOJ and meeting related reporting requirements.

14. To such recipients and under such circumstances and procedures as are mandated by Federal statute or treaty.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records in the PRMS are stored in electronic format in the OJP cloud platforms. Records are stored securely in accordance with applicable Federal laws, regulations, Department directives, and guidance.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records can be retrieved within PRMS by a peer reviewer's personal identifier to obtain profiles or other data matching the search criteria necessary for the merit review of DOJ funding opportunities.

The records are retrievable by the peer reviewer's name, employee type (other Federal agency or other), education level, job category, race, cultural and ethnic identities, subject matter expertise, research expertise, business organization, organization unit, job title,

phone number (home and business), address (home and business), and gender and sexual identities. The records are searchable and retrievable using those identifiers for diversifying the pool of reviewers needed to meet the objectives conducive to a full and fair evaluation of the relevant OJP funding opportunities.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records in this system are stored in electronic format and retained as well as disposed of in accordance with the National Archives and Records Administration, General Records Schedule 1.2, which covers grant and cooperative agreement records.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

This system meets all DOJ requirements for authorization to operate per DOJ Order 0904, Cybersecurity Program. Specifically, information in this system is maintained in accordance with applicable laws, rules, and policies on protecting individual privacy.

The system leverages cloud service providers that maintain an authority to operate in accordance with applicable laws, rules, and policies, including Federal Risk and Authorization Management Program (FedRAMP) requirements.

Backup information is maintained in accordance with a government contract that requires adherence to applicable laws, rules, and policies. Internet connections are protected by multiple firewalls. Security personnel conduct periodic vulnerability scans using DOJ-approved software to ensure security compliance and security logs are enabled for all computers to assist in troubleshooting and forensics analysis during incident investigations. Users of individual computers can only gain access to the data by a valid user's identification and authentication.

RECORD ACCESS PROCEDURES:

All requests for access to records must be in writing and should be addressed to the relevant component:

OJP FOIA Officer; Office of Justice Programs; Office of the General Counsel; 999 North Capitol Street NE, Washington, DC 20002.

The envelope and letter should be clearly marked ''Privacy Act Access Request.'' The request must describe the records sought in sufficient detail to enable DOJ personnel to locate them with a reasonable amount of effort. The request must include a general description of the records sought and must include the requester's full name, current address, and date and place of birth. The request must be signed and either notarized or submitted under penalty of perjury. Although no specific form is required, you may obtain forms for this purpose from the FOIA/Privacy Act Mail Referral Unit, United States Department of Justice, 950 Pennsylvania Avenue NW, Washington, DC 20530, or on the Department of Justice website at *https://www.justice.gov/oip/oip-request.html.*

More information regarding the DOJ's procedures for accessing records in accordance with the Privacy Act can be found at 28 CFR part 16 Subpart D, ''Protection of Privacy and Access to Individual Records Under the Privacy Act of 1974.''

CONTESTING RECORD PROCEDURES:

Individuals seeking to contest or amend records pertaining to them, maintained in this system of records, must direct their requests to the address indicated in the ''RECORD ACCESS PROCEDURES'' paragraph, above. All requests to contest or amend records must be in writing and the envelope and letter should be clearly marked ''Privacy Act Amendment Request.'' All requests must state clearly and concisely what record is being contested, the reasons for contesting it, and the proposed amendment to the record.

More information regarding the DOJ's procedures for amending or contesting records in accordance with the Privacy Act can be found at 28 CFR 16.46, ''Requests for Amendment or Correction of Records.''

NOTIFICATION PROCEDURES:

Individuals may request to be notified if a record in this system of records pertains to them by utilizing the same procedures as those identified in the ''RECORD ACCESS PROCEDURES'' paragraph, above.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

None.

[FR Doc. 2024–27570 Filed 11–26–24; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF JUSTICE

[OMB 1140–0060]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Firearms Disabilities for Nonimmigrant Aliens

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 30 days until December 27, 2024.

FOR FURTHER INFORMATION CONTACT: If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact: Lindsay Babbie, EPS/FEID/FIPB, either by mail at Bureau of Alcohol, Tobacco, Firearms, and Explosives; 99 New York Ave. NE, Mail Stop 6N–518, Washington, DC 20226, by email at *Lindsay.Babbie@atf.gov,* or telephone at 202–648–7252.

SUPPLEMENTARY INFORMATION: The proposed information collection was previously published in the **Federal Register**, volume 89, page 80265, on Wednesday, October 2, 2024, allowing a 60-day comment period. Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Enhance the quality, utility, and clarity of the information to be collected; and/or

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic,

mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Written comments and recommendations for this information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/*PRAMain. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the information collection or the OMB Control Number 1140–0060. This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view Department of Justice, information collections currently under review by OMB.

DOJ seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOJ notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Overview of This Information Collection

1. *Type of Information Collection:* Revision of a previously approved collection.

2. *Title of the Form/Collection:* Firearms Disabilities for Nonimmigrant Aliens.

3. *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* None.

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Affected Public: Individuals or households, Private Sector-for or not for profit institutions.

Abstract: The nonimmigrant alien information will be used to determine if a nonimmigrant alien is eligible to obtain a federal firearms license and purchase, obtain, possess, or import a firearm. Nonimmigrant aliens also must maintain the documents while in possession of firearms or ammunition in the United States for verification purposes. Information Collection (IC) OMB # 1140–0060 is being revised to reflect an increase in costs. The number of persons who annually submit ATF Form 6NIA has increased since this information collection was last renewed.

5. *Obligation to Respond:* As this is not a form, there is no obligation to respond.

6. *Total Estimated Number of Respondents:* 2,531 respondents.

7. *Estimated Time per Respondent:* 3 minutes and 59 seconds.

8. *Frequency:* Once annually.

9. *Total Estimated Annual Time Burden:* 168 hours.

10. *Total Estimated Annual Other Costs Burden:* $3,864.

If additional information is required, contact: Darwin Arceo, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, United States Department of Justice, Two Constitution Square, 145 N Street NE, 4W–218 Washington, DC 20530.

Dated: November 22, 2024.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2024–27821 Filed 11–26–24; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

[OMB Number 1140–0101]

Agency Information Collection Activities; Proposed eCollection eComments Requested; National Firearms Act Division and Firearms and Explosives Services Division Customer Service Survey

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 30 days until December 27, 2024.

FOR FURTHER INFORMATION CONTACT: If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact: Paige Tisserand, National Firearms Division, either by email at *NFAOMBCOMMENTS@ATF.GOV* or *meghan.tissserand@atf.gov,* or telephone at 304–616–4500.

SUPPLEMENTARY INFORMATION: The proposed information collection was previously published in the **Federal Register**, volume 89 page 80935, on Friday, October 4, 2024, allowing a 60-day comment period. Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Enhance the quality, utility, and clarity of the information to be collected; and/or

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Written comments and recommendations for this information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the information collection or the OMB Control Number 1140–0101. This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view Department of Justice, information collections currently under review by OMB.

DOJ seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOJ notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Overview of This Information Collection

1. *Type of Information Collection:* Revision of a previously approved collection.

2. *Title of the Form/Collection:* National Firearms Act Division and

Firearms and Explosives Services Division Customer Service Survey.

3. *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* None.

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Affected Public: State, local and tribal governments, individuals or households, Federal Government.

Abstract: The National Firearms Act Division and Firearms and Explosives Services Division Customer Service Survey is used to gather information about customer service provided to the firearms and explosives industry and government agencies to improve service delivery. Information Collection (IC) OMB 1140–0101 is being revised to include the NFA Division's newest branch: Information Compliance Branch.

5. *Obligation to Respond:* Voluntary.

6. *Total Estimated Number of Respondents:* 100.

7. *Estimated Time per Respondent:* 10 minutes.

8. *Frequency:* Once annually.

9. *Total Estimated Annual Time Burden:* 17 hours.

10. *Total Estimated Annual Other Costs Burden:* $0.

If additional information is required, contact: Darwin Arceo, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, United States Department of Justice, Two Constitution Square, 145 N Street NE, 4W–218, Washington, DC 20530.

Dated: November 22, 2024.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2024–27862 Filed 11–26–24; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

[OMB Number 1110–0065]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension of a Previously Approved Collection; Private Industry Feedback Survey

AGENCY: Department of Justice, Federal Bureau of Investigation, Cyber Division.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Federal Bureau of Investigation (FBI), Cyber Division (CyD) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until January 27, 2025.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Lawrence Quigley, Unit Chief, FBI, CyD, 935 Pennsylvania Ave. NW, Washington, DC 20535; telephone: 304–367–3766, email: *lwquigley@fbi.gov.* Written comments and/or suggestions can also be sent to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503. Additionally, comments may be submitted via email to *OIRA_submissions@omb.eop.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Statistics, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Abstract: The FBI, Cyber Division, provides a voluntary ''Feedback'' Section on reports related to cyber trends and threats for private sector partners.

Overview of this information collection:

1. *Type of Information Collection:* Extensions of a currently approved collection.

2. *The Title of the Form/Collection:* Private Industry Feedback Survey.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* N/A.

4. *Affected public who will be asked or required to respond, as well as the obligation to respond:* The FBI, Cyber Division, produces reports that provide information related to cyber trends and threats for private sector partners. The reports are referred to as Private Industry Notifications (PINs) and FBI Liaison Alert Systems (FLASHs). In order to improve the PIN/FLASH reports, a ''Feedback'' Section has been added to the reports containing a URL that links to a voluntary online survey. The results of the survey are reviewed by CyD and used to improve future reports to better serve the FBI's private sector partners.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 5,000 respondents will complete the survey. It is estimated that it takes each respondent 3 minutes to complete the survey.

6. *An estimate of the total annual burden (in hours) associated with the collection:* The estimated public burden associated with his collection is 250 hours.

7. *An estimate of the total annual cost burden associated with the collection, if applicable:* $0.

TOTAL BURDEN HOURS

Activity	Number of respondents	Frequency (annually)	Total annual responses	Time per response (min)	Total annual burden (hours)
Ex: Survey	5,000		5,000	3	250
Unduplicated Totals	5,000		5,000		250

An estimate of the total annual burden (in hours) associated with the collection: The estimated public burden associated with this collection is 250 hours.

If additional information is required contact: Darwin Arceo, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 4W–218, Washington, DC.

Dated: November 22, 2024.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2024–27809 Filed 11–26–24; 8:45 am]

BILLING CODE 4410–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Air Act

On November 21, 2024, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the Western District of Pennsylvania in the lawsuit entitled *United States and Commonwealth of Pennsylvania* v. *Hilcorp Energy Company,* Civil Action No. 2:24–cv–01596 (W.D. Pa).

The lawsuit seeks injunctive relief and civil penalties for violations of the Clean Air Act and its implementing regulations at oil and natural gas production facilities owned and operated by Hilcorp Energy Company (''Hilcorp'') in Lawrence and Mercer Counties, Pennsylvania. The violations relate to alleged failures to adequately design, operate, and maintain storage tank vapor control systems, resulting in emissions of volatile organic compounds (''VOC'') and other pollutants to the atmosphere.

The proposed consent decree covers nine Hilcorp facilities in Pennsylvania. The proposed decree requires Hilcorp to perform injunctive relief, including conducting engineering evaluations of the vapor control systems at each of the controlled well pads to ensure that they are adequately sized and designed, and complete an environmental mitigation project. Hilcorp must also pay a $1,275,000 civil penalty. Entering into and fully complying with the proposed consent decree would release Hilcorp from past civil liability for violations of Clean Air Act regulations applicable to new and modified storage vessels and related state law at the facilities subject to the proposed consent decree.

The publication of this notice opens a period for public comment on the proposed Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States and Commonwealth of Pennsylvania* v. *Hilcorp Energy Company,* D.J. Ref. No. 90–5–2–1–12372. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the proposed Consent Decree may be examined and downloaded at this Justice Department website: *https://www.justice.gov/enrd/consent-decrees.* If you require assistance accessing the proposed Consent Decree, you may request assistance by email or by mail to the addresses provided above for submitting comments.

Jason A. Dunn,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2024–27780 Filed 11–26–24; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

[OMB 1140–0050]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Identification Markings Placed on Firearms

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 30-Day Notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 30 days until December 27, 2024.

FOR FURTHER INFORMATION CONTACT: If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact: Jennifer Scott, FIPB, 99 New York Avenue NE, Washington, DC 20226, either by email at *fipb-informationcollection@atf.gov* or *jennifer.scott@atf.gov* or telephone at 202–648–7190.

SUPPLEMENTARY INFORMATION: The proposed information collection was previously published in the **Federal Register**, volume 89, page 81111, on Monday, October 7, 2024, allowing a 60-day comment period. Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information,

including the validity of the methodology and assumptions used;
—Enhance the quality, utility, and clarity of the information to be collected; and/or
—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Written comments and recommendations for this information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/*PRAMain. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the information collection or the OMB Control Number 1140–0052. This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view Department of Justice, information collections currently under review by OMB.

DOJ seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOJ notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Overview of This Information Collection

1. *Type of Information Collection:* Revision of a previously approved collection.

2. *Title of the Form/Collection:* Identification Markings Placed on Firearms.

3. *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* None. *Component:* Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract: Affected Public:* Private Sector-for or not for profit institutions. *Abstract:* Each licensed firearms manufacturer and licensed firearms importer must legibly identify each firearm by engraving, casting, stamping (impressing), or otherwise conspicuously placing on the frame or receiver an individual serial number, any associated license number, and all other additional required information to a depth of at least .003 inch and in a print size no smaller than 1/16 inch. Used to facilitate the investigations of the criminal use of firearms. Information Collection (IC) OMB #1140–0050 is being revised to reflect an increase in costs resulting from an increase in the number of respondents and firearms covered by the information collection, and from adding both a burden hour monetized value and start-up costs based on a rulemaking that occurred since the last time this collection was renewed.

5. *Obligation to Respond:* The obligation to respond is mandatory per 18 U.S.C. Chapter 44 and 26 U.S.C. § 5842.

6. *Total Estimated Number of Respondents:* 22,662 total respondents.

7. *Estimated Time per Respondent:* 1 minute.

8. *Frequency:* One per firearm.

9. *Total Estimated Annual Time Burden:* 257,419,782 hours.

10. *Total Estimated Annual Other Costs Burden:* $45,598,278.00.

If additional information is required, contact: Darwin Arceo, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, United States Department of Justice, Two Constitution Square, 145 N Street NE, 4W–218 Washington, DC 20530.

Dated: November 22, 2024.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2024–27861 Filed 11–26–24; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

[OMB Number 1110–0082]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Law Enforcement Suicide Data Collection (LESDC)

AGENCY: Federal Bureau of Investigation, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Federal Bureau of Investigation (FBI), Department of Justice (DOJ), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 30 days until December 27, 2024.

FOR FURTHER INFORMATION CONTACT: If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact: [Edward L. Abraham, Crime and Law Enforcement Statistics Unit Chief, FBI, CJIS Division, Module D–2, 1000 Custer Hollow Road, Clarksburg, West Virginia 26306; email: *elabraham@fbi.gov* or *UCR@fbi.gov;* telephone: 304–625–4830].

SUPPLEMENTARY INFORMATION: The proposed information collection was previously published in the **Federal Register** on October 15, 2024 allowing a 60-day comment period. Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:
—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
—Enhance the quality, utility, and clarity of the information to be collected; and/or
—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Written comments and recommendations for this information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the information collection or the OMB Control Number 1110–0082. This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view Department of Justice, information collections currently under review by OMB.

DOJ seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years

without renewal. The DOJ notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Overview of This Information Collection

1. *Type of Information Collection:* Extension of a previously approved collection.

2. *Title of the Form/Collection:* Law Enforcement Suicide Data Collection.

3. *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Criminal Justice Information Services (CJIS) Division, FBI.

4. *Affected public who will be asked or required to respond, as well as a brief abstract*:

Affected Public: Law Enforcement Agencies.

Abstract: In response to the *Law Enforcement Suicide Data Collection Act* (Title 34, United States Code, Section 50701), the FBI's Uniform Crime Reporting Program established the LESDC which is designed to gather information on occurrences of suicide and attempted suicide within the law enforcement community. The data will be used to produce a report of information surrounding these incidents which will help promote the understanding of, and elicit further discussion within society about, law enforcement suicide and attempted suicide.

5. *Obligation to Respond:* Voluntary.

6. *Total Estimated Number of Respondents:* 50 respondents.

7. *Estimated Time per Respondent:* 15 minutes.

8. *Frequency:* Annually.

9. *Total Estimated Annual Time Burden:* 15 minutes.

10. *Total Estimated Annual Other Costs Burden:* $0.

If additional information is required, contact: Darwin Arceo, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, United States Department of Justice, Two Constitution Square, 145 N Street NE, 4W–218, Washington, DC 20530.

Dated: November 22, 2024.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2024–27825 Filed 11–26–24; 8:45 am]

BILLING CODE 4410–02–P

DEPARTMENT OF JUSTICE

[OMB Number 1121–0269]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Reinstatement, With Change, of a Previously Approved Collection for Which Approval Has Expired: Census of Publicly Funded Forensic Crime Laboratories (CPFFCL)

AGENCY: Bureau of Justice Statistics, Department of Justice

ACTION: 60-Day notice.

SUMMARY: The Bureau of Justice Statistics, Department of Justice (DOJ) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until January 27, 2025.

FOR FURTHER INFORMATION CONTACT: If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Matt Durose, Bureau of Justice Statistics, 999 North Capital Street NE, Washington, DC 20531 (email: *Matt.Durose@usdoj.gov;* telephone: 202–598–0295).

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Statistics, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so, how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Abstract: Since 2002, the Bureau of Justice Statistics (BJS) has periodically conducted the Census of Publicly Funded Forensic Crime Laboratories (CPFFCL) through a survey that collects data on the staffing, budgets, workloads, resources, policies, and procedures among federal, state, and local crime labs. The 2024 CPFFCL will be the sixth administration. It will provide insight on emerging issues and challenges facing crime labs since the CPFFCL was last conducted in 2020. BJS uses the information gathered in CPFFCL in published reports and statistics. The reports will be made available to the U.S. Congress, Executive Office of the President, practitioners, researchers, students, the media, others interested in criminal justice statistics, and the general public via the BJS website.

Overview of This Information Collection

1. *Type of Information Collection:* Reinstatement, with changes, of a previously approved collection for which approval has expired.

2. *Title of the Form/Collection:* 2024 Census of Publicly Funded Forensic Crime Laboratories (CPFFCL).

3. *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* The form number is CPFFCL–24. The applicable component within the Department of Justice is the Bureau of Justice Statistics (BJS), in the Office of Justice Programs.

4. *Affected public who will be asked or required to respond, as well as the obligation to respond:* Affected public are federal, state, and local government agencies. The 2024 CPFFCL is revised from the 2020 CPFFCL. BJS plans to field the 2024 CPFFCL from February through August 2025. Respondents will be the staff at the publicly funded forensic crime labs. The obligation to respond is voluntary.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* A projected 350 respondents from individual labs and multi-lab systems will take an average of 90 minutes (1.5 hours) each to complete form CPFFCL–24, including time to research or find information not readily available. In addition, an estimated 225 respondents will be contacted for data quality follow-up at 15 minutes (.25 hours) per respondent.

6. *An estimate of the total public burden (in hours) associated with the collection:* The total burden hours for this collection is 581 hours.

7. *An estimate of the total annual cost burden associated with the collection, if applicable:* $907,183.

TOTAL BURDEN HOURS

Activity	Number of respondents	Frequency	Total annual responses	Time per response	Total annual burden (hours)
Survey	350	1	350	90 min (1.5 hrs.).	525
Data Quality Follow-Up	225	1	225	15 min (.25 hrs.).	56
Unduplicated Totals	350		300		581

If additional information is required, contact: Darwin Arceo, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 4W–218, Washington, DC.

Dated: November 22, 2024.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2024–27802 Filed 11–26–24; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Davis-Bacon Certified Payroll

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Wage and Hour Division (WHD)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before December 27, 2024.

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

FOR FURTHER INFORMATION CONTACT: Nora Hernandez by telephone at 202–693–8633, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: The Copeland Act requires contractors and subcontractors performing work on federally financed or assisted construction contracts to furnish weekly a statement on the wages paid each covered worker during the prior week. See 40 U.S.C. 3145; 29 CFR 3.3(b). This Copeland Act provision specifically requires the regulations to ''include a provision that each contractor and subcontractor each week must furnish a statement on the wages paid each worker during the prior week.'' This requirement is implemented by 29 CFR 3.3 and 3.4 and the standard Davis-Bacon contract clauses set forth at 29 CFR 5.5. The regulation at 29 CFR 5.5 (a)(3)(ii)(A) (''Frequency and method of submission'') requires contractors to submit weekly a copy of all payrolls to the federal agency contracting for or financing the construction project. If the agency is not a party to the contract, the contractor will submit the payrolls to the applicant, sponsor, or owner, as the case may be, for transmission to the contracting agency. This provision requires that the payrolls submitted shall set out accurately and completely information required to be maintained under 29 CFR 5.5(a)(3)(ii)(B) (''Information required'').

The information that must be included in the weekly transmittals includes the name of each covered worker; each worker's correct classification(s) of work actually performed; hourly rates of wages paid (including rates of contributions or costs anticipated for bona fide fringe benefits or cash equivalents thereof of the types described in 40 U.S.C. 3141(2)(B) of the Davis-Bacon Act); daily and weekly number of hours actually worked in total and on each covered contract; deductions made; and actual wages paid. *See* 29 CFR 5.5(a)(3)(i)(B); 29 CFR 5.5(a)(3)(ii)(B). The weekly transmittals also must include an individually identifying number for each employee (*e.g.,* the last four digits of the employee's Social Security number). *See* 29 CFR 5.5(a)(3)(ii)(B).

The provision at 29 CFR 5.5(a)(3)(ii)(B) also states what must not be included in the weekly transmittal. The weekly transmittal must not include workers' full social security numbers, last known addresses, telephone numbers, and email addresses. That information must be recorded and maintained by the contractors as part of the record-keeping provisions in the regulations at 29 CFR 5.5(a)(3)(i)(B), but it must not be included in the weekly transmittals.

The regulations at 29 CFR 5.5(a)(3)(ii)(C) and 29 CFR 3.3(b) require each contractor to furnish weekly a signed ''Statement of Compliance'' accompanying the payroll indicating the payrolls are correct and complete and that each covered worker has been paid not less than the proper Davis-Bacon Act prevailing wage rate for the work performed.

The required weekly payroll information may be submitted in any form desired. The information collection request that is the subject of this notice, Optional Form WH–347, is designed to include fields for all of the necessary information so as to satisfy the regulatory and contractual requirements. The weekly submission of a properly executed certification, with the prescribed language set forth on page 2 of Optional Form WH–347, satisfies the requirement for submission of the required ''Statement of Compliance.'' 29 CFR 5.5(a)(3)(ii)(C).

In addition to the weekly transmittal requirements, the regulations contain separate record retention requirements that require the retention of the weekly

transmittals themselves as well as a broader subset of documents and information. Regulations 29 CFR 3.4(b) and 5.5(a)(3)(ii)(G) require contractors to maintain copies of these transmitted weekly certified payrolls for three years after all the work on the prime contract is completed. The record retention provision at 29 CFR 5.5(a)(3)(i) requires contractors performing work on projects subject to the Davis-Bacon and Related Acts (DBRA) to retain the address, telephone number, email address, and social security number of each covered worker, in addition to all of the worker-specific information that must be included on the weekly certified payroll. In addition, whenever a contractor seeks to provide a portion of its required fringe benefits though an unfunded plan (as described in 29 CFR 5.5(a)(1)(v)), the contractor must maintain records showing that the commitment to provide such benefits is enforceable, that the plan or program is financially responsible, that the plan or program has been communicated in writing to the laborers or mechanics affected, and the costs anticipated or the actual cost incurred in providing such benefits. See 29 CFR 5.5(a)(3)(i)(C). Contractors employing apprentices or trainees under approved programs also must maintain written evidence of the registration of apprenticeship programs and certification of trainee programs, the registration of the apprentices and trainees, and the ratios and wage rates prescribed in the applicable programs. Id. § 5.5(a)(3)(i)(D). 29 CFR 5.5(a)(3)(iii) provides that contractors and subcontractors must maintain copies of covered contracts, subcontracts, and related documents.

The Department periodically reviews its information collection requests to ensure that they are necessary and sufficient to effectively and efficiently fulfill the Department's statutory directive to oversee and enforce the Davis-Bacon Act. Substantive edits to the WH–347 form were last made in 2011. The Department reviewed the current form WH–347 and proposed several edits. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on August 30, 2024 (89 FR 70670).

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–WHD.

Title of Collection: Davis-Bacon Certified Payroll.

OMB Control Number: 1235–0008.

Affected Public: Businesses or other for-profits, Farms.

Total Estimated Number of Respondent: 11,310,112.

Total Estimated Number of Responses: 122,936.

Total Estimated Annual Time Burden: 10,556,105 hours.

Total Estimated Annual Other Costs Burden: $0.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Nora Hernandez,

PRA Department Clearance Officer.

[FR Doc. 2024–27720 Filed 11–26–24; 8:45 am]

BILLING CODE 4510–27–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Unemployment Insurance (UI) Title XII Advances and Voluntary Repayment Process

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Employment and Training Administration (ETA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before December 27, 2024.

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

FOR FURTHER INFORMATION CONTACT: Michael Howell by telephone at 202–693–6782, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: This information collection's purpose is to maintain a process for state governors for requesting advances and repaying advances through their correspondence with the Secretary of Labor. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on May 9, 2024 (89 FR 39648).

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years

without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–ETA.

Title of Collection: Unemployment Insurance (UI) Title XII Advances and Voluntary Repayment Process.

OMB Control Number: 1205–0199.

Affected Public: State, Local and Tribal Governments.

Total Estimated Number of Respondents: 4.

Total Estimated Number of Responses: 12.

Total Estimated Annual Time Burden: 12 hours.

Total Estimated Annual Other Costs Burden: $0.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Michael Howell,

Senior Paperwork Reduction Act Analyst.

[FR Doc. 2024–27719 Filed 11–26–24; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2010–0055]

Recordkeeping and Reporting Occupational Injuries and Illnesses; Revision of the Office of Management and Budget's (OMB) Approval of Information Collection (Paperwork) Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for public comments.

SUMMARY: OSHA solicits public comments concerning the proposed revision to combine two separate OMB approved Recordkeeping and Reporting Occupational Injuries and Illnesses Information Collections.

DATES: Comments must be submitted (postmarked, sent, or received) by January 27, 2025.

ADDRESSES:

Electronically: You may submit comments and attachments electronically at *https://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Docket: To read or download comments or other material in the docket, go to *https://www.regulations.gov.* Documents in the docket are listed in the *https://www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download through the websites. All submissions, including copyrighted material, are available for inspection through the OSHA Docket Office. Contact the OSHA Docket Office at (202) 693–2350 (TTY (877) 889–5627) for assistance in locating docket submissions.

Instructions: All submissions must include the agency name and OSHA docket number (OSHA–2010–0055) for the Information Collection Request (ICR). OSHA will place all comments, including any personal information, in the public docket, which may be made available online. Therefore, OSHA cautions interested parties about submitting personal information such as social security numbers and birthdates.

For further information on submitting comments, see the ''Public Participation'' heading in the section of this notice titled **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Seleda Perryman, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor; telephone (202) 693–2222.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of the continuing effort to reduce paperwork and respondent (*i.e.,* employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)). This program ensures that information is in the desired format, reporting burden (time and costs) is minimal, the collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (OSH Act) (29 U.S.C. 651 *et seq.*) authorizes information collection by employers as necessary or appropriate for enforcement of the OSH Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (29 U.S.C. 657). The OSH Act also requires that OSHA obtain such information with minimum burden upon employers, especially those operating small businesses, and to reduce to the maximum extent feasible unnecessary duplication of effort in obtaining information (29 U.S.C. 657).

The Agency requests a revision to incorporate the *Improve Tracking of Workplace Injuries and Illnesses* paperwork package, OMB Control Number 1218–0279, into the *Recordkeeping and Reporting Occupational Injuries and Illnesses (29 CFR part 1904)* paperwork package, OMB Control Number 1218–0176. While both paperwork packages contain information collections contained in the Recording and Reporting Occupational Injuries and Illnesses (29 CFR part 1904), a separate paperwork package for the Improve Tracking of Workplace Injuries and Illnesses rulemaking was necessary to ensure continued OMB approval of the existing information collections in the Recordkeeping and Reporting Occupational Injuries and Illnesses (29 CFR part 1904) paperwork package. The Occupational Safety and Health Act (OSH Act) and 29 CFR part 1904 prescribe that certain employers maintain records of job-related injuries and illnesses. Other employers with 100 or more employees in certain designated industries are required to submit electronically to OSHA information captured on their completed OSHA 300, 301, and 300A Forms. The injury and illness records are intended to have multiple purposes. One purpose is to provide data needed by OSHA to carry out enforcement and intervention activities to provide workers a safe and healthful work environment. Access to this data allows the Agency to more efficiently focus its enforcement and outreach resources toward establishments that are experiencing specific types of occupational injury and illness Expanded public access to establishment-specific, case-specific, injury and illness data will allow employers, employees, potential employees, employee representatives, customers, potential customers, researchers, and the general public to make informed decisions about the workplace safety and health at a given establishment, and this accessibility will ultimately result in the reduction of occupational injuries and illnesses.

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirements are necessary for the proper performance of the agency's functions to protect workers, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the information collection requirements, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and

• Ways to minimize the burden on employers who must comply; for example, by using automated or other technological information, and transmission techniques.

III. Proposed Actions

OSHA is requesting a revision the currently approved collection of information requirements contained in the paperwork package for Recordkeeping and Reporting Occupational Injuries and Illnesses (29 CFR part 1904) by OMB. This revision is incorporating the collections of information contained in the paperwork package for Improve Tracking of Injuries and Illnesses, OMB Control Number 1218–0279, with the paperwork package for Recordkeeping and Reporting Occupational Injuries and Illnesses paperwork package, OMB Control Number 1218–0176. As a result, the agency is requesting a program change increase of 112,551 hours and an adjustment decrease of 5,934 hours the burden going from 2,167,111 to 2,161,177 hours.

OSHA will summarize the comments submitted in response to this notice and will include this summary in the request to OMB to extend the approval of the information collection requirements.

Type of Review: Revision of a currently approved collection.

Title: Recordkeeping and Reporting Occupational Injuries and Illnesses (29 CFR part 1904).

OMB Control Number: 1218–0176.

Affected Public: Business or other for-profits.

Number of Respondents: 1,239,687.

Number of Responses: 5,571,568.

Frequency of Responses: On occasion, Annual.

Average Time per Response: Varies.

Estimated Total Burden Hours: 2,161,177.

Estimated Cost (Operation and Maintenance): $0.

IV. Public Participation—Submission of Comments on This Notice and Internet Access to Comments and Submissions

You may submit comments in response to this document as follows: (1) electronically at *https://www.regulations.gov,* which is the Federal eRulemaking Portal; or (2) by facsimile (fax), if your comments, including attachments, are not longer than 10 pages you may fax them to the OSHA Docket Office at (202) 693–1648. All comments, attachments, and other material must identify the agency name and the OSHA docket number for the ICR (Docket No. OSHA–2010–0055). You may supplement electronic submission by uploading document files electronically.

Comments and submissions are posted without change at *https://www.regulations.gov.* Therefore, OSHA cautions commenters about submitting personal information such as social security numbers and dates of birth. Although all submissions are listed in the *https://www.regulations.gov* index, some information (*e.g.,* copyrighted material) is not publicly available to read or download from this website. All submission, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the *https://www.regulations.gov* website to submit comments and access the docket is available at the website's ''User Tips'' link.

Contact the OSHA Docket Office at (202) 693–2350, (TTY (877) 889–5627) for information about materials not available from the website, and for assistance in using the internet to locate docket submissions.

V. Authority and Signature

James S. Frederick, Deputy Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order No. 8–2020 (85 FR 58393).

Signed at Washington, DC, on November 20, 2024.

James S. Frederick,

Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2024–27718 Filed 11–26–24; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2024–0002]

Advisory Committee on Construction Safety and Health (ACCSH)

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for Nominations.

SUMMARY: The Acting Secretary of Labor requests nominations for membership on the Advisory Committee for Construction Safety and Health (ACCSH).

DATES: Submit nominations for ACCSH membership by January 2, 2025.

ADDRESSES:

Nominations: You must submit nominations and supporting materials, identified by Docket No. OSHA–2024–0002, electronically at *https://www.regulations.gov,* which is the Federal e-Rulemaking Portal. Follow the online instructions for submissions.

Instructions: All submissions must include the agency name and the OSHA docket number for this **Federal Register** notice (Docket No. OSHA–2024–0002). OSHA will post all submissions, including personal information, in the public docket without change, which may be made available online at *https://www.regulations.gov*. Therefore, OSHA cautions interested parties about submitting information they do not want made available to the public or submitting materials that contain personal information (either about themselves or others), such as Social Security numbers and birthdates. For further information on submitting nominations, see the ''Submission requirements'' heading in the section of this notice titled **SUPPLEMENTARY INFORMATION.**

Docket: To read or download nominations or other materials in the docket, go to *https://www.regulations.gov*. Documents in the docket are listed in the *https://www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download through the website. All submissions, including copyrighted material, are available for inspection through the OSHA Docket Office. Contact the OSHA Docket Office at (202) 693–2350 (TTY number: (877) 889–5627) for assistance in locating docket submissions.

FOR FURTHER INFORMATION CONTACT:

For press inquiries: Mr. Frank Meilinger, Director, OSHA Office of Communications; telephone: (202) 693–1999; email: *meilinger.francis2@dol.gov*.

For general information about ACCSH and ACCSH membership: Mr. Jose Hererra, OSHA, Directorate of Construction; telephone: (202) 693–2020; email: *herrera.jose.h@dol.gov*.

Copies of this ***Federal Register*** *document:* Electronic copies of this **Federal Register** document are available at *https://www.regulations.gov*. This document, as well as news releases and other relevant information are also available on the OSHA web page at *https://www.osha.gov/*.

SUPPLEMENTARY INFORMATION: The Secretary of Labor invites interested persons to submit nominations for membership on ACCSH.

A. Background

ACCSH advises the Secretary of Labor and the Assistant Secretary of Labor for

Occupational Safety and Health (Assistant Secretary) in the formulation of standards affecting the construction industry, and on policy matters arising in the administration of the safety and health provisions under the Contract Work Hours and Safety Standards Act (Construction Safety Act (CSA)) (40 U.S.C. 3701 *et seq.*) and the Occupational Safety and Health Act of 1970 (OSH Act) (29 U.S.C. 651 *et seq.*) (see also 29 CFR 1911.10 and 1912.3). In addition, the CSA and OSHA regulations require the Assistant Secretary to consult with ACCSH before the agency proposes occupational safety and health standards affecting construction activities (40 U.S.C. 3704; 29 CFR 1911.10).

ACCSH operates in accordance with the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. 1001, *et seq.*), and the implementing regulations (41 CFR 102–3 *et seq.*); and Department of Labor Manual Series Chapter 1–900 (3/25/2022). ACCSH generally meets two to four times a year.

B. ACCSH Membership

ACCSH consists of 15 members whom the Secretary appoints. ACCSH members generally serve two-year terms, unless they resign, cease to be qualified, become unable to serve, or the Secretary removes them (29 CFR 1912.3(e)). The Secretary may appoint ACCSH members to successive terms. No member of ACCSH, other than members who represent employers or employees, shall have an economic interest in any proposed rule that affects the construction industry (29 CFR 1912.6).

The categories of ACCSH membership are, and number of new members to be appointed to replace members whose terms will expire are:

- Five members who are qualified by experience and affiliation to present the viewpoint of employers in the construction industry-five employer representatives will be appointed;
- Five members who are similarly qualified to present the viewpoint of employees in the construction industry-five employee representatives will be appointed;
- Two representatives of State safety and health agencies-two representatives from a State safety and health agency will be appointed;
- Two public members, qualified by knowledge and experience to make a useful contribution to the work of ACCSH, such as those who have professional or technical experience and competence with occupational safety and health in the construction industry-two public representatives will be appointed; and
- One representative designated by the Secretary of the Department of Health and Human Services and appointed by the Secretary-no new appointment will be made.

Any interested person or organization may nominate one or more individuals for membership on ACCSH. Interested persons also are invited and encouraged to submit statements in support of nominees.

C. Submission Requirements

Nominations must include the following information:

- Nominee's contact information and current employment or position;
- Nominee's résumé or curriculum vitae, including prior membership on ACCSH and other relevant organizations and associations;
- Category of membership (employer, employee, public, State safety and health agency) that the nominee is qualified to represent;
- A summary of the background, experience, and qualifications that addresses the nominee's suitability for each of the nominated membership categories;
- Articles or other documents the nominee has authored that indicate the nominee's knowledge, experience, and expertise in occupational safety and health, particularly as it pertains to the construction industry; and
- A statement that the nominee is aware of the nomination, is willing to regularly attend and participate in ACCSH meetings and has no conflicts of interest that would preclude membership on ACCSH.

D. Member Selection

The Department of Labor is committed to equal opportunity in the workplace and seeks broad-based and diverse ACCSH membership. To the extent permitted by FACA and other laws, ACCSH membership will be consistent with achieving the greatest impact, scope, and credibility among diverse stakeholders. The diversity in such membership includes, but is not limited to, race, sex, disability, sexual orientation, and gender identity. The Secretary will select the ACCSH members on the basis of their experience, knowledge, and competence in the field of occupational safety and health, particularly as it pertains to the construction industry. Information received through this nomination process, in addition to other relevant sources of information, will assist the Secretary in making these appointments to ACCSH. The Secretary will consider individuals nominated in response to this **Federal Register** document, as well as other qualified individuals, in selecting members to ACCSH. OSHA will publish a list of ACCSH members in the **Federal Register**.

Authority and Signature

James S. Frederick, Deputy Assistant Secretary of Labor for Occupational Safety and Health, authorized the preparation of this notice pursuant to 29 U.S.C. 655, 40 U.S.C. 3704, Secretary of Labor's Order No. 8–2020 (85 FR 58393), 5 U.S.C. 1001, *et seq.,* and 29 CFR part 1912.

Signed at Washington, DC, on November 21, 2024.

James S. Frederick,

Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2024–27822 Filed 11–26–24; 8:45 am]

BILLING CODE 4510–26–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2025–459 and K2025–456; MC2025–460 and K2025–457; MC2025–461 and K2025–458; MC2025–462 and K2025–459; MC2025–463 and K2025–460; MC2025–464 and K2025–461; MC2025–465 and K2025–462; MC2025–466 and K2025–463]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* December 2, 2024.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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III. Summary Proceeding(s)

I. Introduction

Pursuant to 39 CFR 3041.405, the Commission gives notice that the Postal

Service filed request(s) for the Commission to consider matters related to Competitive negotiated service agreement(s). The request(s) may propose the addition of a negotiated service agreement from the Competitive product list or the modification of an existing product currently appearing on the Competitive product list.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

Section II identifies the docket number(s) associated with each Postal Service request, if any, that will be reviewed in a public proceeding as defined by 39 CFR 3010.101(p), the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each such request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 and 39 CFR 3000.114 (Public Representative). Section II also establishes comment deadline(s) pertaining to each such request.

The Commission invites comments on whether the Postal Service's request(s) identified in Section II, if any, are consistent with the policies of title 39. Applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3041. Comment deadline(s) for each such request, if any, appear in Section II.

Section III identifies the docket number(s) associated with each Postal Service request, if any, to add a standardized distinct product to the Competitive product list or to amend a standardized distinct product, the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. Standardized distinct products are negotiated service agreements that are variations of one or more Competitive products, and for which financial models, minimum rates, and classification criteria have undergone advance Commission review. *See* 39 CFR 3041.110(n); 39 CFR 3041.205(a). Such requests are reviewed in summary proceedings pursuant to 39 CFR 3041.325(c)(2) and 39 CFR 3041.505(f)(1). Pursuant to 39 CFR 3041.405(c)-(d), the Commission does not appoint a Public Representative or request public comment in proceedings to review such requests.

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

II. Public Proceeding(s)

1. *Docket No(s).:* MC2025–459 and K2025–456; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 766 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 20, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Kenneth Moeller; *Comments Due:* December 2, 2024.

2. *Docket No(s).:* MC2025–460 and K2025–457; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 473 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 20, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Kenneth Moeller; *Comments Due:* December 2, 2024.

3. *Docket No(s).:* MC2025–461 and K2025–458; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 767 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 20, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Kenneth Moeller; *Comments Due:* December 2, 2024.

4. *Docket No(s).:* MC2025–462 and K2025–459; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 768 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 20, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Jana Slovinska; *Comments Due:* December 2, 2024.

5. *Docket No(s).:* MC2025–463 and K2025–460; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 769 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 20, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Jana Slovinska; *Comments Due:* December 2, 2024.

6. *Docket No(s).:* MC2025–464 and K2025–461; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 770 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 20, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Almaroof Agoro; *Comments Due:* December 2, 2024.

7. *Docket No(s).:* MC2025–465 and K2025–462; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 474 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 20, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Almaroof Agoro; *Comments Due:* December 2, 2024.

8. *Docket No(s).:* MC2025–466 and K2025–463; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 771 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 20, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Almaroof Agoro; *Comments Due:* December 2, 2024.

III. Summary Proceeding(s)

None. *See* Section II for public proceedings.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2024–27726 Filed 11–26–24; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2025–467 and K2025–464; MC2025–468 and K2025–465; MC2025–469 and K2025–466; MC2025–470 and K2025–467; MC2025–471 and K2025–468; MC2025–472 and K2025–469; MC2025–473 and K2025–470; MC2025–474 and K2025–471; MC2025–475 and K2025–472; MC2025–476 and K2025–473; MC2025–478 and K2025–475; MC2025–479 and K2025–476; MC2025–480 and K2025–477; MC2025–481 and K2025–478; MC2025–482 and K2025–479]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* December 3, 2024.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction

Pursuant to 39 CFR 3041.405, the Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to Competitive negotiated service agreement(s). The request(s) may propose the addition of a negotiated service agreement from the Competitive product list or the modification of an existing product currently appearing on the Competitive product list.

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Section II identifies the docket number(s) associated with each Postal Service request, if any, that will be reviewed in a public proceeding as defined by 39 CFR 3010.101(p), the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each such request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 and 39 CFR 3000.114 (Public Representative). Section II also establishes comment deadline(s) pertaining to each such request.

The Commission invites comments on whether the Postal Service's request(s) identified in Section II, if any, are consistent with the policies of title 39. Applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3041.

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

Comment deadline(s) for each such request, if any, appear in Section II.

Section III identifies the docket number(s) associated with each Postal Service request, if any, to add a standardized distinct product to the Competitive product list or to amend a standardized distinct product, the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. Standardized distinct products are negotiated service agreements that are variations of one or more Competitive products, and for which financial models, minimum rates, and classification criteria have undergone advance Commission review. *See* 39 CFR 3041.110(n); 39 CFR 3041.205(a). Such requests are reviewed in summary proceedings pursuant to 39 CFR 3041.325(c)(2) and 39 CFR 3041.505(f)(1). Pursuant to 39 CFR 3041.405(c)–(d), the Commission does not appoint a Public Representative or request public comment in proceedings to review such requests.

II. Public Proceeding(s)

1. *Docket No(s).:* MC2025–467 and K2025–464; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 475 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 21, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Gregory Stanton; *Comments Due:* December 3, 2024.

2. *Docket No(s).:* MC2025–468 and K2025–465; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 476 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 21, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Gregory Stanton; *Comments Due:* December 3, 2024.

3. *Docket No(s).:* MC2025–469 and K2025–466; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 477 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 21, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Gregory Stanton; *Comments Due:* December 3, 2024.

4. *Docket No(s).:* MC2025–470 and K2025–467; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 772 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 21, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Christopher Mohr; *Comments Due:* December 3, 2024.

5. *Docket No(s).:* MC2025–471 and K2025–468; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 773 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 21, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Christopher Mohr; *Comments Due:* December 3, 2024.

6. *Docket No(s).:* MC2025–472 and K2025–469; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 774 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 21, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Christopher Mohr; *Comments Due:* December 3, 2024.

7. *Docket No(s).:* MC2025–473 and K2025–470; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 775 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 21, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Katalin Clendenin; *Comments Due:* December 3, 2024.

8. *Docket No(s).:* MC2025–474 and K2025–471; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 776 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 21, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Almaroof Agoro; *Comments Due:* December 3, 2024.

9. *Docket No(s).:* MC2025–475 and K2025–472; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 777 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 21, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Almaroof Agoro; *Comments Due:* December 3, 2024.

10. *Docket No(s).:* MC2025–476 and K2025–473; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage

Contract 778 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 21, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Almaroof Agoro; *Comments Due:* December 3, 2024.

11. *Docket No(s).:* MC2025–478 and K2025–475; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 479 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 21, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Jennaca Upperman; *Comments Due:* December 3, 2024.

12. *Docket No(s).:* MC2025–479 and K2025–476; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 480 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 21, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Jennaca Upperman; *Comments Due:* December 3, 2024.

13. *Docket No(s).:* MC2025–480 and K2025–477; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 779 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 21, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Maxine Bradley; *Comments Due:* December 3, 2024.

14. *Docket No(s).:* MC2025–481 and K2025–478; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 780 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 21, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Maxine Bradley; *Comments Due:* December 3, 2024.

15. *Docket No(s).:* MC2025–482 and K2025–479; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 781 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 21, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Maxine Bradley; *Comments Due:* December 3, 2024.

III. Summary Proceeding(s)

None. *See* Section II for public proceedings.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2024–27881 Filed 11–26–24; 8:45 am]

BILLING CODE 7710–FW–P

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Notice of Request for Information; Downscaled Climate Projection Datasets Available To Be Considered for Use in the Sixth National Climate Assessment

AGENCY: Office of Science and Technology Policy (OSTP).

ACTION: Request for Information (RFI).

SUMMARY: With this notice, the U.S. Global Change Research Program (USGCRP) is issuing a Request for Information (RFI) on downscaled climate projection datasets for possible use in the 6th National Climate Assessment (NCA6). USGCRP will use the information submitted in response to this RFI to identify downscaled datasets that may be used by NCA6 authors at their discretion and to develop an updated data atlas for NCA6.

DATES: Comments and nominations must be submitted to the web address specified below and received on or before January 17th, 2025.

ADDRESSES: Submitted information will be accepted electronically via the USGCRP Public Contribution System: *https://contribute.globalchange.gov.* Instructions for submitting comments are available on the website.

FOR FURTHER INFORMATION CONTACT: Aaron Grade (202) 419–3488, *agrade@usgcrp.gov,* U.S. Global Change Research Program.

SUPPLEMENTARY INFORMATION: The Global Change Research Act (GCRA) of 1990 mandates that USGCRP deliver a National Climate Assessment to Congress and the President not less frequently than every four years that ''(1) integrates, evaluates, and interprets the findings of the Program; (2) analyzes the effects of global change on the natural environment, agriculture, energy production and use, land and water resources, transportation, human health and welfare, human social systems, and biological diversity; and (3) analyzes current trends in global change, both human-induced and natural, and projects major trends for the subsequent 25 to 100 years.'' One of the ways that projected changes across the United States are assessed is through the use of downscaled datasets, which are used by chapter author teams to support their understanding of the future impacts of climate change in each of the 50 states and in the U.S. territories so as to inform the assessment findings, narrative texts, and figures.

To date, five NCAs have been released. The most recent (NCA5) was released in November 2023, and can be found at *https://nca2023.globalchange.gov.* NCA6 is being developed in a way that maximizes transparency and inclusivity, offering opportunities for diverse public participation throughout the process. The production and review processes are designed to result in a report that is authoritative, timely, relevant, and policy-neutral; valued by authors and users; accessible to the widest possible audience; and fully compliant with the GCRA and federal Information Quality Act requirements.

A previous **Federal Register** Notice (*https://www.federalregister.gov/documents/2024/05/02/2024-09575/national-oceanic-and-atmospheric-administration-noaa-availability-for-public-comment-on-nca6-draft*) called for public input on themes, information for assessment, and volunteers to participate in the NCA6 development process. This RFI asks for input from the public on the availability of downscaled climate projection datasets that would advance NCA's efforts to inform decisions at more localized scales.

This voluntary request for information is intended to support USGCRP's selection, processing, aggregation, and use of downscaled data in NCA6. NCA6 is currently under development, and it is projected to be publicly released between late 2027 and early 2028. USGCRP intends to use information from this RFI to plan for the appropriate volume and methods of data processing, aggregation, and data display techniques that reflect the expected increase in breadth of downscaled datasets that could be contributed to NCA6.

Information submitted through this form will be reviewed by a federal interagency group tasked with making recommendations to report leadership for appropriate downscaled datasets for use in NCA6. The USGCRP anticipates this process will require an ongoing dialogue with the groups that provide the selected downscaled datasets and has designed it to be as flexible as possible to be inclusive, while also mindful of NCA6 requirements as a Highly Influential Scientific Assessment. Responses to this request

are strongly encouraged and will serve as a starting point for this dialogue.

Information submissions will be accepted electronically via the USGCRP Public Contribution System: *https://contribute.globalchange.gov.* Instructions for submitting technical inputs are available on the website. Submitters may enter text or upload files in response to this notice. See *https://www.globalchange.gov/nca6* for more information. While submissions to this RFI are not required, they are highly encouraged for consideration for inclusion in NCA6. If you wish to submit a downscaled data set to the NCA6 for consideration outside of this RFI, please contact Aaron Grade, *agrade@usgcrp.gov* no later than March 1, 2025.

Please note that submission in response to this RFI is entirely voluntary. More information, as well as information on asking questions beforehand, is available at *https://www.globalchange.gov/nca6.* Please also note that responses to this RFI may be made public as needed at USGCRP's discretion.

Via a questionnaire, submitters can provide the requested information on appropriate datasets that are either completed or in progress. Creation of these datasets may use statistical, dynamical, or other techniques, but are expected to be based on the latest generation of global climate models (GCMs) used in the Coupled Model Intercomparison Project—Phase 6 (CMIP6). NCA6 will prioritize the inclusion of datasets that fully encompass the entire conterminous United States and/or specialize in or incorporate U.S. regions outside of the conterminous United States (*i.e.,* Alaska, Hawai'i, U.S.-Affiliated Pacific Islands, Puerto Rico, and/or the U.S. Virgin Islands) using a consistent and peer-reviewed technique. In addition to seeking details on dataset attributes, the USGCRP Public Contribution System (*https://contribute.globalchange.gov*) includes important requirements and considerations for the NCA timeline and project management.

Given limited resources, considerations of overall fit for NCA priorities, and scientific rigor, NCA6 may not include all information submitted to through this RFI. Report leadership will make the final decision regarding datasets used in NCA6, including potentially combining information from multiple products. If a submission is identified as relevant for potential use, USGCRP will engage with the submitter to develop and format datasets and metadata for use. This process is expected to become a recurring opportunity that will accommodate the evolving science and the rapid expansion of downscaling approaches and products for future NCAs and other federal products.

Dated: November 22, 2024.

Stacy Murphy,

Deputy Chief Operations Officer/Security Officer.

[FR Doc. 2024–27858 Filed 11–26–24; 8:45 am]

BILLING CODE 3270–F1–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101701; File No. SR–PEARL–2024–52]

Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rule 402, Criteria for Underlying Securities, Exchange To Allow the Exchange To List and Trade Options on the iShares Bitcoin Trust (the ''Trust'')

November 21, 2024.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 18, 2024, MIAX PEARL, LLC (''MIAX Pearl'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend Exchange Rule 402, Criteria for Underlying Securities.

The text of the proposed rule change is available on the Exchange's website at *https://www.miaxglobal.com/markets/us-equities/pearl-equities/rule-filings,* at MIAX Pearl's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Exchange Rule 402, Criteria for Underlying Securities,[3] to allow the Exchange to list and trade options on the iShares Bitcoin Trust (the ''Trust''), designating the Trust as appropriate for options trading on the Exchange.[4] This is a competitive filing based on a similar proposal submitted by Nasdaq ISE, LLC (''ISE'') and approved by the Securities and Exchange Commission (''Commission'').[5]

Current Exchange Rule 402(i)(4) provides that securities deemed appropriate for options trading include shares or other securities (''Exchange Traded Fund Shares'') that are traded on a national securities exchange and are defined as ''NMS stock'' under Rule 600 of Regulation NMS, and that meet specified criteria enumerated in the rule. Sub Section 4 of Exchange Rule 402(i) provides that such shares or other securities:

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Exchange notes that its affiliate exchanges, MIAX Options and MIAX Sapphire, submitted substantively identical proposals. The Exchange notes that all the rules of Chapter III of the MIAX Options Exchange, including Rules 307 and 309, are incorporated by reference to MIAX Pearl and MIAX Sapphire. The Exchange also notes that all of the rules of Chapter III of the MIAX Options Exchange, including Rules 307 and 309, and the rules of Chapter IV of the MIAX Options Exchange, including Rule 402, are incorporated by reference to MIAX Emerald.

[4] On January 10, 2024, the Commission approved proposals by NYSE Arca, Inc., The Nasdaq Stock Market LLC, and Cboe BZX Exchange, Inc. to list and trade the shares of 11 bitcoin-based commodity-based trust shares and trust units, including the iShares Bitcoin Trust. *See* Securities Exchange Act Release No. 99306 (Jan. 10, 2024), 89 FR 3008 (Jan. 17, 2024) (order approving File Nos. SR–NYSEARCA–2021–90; SR–NYSEARCA–2023–44; SR–NYSEARCA–2023–58; SR–NASDAQ–2023–016; SR–NASDAQ–2023–019; SR–CboeBZX–2023–028; SR–CboeBZX–2023–038; SR–CboeBZX–2023–040; SR–CboeBZX–2023–042; SR–CboeBZX–2023–044; SR–CboeBZX–2023–072) (''Bitcoin ETP Order'').

[5] *See* Securities Exchange Act Release No. 101128 (September 20, 2024), 89 FR 78942 (September 26, 2024) (SR–ISE–2024–03) (Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing of Amendment Nos. 4 and 5 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment Nos. 1, 4, and 5, to Permit the Listing and Trading of Options on the iShares Bitcoin Trust).

(4) are issued by the SPDR® Gold Trust or the iShares COMEX Gold Trust or the iShares Silver Trust or the ETFS Silver Trust or the ETFS Gold Trust or the ETFS Palladium Trust or the ETFS Platinum Trust or the Sprott Physical Gold Trust; or

In addition, the underlying securities and Exchange Rule 402i, including the commodity based trusts in Exchange Rule 402(i)(4), must meet the requirements of Exchange Rule 402(i), Sections i(5)(i)(A) or (B).

Proposal

The Exchange proposes to amend Exchange Rule 402(i)(4) to expand the list of securities that are appropriate for options trading on the Exchange .

Description of the Trust [6]

The shares are issued by the Trust, a Delaware statutory trust. The Trust operates pursuant to a trust agreement (the ''Trust Agreement'') between the Sponsor, BlackRock Fund Advisors (the ''Trustee'') as the trustee of the Trust and Wilmington Trust, National Association, as Delaware trustee. The Trust issues shares representing fractional undivided beneficial interests in its net assets. The assets of the Trust consist only of bitcoin, held by a custodian on behalf of the Trust except under limited circumstances when transferred through the Trust's prime broker temporarily (described below), and cash. Coinbase Custody Trust Company, LLC (the ''Bitcoin Custodian'') is the custodian for the Trust's bitcoin holdings, and maintains a custody account for the Trust (''Custody Account''); Coinbase, Inc. (the ''Prime Execution Agent''), an affiliate of the Bitcoin Custodian, is the prime broker for the Trust and maintains a trading account for the Trust (''Trading Account''); and Bank of New York Mellon is the custodian for the Trust's cash holdings (the ''Cash Custodian'' and together with the Bitcoin Custodian, the ''Custodians'') and the administrator of the Trust (the ''Trust Administrator''). Under the Trust Agreement, the Trustee may delegate all or a portion of its duties to any agent, and has delegated the bulk of the day to day responsibilities to the Trust Administrator and certain other administrative and record-keeping functions to its affiliates and other agents. The Trust is not an investment company registered under the Investment Company Act of 1940, as amended.

The investment objective of the Trust is to reflect generally the performance of the price of bitcoin. The Trust seeks to reflect such performance before payment of the Trust's expenses and liabilities. The shares are intended to constitute a simple means of making an investment similar to an investment in bitcoin through the public securities market rather than by acquiring, holding and trading bitcoin directly on a peer-to-peer or other basis or via a digital asset exchange. The shares have been designed to remove the obstacles represented by the complexities and operational burdens involved in a direct investment in bitcoin, while at the same time having an intrinsic value that reflects, at any given time, the investment exposure to the bitcoin owned by the Trust at such time, less the Trust's expenses and liabilities. Although the shares are not the exact equivalent of a direct investment in bitcoin, they provide investors with an alternative method of achieving investment exposure to bitcoin through the public securities market, which may be more familiar to them.

Custody of the Trust's Bitcoin

An investment in the shares is backed by bitcoin held by the Bitcoin Custodian on behalf of the Trust. All of the Trust's bitcoin will be held in the Custody Account, other than the Trust's bitcoin which is temporarily maintained in the Trading Account under limited circumstances, *i.e.,* in connection with creation and redemption Basket [7] activity or sales of bitcoin deducted from the Trust's holdings in payment of Trust expenses or the Sponsor's fee (or, in extraordinary circumstances, upon liquidation of the Trust). The Custody Account includes all of the Trust's bitcoin held at the Bitcoin Custodian, but does not include the Trust's bitcoin temporarily maintained at the Prime Execution Agent in the Trading Account from time to time. The Bitcoin Custodian will keep all of the private keys associated with the Trust's bitcoin held in the Custody Account in ''cold storage''.[8] The hardware, software, systems, and procedures of the Bitcoin Custodian may not be available or cost-effective for many investors to access directly.

The Exchange believes that offering options on the Trust will benefit investors by providing them with an additional, relatively lower cost investing tool to gain exposure to spot Bitcoin as well as a hedging vehicle to meet their investment needs in connection with Bitcoin products and positions. Similar to other commodity-based trusts on which options may be listed on the Exchange (*e.g.,* SPDR® Gold Trust, the iShares COMEX Gold Trust, the iShares Silver Trust, or the ETFS Gold Trust),[9] the Trust essentially offers the same objectives and benefits to investors as do other commodity-based trusts on which options may be listed on the Exchange.

Options on the Trust will trade in the same manner as options on other ETFs on the Exchange. Exchange Rules that currently apply to the listing and trading of all options on ETFs on the Exchange, including, for example, Rules that govern listing criteria, expirations, exercise prices, minimum increments, position and exercise limits (including as proposed in the filing submitted by Exchange's affiliate, MIAX Options filing), margin requirements, customer accounts and trading halt procedures, will apply to the listing and trading of options on the Trust on the Exchange. Today, these rules apply to options on the various commodities-based trusts deemed appropriate for options trading on the Exchange pursuant to Exchange Rule 402(i)(4).

The Exchange's initial listing standards for ETFs on which options may be listed and traded on the Exchange will apply to the Trust. Pursuant to Exchange Rule 402(a), a security (which includes ETFs) on which options may be listed and traded on the Exchange must be duly registered (with the Commission) and be an NMS stock (as defined in Rule 600 of Regulation NMS under the Act,) and be characterized by a substantial number of outstanding shares that are widely held and actively traded. Exchange Rule 402(i) requires that, in relevant part, ETFs must either (1) meet the criteria and standards set forth in Exchange Rule 402(a) or Exchange Rule 402(b), or (2) be available for creation or redemption each business day from or

[6] *See* Securities Exchange Act Release No. 99306 (Jan. 10, 2024), 89 FR 3008 (Jan. 17, 2024) (order approving File Nos. SR–NYSEARCA–2021–90; SR–NYSEARCA–2023–44; SR–NYSEARCA–2023–58; SR–NASDAQ–2023–016; SR–NASDAQ–2023–019; SR–CboeBZX–2023–028; SR–CboeBZX–2023–038; SR–CboeBZX–2023–040; SR–CboeBZX–2023–042; SR–CboeBZX–2023–044; SR–CboeBZX–2023–072)(Order Granting Accelerated Approval of Proposed Rule Changes, as Modified by Amendments Thereto, To List and Trade Bitcoin-Based Commodity-Based Trust Shares and Trust Units) for a complete description of the Trust.

[7] The Trust issues and redeems Shares only in blocks of 40,000 or integral multiples thereof. A block of 40,000 Shares is called a ''Basket.'' These transactions take place in exchange for Bitcoin.

[8] The term ''cold storage'' refers to a safeguarding method by which the private keys corresponding to the Trust's bitcoins are generated and stored in an offline manner, subject to layers of procedures designed to enhance security. Private keys are generated by the Bitcoin Custodian in offline computers that are not connected to the internet so that they are more resistant to being hacked.

[9] *See* Exchange Rule 402(i)(4).

through the issuer in cash or in kind at a price related to net asset value, and the issuer must be obligated to issue ETFs in a specified aggregate number even if some or all of the investment assets required to be deposited have not been received by the issuer, subject to the condition that the person obligated to deposit the investments has undertaken to deliver the investment assets as soon as possible and such undertaking is secured by the delivery and maintenance of collateral consisting of cash or cash equivalents satisfactory to the issuer, as provided in the respective prospectus.

Options on the Trust will also be subject to the Exchange's continued listing standards set forth in Exchange Rule 403(g), for ETFs deemed appropriate for options trading pursuant to Exchange Rule 402(i). Specifically, Exchange Rule 403(g) provides that ETFs that were initially approved for options trading pursuant to Exchange Rule 402(i) shall be deemed not to meet the requirements for continued approval, and the Exchange shall not open for trading any additional series of option contracts of the class covering that such ETFs, if the ETFs are delisted from trading pursuant to Exchange Rule 403(b)(4), are halted or suspended from trading in their primary market. Additionally, options on ETFs may be subject to the suspension of opening transactions in any of the following circumstances: (1) in the case of options covering ETFs approved for trading under Exchange Rule 402(i)(5)(i)(A), in accordance with the terms of paragraphs (b)(1), (2), and (3) of Exchange Rule 403; (2) in the case of options covering ETFs approved for trading under Exchange Rule 402(i)(5)(i)(B), following the initial twelve-month period beginning upon the commencement of trading in the ETFs on a national securities exchange and are defined as an NMS stock, there are fewer than 50 record and/or beneficial holders of such ETFs for 30 or more consecutive trading days; (3) the value of the index or portfolio of securities, non-U.S. currency, or portfolio of commodities including commodity futures contracts, options on commodity futures contracts, swaps, forward contracts and/or options on physical commodities and/or financial instruments and money market instruments on which the ETFs are based is no longer calculated or available; or (4) such other event shall occur or condition exist that in the opinion of the Exchange makes further dealing in such options on the Exchange inadvisable.

Options on the Trust would be physically settled contracts with American-style exercise.[10] Consistent with current Exchange Rule 404, which governs the opening of options series on a specific underlying security (including ETFs), the Exchange will open at least one expiration month for options on the Trust [11] and may also list series of options on the Trust for trading on a weekly,[12] monthly,[13] or quarterly [14] basis. The Exchange may also list long-term equity option series (''LEAPS'') that expire from 12 to 39 months from the time they are listed.[15]

Pursuant to Exchange Rule 404, Interpretation and Policy .06, which governs strike prices of series of options on ETFs, the interval between strike prices of series of options on ETFs approved for options trading pursuant to Exchange Rule 402(i) shall be fixed at a price per share which is reasonably close to the price per share at which the underlying security is traded in the primary market at or about the same time such series of options is first open for trading on the Exchange, or at such intervals as may have been established on another options exchange prior to the initiation of trading on the Exchange. With respect to the Short Term Options Series or Weekly Program, during the month prior to expiration of an option class that is selected for the Short Term Option Series Program, the strike price intervals for the related non-Short Term Option (''Related non-Short Term Option'') shall be the same as the strike price intervals for the Short Term Option.[16] Specifically, the Exchange may open for trading Short Term Option Series at strike price intervals of (i) $0.50 or greater where the strike price is less than $100, and $1 or greater where the strike price is between $100 and $150 for all option classes that participate in the Short Term Options Series Program; (ii) $0.50 for option classes that trade in one dollar increments and are in the Short Term Option Series Program; or (iii) $2.50 or greater where the strike price is above $150.[17] Additionally, the Exchange may list series of options pursuant to the $1 Strike Price Interval Program,[18] the $0.50 Strike Program,[19] and the $2.50 Strike Price Program.[20] Pursuant to Exchange Rule 510, where the price of a series of options for the Trust is less than $3.00, the minimum increment will be $0.05, and where the price is $3.00 or higher, the minimum increment will be $0.10 [21] consistent with the minimum increments for options on other ETFs listed on the Exchange. Any and all new series of Trust options that the Exchange lists will be consistent and comply with the expirations, strike prices, and minimum increments set forth in Rules 404 and 510, as applicable.

Position and exercise limits for options on ETFs, including options on the Trust, are determined pursuant to the Exchange's affiliate MIAX Options Rules 307 and 309, respectively. Position and exercise limits for ETF options vary according to the number of outstanding shares and the trading volumes of the underlying ETF over the past six months, where the largest in capitalization and the most frequently traded ETFs have an option position and exercise limit of 250,000 contracts (with adjustments for splits, re-capitalizations, etc.) on the same side of the market; and smaller capitalization ETFs have position and exercise limits of 200,000, 75,000, 50,000 or 25,000 contracts (with adjustments for splits, re-capitalizations, etc.) on the same side of the market. The Exchange further notes that the Exchange's affiliate MIAX

[10] *See* Exchange Rule 401, which provides that the rights and obligations of holders and writers are set forth in the Rules of the Options Clearing Corporation (''OCC''); *see also* OCC Rules, Chapters VIII (which governs exercise and assignment) and Chapter IX (which governs the discharge of delivery and payment obligations arising out of the exercise of physically settled stock option contracts).

[11] *See* Exchange Rule 404(b). The monthly expirations are subject to certain listing criteria for underlying securities described within Exchange Rule 404 and its Interpretations and Policies. Monthly listings expire the third Friday of the month. The term ''expiration date'' (unless separately defined elsewhere in the OCC By-Laws), when used in respect of an option contract (subject to certain exceptions), means the third Friday of the expiration month of such option contract, or if such Friday is a day on which the exchange on which such option is listed is not open for business, the preceding day on which such exchange is open for business. *See* OCC By-Laws Article I, Section 1. Pursuant to Exchange Rule 404(c), additional series of options of the same class may be opened for trading on the Exchange when the Exchange deems it necessary to maintain an orderly market, to meet customer demand or when the market price of the underlying stock moves more than five strike prices from the initial exercise price or prices. Pursuant to Exchange Rule 404(e), new series of options on an individual stock may be added until the beginning of the month in which the options contract will expire. Due to unusual market conditions, the Exchange, in its discretion, may add a new series of options on an individual stock until the close of trading on the business day prior to expiration.

[12] *See* Exchange Rule 404, Interpretations and Policies .02.

[13] *See* Exchange Rule 404, Interpretations and Policies .13.

[14] *See* Exchange Rule 404, Interpretations and Policies .03.

[15] *See* Exchange Rule 406(a).

[16] *See* Exchange Rule 404, Interpretations and Policies .02(e).

[17] *Id.*

[18] *See* Exchange Rule 404, Interpretation and Policy .01.

[19] *See* Exchange Rule 404, Interpretation and Policy .04.

[20] *See* Exchange Rule 404(f).

[21] *See* Exchange Rule 510.

Options Rule 1502, which governs margin requirements applicable to trading on the Exchange, including options on ETFs, will also apply to the trading of the Trust options. Notwithstanding the position limits in the Exchange's affiliate MIAX Options Rule 307(d) and exercise limits in the Exchange's affiliate MIAX Options Rule 309, the Exchange proposes the position and exercise limits for the options on the Trust to be 25,000 contracts on the same side pursuant to proposed Supplementary Material .01 to the Exchange's affiliate MIAX Options Rule 307 and proposed Supplementary Material .01 to the Exchange's affiliate MIAX Options Rule 309.

The Exchange represents that the same surveillance procedures applicable to all other options on other ETFs currently listed and traded on the Exchange will apply to options on the Trust. Also the Exchange represents that it has the necessary systems capacity to support the new option series. The Exchange believes that its existing surveillance and reporting safeguards are designed to deter and detect possible manipulative behavior which might potentially arise from listing and trading options on ETFs, including the proposed Trust options.

Today, the Exchange has an adequate surveillance program in place for options. The Exchange intends to apply those same program procedures to options on the Trust that it applies to the Exchange's other options products.[22] The Exchange's staff will have access to the surveillance programs conducted by its affiliate exchanges, MIAX Options and MIAX Sapphire with respect to trading in the shares of the underlying Trust when conducting surveillances for market abuse or manipulation in the options on the Trust. Additionally, the Exchange is a member of the Intermarket Surveillance Group (''ISG'') under the Intermarket Surveillance Group Agreement. ISG members work together to coordinate surveillance and investigative information sharing in the stock, options, and futures markets. In addition to obtaining surveillance data from MIAX Options and MIAX Sapphire, the Exchange will be able to obtain information regarding trading in the shares of the underlying Trust from Nasdaq, LLC and other markets through ISG. In addition, the Exchange has a Regulatory Services Agreement with the Financial Industry Regulatory Authority (''FINRA''). Pursuant to a multi-party 17d–2 joint plan, all options exchanges allocate regulatory responsibilities to FINRA to conduct certain options-related market surveillance that are common to rules of all options exchanges.[23]

The underlying shares of spot bitcoin ETPs, including the Trust, are also subject to safeguards related to addressing market abuse and manipulation. As the Commission stated in Bitcoin ETP Order:

Each Exchange has a comprehensive surveillance-sharing agreement with the CME via their common membership in the Intermarket Surveillance Group. This facilitates the sharing of information that is available to the CME through its surveillance of its markets, including its surveillance of the CME bitcoin futures market.[24]

The Exchange states that, given the consistently high correlation between the CME bitcoin futures market and the spot bitcoin market, as confirmed by the Commission through robust correlation analysis, the Commission was able to conclude that such surveillance sharing agreements could reasonably be ''expected to assist in surveilling for fraudulent and manipulative acts and practices in the specific context of the [Bitcoin ETPs].'' [25]

In light of surveillance measures related to both options and futures as well as the underlying Trust,[26] the Exchange believes that existing surveillance procedures are designed to deter and detect possible manipulative behavior which might potentially arise from listing and trading the proposed options on the Trust. Further, the Exchange represents that it will implement any new surveillance procedures it deems necessary to effectively monitor the trading of options on the Trust.

The Exchange has also analyzed its capacity and represents that it believes the Exchange and Options Price Reporting Authority or ''OPRA'' have the necessary systems capacity to handle the additional traffic associated with the listing of new series that may result from the introduction of options on the Trust up to the number of expirations currently permissible under the Rules. Because the proposal is limited to one class, the Exchange believes any additional traffic that may be generated from the introduction of the Trust options will be manageable. Finally, the Exchange proposes a technical amendment to Exchange Rule 402(i)(4) to amend the name ''ETFS Gold Trust'' to ''Aberdeen Standard Physical Gold Trust.'' In 2018 ETFS Gold Trust was renamed.[27] At this time, the Exchange proposes to amend the name of the ETF to reflect its current name.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[28] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [29] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section (6)(b)(5) [30] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes that the proposal to list and trade options on the Trust will remove impediments to and perfect the mechanism of a free and open market

[22] The surveillance program includes real-time patterns for price and volume movements and post-trade surveillance patterns (*e.g.,* spoofing, marking the close, pinging, phishing).

[23] Section 19(g)(1) of the Act, among other things, requires every SRO registered as a national securities exchange or national securities association to comply with the Act, the rules and regulations thereunder, and the SRO's own rules, and, absent reasonable justification or excuse, enforce compliance by its members and persons associated with its members. See 15 U.S.C. 78q(d)(1) and 17 CFR 240.17d–2. Section 17(d)(1) of the Act allows the Commission to relieve an SRO of certain responsibilities with respect to members of the SRO who are also members of another SRO (''common members''). Specifically, Section 17(d)(1) allows the Commission to relieve an SRO of its responsibilities to: (i) receive regulatory reports from such members; (ii) examine such members for compliance with the Act and the rules and regulations thereunder, and the rules of the SRO; or (iii) carry out other specified regulatory responsibilities with respect to such members.

[24] *See supra* note 4.

[25] *See* Bitcoin ETP Order, 89 FR at 3010–11.

[26] *See* Securities Exchange Act Release No. 99295 (January 8, 2024), 89 FR 2321, 2334–35 (January 12, 2024) (SR–NASDAQ–2023–016) (Notice of Filing of Amendment No. 1 to a Proposed Rule Change To List and Trade Shares of the iShares Bitcoin Trust Under Nasdaq Rule 5711(d)).

[27] Effective October 1, 2018 ETFS Gold Trust was renamed Aberdeen Standard Gold ETF Trust. *https://www.sec.gov/Archives/edgar/data/1450923/000138713118005292/ex10-2.htm.*

[28] 15 U.S.C. 78f(b).

[29] 15 U.S.C. 78f(b)(5).

[30] *Id.*

and a national market system and, in general, protect investors because offering options on the Trust will provide investors with a greater opportunity to realize the benefits of utilizing options on an ETF based on spot bitcoin, including cost efficiencies and increased hedging strategies. The Exchange believes that offering options on a competitively priced ETF based on spot bitcoin will benefit investors by providing them with an additional, relatively lower-cost risk management tool, allowing them to manage, more easily, their positions and associated risks in their portfolios in connection with exposure to spot bitcoin. Today, the Exchange lists options on other commodity ETFs structured as a trust, which essentially offer the same objectives and benefits to investors, and for which the Exchange has not identified any issues with the continued listing and trading of options on those ETFs.

The Exchange also believes the proposal to permit options on the Trust will remove impediments to and perfect the mechanism of a free and open market and a national market system, because options on the Trust will comply with current Exchange Rules. Options on the Trust must satisfy the initial listing standards and continued listing standards currently in the Exchange Rules, applicable to options on all ETFs, including options on other commodity ETFs already deemed appropriate for options trading on the Exchange pursuant to Exchange Rule 402(i)(4). Further, Exchange Rules that currently govern the listing and trading of options on ETFs, including permissible expirations, strike prices, minimum increments, position and exercise limits (including as proposed in the filing submitted by Exchange's affiliate, MIAX Options), and margin requirements, will govern the listing and trading of options on the Trust. The proposed position and exercise limits for options on the Trust is 25,000 contracts. These position and exercise limits are the lowest position and exercise limits available in the options industry, are extremely conservative and more than appropriate given the Trust's market capitalization, average daily volume, and high number of outstanding shares. The proposed position limit, and exercise limit, is consistent with the Act as it addresses concerns related to manipulation and protection of investors because the position limit (and exercise limit) is extremely conservative and more than appropriate given the Trust is actively traded.

The Exchange represents that it has the necessary systems capacity to support options on the Trust. The Exchange believes that its existing surveillance and reporting safeguards are designed to deter and detect possible manipulative behavior which might arise from listing and trading options on ETFs, including the Trust options. Today, the Exchange has an adequate surveillance program in place for options. The Exchange intends to apply those same program procedures to options on the Trust that it applies to the Exchange's other options products.[31] The Exchange's staff will have access to the surveillance programs conducted by its affiliate exchanges, MIAX Options and MIAX Sapphire with respect to the underlying Trust when conducting surveillances for market abuse or manipulation in the options on the Trust. The Exchange will review activity in the underlying Trust when conducting surveillances for market abuse or manipulation in the options on the Trust. Additionally, the Exchange is a member of the ISG under the Intermarket Surveillance Group Agreement. ISG members work together to coordinate surveillance and investigative information sharing in the stock, options, and futures markets. In addition to obtaining surveillance data from MIAX Options and MIAX Sapphire, the Exchange will be able to obtain information from ISE and other markets through ISG. In addition, the Exchange has a Regulatory Services Agreement with FINRA. Pursuant to a multi-party 17d–2 joint plan, all options exchanges allocate regulatory responsibilities to FINRA to conduct certain options-related market surveillance that are common to rules of all options exchanges.[32]

The underlying shares of spot bitcoin ETPs, including the Trust, are also subject to safeguards related to addressing market abuse and manipulation. As the Commission stated in Bitcoin ETP Order:

Each Exchange has a comprehensive surveillance-sharing agreement with the CME via their common membership in the Intermarket Surveillance Group. This facilitates the sharing of information that is available to the CME through its surveillance of its markets, including its surveillance of the CME bitcoin futures market.[33]

The Exchange states that, given the consistently high correlation between the CME bitcoin futures market and the spot bitcoin market, as confirmed by the Commission through robust correlation analysis, the Commission was able to conclude that such surveillance sharing agreements could reasonably be ''expected to assist in surveilling for fraudulent and manipulative acts and practices in the specific context of the [Bitcoin ETPs].'' [34]

In light of surveillance measures related to both options and futures as well as the underlying Trust,[35] the Exchange believes that existing surveillance procedures are designed to deter and detect possible manipulative behavior which might potentially arise from listing and trading the proposed options on the Trust. Further, the Exchange represents that it will implement any new surveillance procedures it deems necessary to effectively monitor the trading of options on the Trust.

Finally, the Commission has previously approved the listing and trading of options on other commodity ETFs structured as a trust, such as SPDR® Gold Trust,[36] the iShares COMEX Gold Trust [37] the iShares Silver

[31] The surveillance program includes real-time patterns for price and volume movements and post-trade surveillance patterns (*e.g.,* spoofing, marking the close, pinging, phishing).

[32] Section 19(g)(1) of the Act, among other things, requires every SRO registered as a national securities exchange or national securities association to comply with the Act, the rules and regulations thereunder, and the SRO's own rules, and, absent reasonable justification or excuse, enforce compliance by its members and persons associated with its members. See 15 U.S.C. 78q(d)(1) and 17 CFR 240.17d–2. Section 17(d)(1) of the Act allows the Commission to relieve an SRO of certain responsibilities with respect to members of the SRO who are also members of another SRO (''common members''). Specifically, Section 17(d)(1) allows the Commission to relieve an SRO of its responsibilities to: (i) receive regulatory reports from such members; (ii) examine such members for compliance with the Act and the rules and regulations thereunder, and the rules of the SRO; or (iii) carry out other specified regulatory responsibilities with respect to such members.

[33] *See supra* note 4.

[34] *See* Bitcoin ETP Order, 89 FR at 3010–11.

[35] *See* Securities Exchange Act Release No. 99295 (January 8, 2024), 89 FR 2321, 2334–35 (January 12, 2024) (SR–NASDAQ–2023–016) (Notice of Filing of Amendment No. 1 to a Proposed Rule Change To List and Trade Shares of the iShares Bitcoin Trust Under Nasdaq Rule 5711(d)).

[36] *See* Securities Exchange Act Release No. 57897 (May 30, 2008), 73 FR 32061 (June 5, 2008) (SR–Amex–2008–15; SR–CBOE–2005–11; SR–ISE–2008–12; SR–NYSEArca–2008–52; and SRPhlx–2008–17) (Order Granting Approval of a Proposed Rule Change, as Modified, and Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Changes, as Modified, Relating to Listing and Trading Options on the SPDR Gold Trust).

[37] *See* Securities Exchange Act Release No. 59055 (December 4, 2008), 73 FR 75148 (December 10, 2008) (SR–Amex–2008–68; SR–BSE–2008–51; SR–CBOE–2008–72; SR–ISE–2008–58; SRNYSEArca–2008–66; and SR–Phlx–2008–58) (Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Changes Relating to the Listing and Trading Options on Shares of the iShares COMEX Gold Trust and the iShares Silver Trust).

Trust,[38] the ETFS Gold Trust,[39] and the ETFS Silver Trust.[40]

Further, the Exchange's proposal to amend the name ''ETFS Gold Trust'' to ''Aberdeen Standard Physical Gold Trust'' in Exchange Rule 402(i)(4) is consistent with the Act and the protection of investors as this amendment reflects the current name of this product.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. In this regard and as indicated above, the Exchange notes that the rule change is being proposed as a competitive response to filings submitted by ISE.[41]

The Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act as options on the Trust will be subject to initial listing standards and continued listing standards the same as other options on ETFs listed on the Exchange. Further, options on the Trust will be subject to Exchange Rules that currently govern the listing and trading of options on ETFs, including permissible expirations, strike prices, minimum increments, position and exercise limits (including as proposed in the filing submitted by Exchange's affiliate, MIAX Options), and margin requirements. Options on the Trust will be equally available to all market participants who wish to trade such options. Also, and as stated above, the Exchange already lists options on other commodity ETFs structured as a trust.

The Exchange does not believe that the proposal to list to list and trade options on the Trust will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. To the extent that permitting options on the Trust to trade on the Exchange may make the Exchange a more attractive marketplace to market participants, such market participants are free to elect to become market participants on the Exchange. Additionally, other options exchanges are free to amend their listing rules, as applicable, to permit them to list and trade options on the Trust. The Exchange believes that the proposed rule change may relieve any burden on, or otherwise promote, competition as it is designed to increase competition for order flow on the Exchange in a manner that is beneficial to investors by providing them with a lower-cost option to hedge their investment portfolios. The Exchange notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues that offer similar products. Ultimately, the Exchange believes that offering options on the Trust for trading on the Exchange will promote competition by providing investors with an additional, relatively low-cost means to hedge their portfolios and meet their investment needs in connection with spot bitcoin prices and bitcoin related products and positions.

Finally, the Exchange's proposal to amend the name ''ETFS Gold Trust'' to ''Aberdeen Standard Physical Gold Trust'' in Exchange Rule 402(i)(4) does not impose an undue burden on competition as this amendment reflects the current name of this product.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[42] and Rule 19b–4(f)(6) thereunder.[43] Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[44] and subparagraph (f)(6) of Rule 19b–4 thereunder.[45]

A proposed rule change filed under Rule 19b–4(f)(6)[46] under the Act does not normally become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[47] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Commission previously approved the listing of options on iShares Bitcoin Trust.[48] The Exchange has provided information regarding the underlying iShares Bitcoin Trust, including, among other things, information regarding trading volume, the number of beneficial holders, and the market capitalization of the iShares Bitcoin Trust. The proposal also establishes position and exercise limits for options on the iShares Bitcoin Trust and provides information regarding the surveillance procedures that will apply to iShares Bitcoin Trust options. The Commission believes that waiver of the operative delay could benefit investors by providing an additional venue for trading iShares Bitcoin Trust options. Therefore, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.[49]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

[38] *Id.*

[39] *See* Securities Exchange Act Release No. 61483 (February 3, 2010), 75 FR 6753 (February 10, 2010) (SR–CBOE–2010–007; SR–ISE–2009–106; SR–NYSEAmex–2009–86; and SR–NYSEArca–2009–110) (Order Granting Approval of Proposed Rule Changes and Notice of Filing and Order Granting Accelerated Approval of a Proposed Rule Change Relating to Listing and Trading Options on the ETFS Gold Trust and the ETFS Silver Trust).

[40] *Id.*

[41] *See supra* note 5.

[42] 15 U.S.C. 78s(b)(3)(A)(iii).

[43] 17 CFR 240.19b–4(f)(6).

[44] 15 U.S.C. 78s(b)(3)(A)(iii).

[45] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[46] 17 CFR 240.19b–4(f)(6).

[47] 17 CFR 240.19b–4(f)(6)(iii).

[48] *See* Securities Exchange Act Release No. 101128 (September 20, 2024), 89 FR 78942 (September 26, 2024) (SR–ISE–2024–03) (Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing of Amendment Nos. 4 and 5 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment Nos. 1, 4, and 5, to Permit the Listing and Trading of Options on the iShares Bitcoin Trust).

[49] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–PEARL–2024–52 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–PEARL–2024–52. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–PEARL–2024–52 and should be submitted on or before December 18, 2024.

[50] 17 CFR 200.30–3(a)(12).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[50]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–27743 Filed 11–26–24; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101689; File No. SR–BX–2024–049]

Self-Regulatory Organizations; Nasdaq BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Fees for Connectivity and Co-Location Services

November 21, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 18, 2024, Nasdaq BX, Inc. (''BX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's fees for connectivity and co-location services, as described further below.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/bx/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the Exchange's fees relating to connectivity and co-location services.[3] Specifically, the Exchange proposes a one-time adjustment to raise its fees for connectivity and co-location services in General 8, fees assessed for remote multi-cast ITCH (''MITCH'') Wave Ports in Equity 7, Section 115, and certain fees related to Nasdaq Testing Facilities in Equity 7, Section 130 by 10%, with certain exceptions.

General 8, Section 1 includes the Exchange's fees that relate to connectivity, including fees for cabinets, external telco/inter-cabinet connectivity fees, fees for connectivity to the Exchange, fees for connectivity to third party services, fees for market data connectivity, fees for cabinet power install, and fees for additional charges and services. General 8, Section 2 includes the Exchange's fees for direct connectivity services, including fees for direct circuit connection to the Exchange, fees for direct circuit connection to third party services, and fees for point of presence connectivity. With the exceptions of the Exchange's GPS Antenna fees and the Cabinet Proximity Option Fee for cabinets with power density >10kW,[4] the Exchange proposes to increase its fees throughout General 8 by 10%.

In addition to increasing fees in General 8, the Exchange also proposes

[3] The Exchange initially filed the proposed pricing change on March 1, 2024 (SR–BX–2024–008). On April 29, 2024, the Exchange withdrew that filing and submitted SR–BX–2024–014. The Exchange withdrew BX–2024–14 and replaced it with SR–BX–2024–20. The Exchange withdrew SR–BX–2024–020 and replaced it with SR–BX–2024–033 on September 10, 2024. On October 11, 2024, the Exchange replaced SR–BX–2024–033 with SR–BX–2024–042. On November 08, 2024, the Exchange replaced SR–BX–2024–042 with SR–BX–2024–046. The instant filing replaces SR–BX–2024–046.

[4] The Exchange proposes to exclude the GPS Antenna fees from the proposed fee increase because, unlike the other fees in General 8, the Exchange recently increased its GPS Antenna fees. *See* Securities Exchange Act Release No. 34–99124 (December 8, 2023), 88 FR 86715 (December 14, 2023) (SR–BX–2023–033). The Exchange also proposes to exclude the Cabinet Proximity Option Fee for cabinets with power density >10kW from the proposed fee increase because the Exchange recently established such fee. *See* Securities Exchange Act Release No. 34–100195 (May 21, 2024), 89 FR 46180 (May 28, 2024) (SR–BX–2024–017). Similarly, the Exchange proposes to exclude from the proposed fee increase those fees that the Exchange recently established for services in its new NY11–4 expansion facility. *See* Securities Exchange Act Release No. 34–101265 (October 7, 2024), 89 FR 82663 (October 11, 2024) (SR–BX–2024–037).

to increase certain fees in Equity 7. First, the Exchange proposes to increase the installation and recurring monthly fees assessed for remote MITCH Wave Ports [5] in Equity 7, Section 115(g)(1) by 10%. In addition, the Exchange proposes to increase certain fees in Section 130(d), which relate to the Nasdaq Testing Facility. Equity 7, Section 130(d)(1)(C) provides that subscribers to the Nasdaq Testing Facility (''NTF'') located in Carteret, New Jersey shall pay a fee of $1,000 per hand-off, per month for connection to the NTF. The hand-off fee includes either a 1Gb or 10Gb switch port and a cross connect to the NTF. In addition, Equity 7, Section 130(d)(1)(C) provides that subscribers shall also pay a one-time installation fee of $1,000 per hand-off. The Exchange proposes to increase these aforementioned fees by 10% to require that subscribers to the NTF shall pay a fee of $1,100 per hand-off, per month for connection to the NTF and a one-time installation fee of $1,100 per hand-off.

The proposed increases in fees would enable the Exchange to maintain and improve its market technology and services to remain competitive with its peers. Over the years, customer demand for more sophisticated, higher-throughput, lower-latency, and higher-power connectivity solutions has increased. The Exchange continues to invest in maintaining, improving, and enhancing its connectivity and co-location products, services, and facilities—for the benefit and often at the behest of its customers. Such enhancements include refreshing hardware and expanding Nasdaq's existing co-location facility to offer customers additional space and power. Nevertheless, and with the exception of fees that were established as part of a new service in 2017 (and have remained unchanged since their adoption), the Exchange has not increased any of the fees included in the proposal since prior to 2017, and many of the fees date back to between 2010 and 2014. For each of the connectivity products and services that pre-date 2017, inflation (as measured using the ''Data PPI'' metric described below) has been between roughly 15–17%, and in no instance has such inflation been less than 10%. Nevertheless, the Exchange proposes to increase its fees only with respect to the 10% inflation that has occurred since 2017.

As discussed below, the Exchange proposes to adjust its fees by an industry- and product-specific inflationary measure. It is reasonable and consistent with the Act for the Exchange to recoup its investments, at least in part, by adjusting its fees. Continuing to operate at fees frozen at 2010–2017 levels impacts the Exchange's ability to enhance its offerings and the interests of market participants and investors.

The fee increases the Exchange proposes are based on an industry-specific Producer Price Index (''PPI''), which is a tailored measure of inflation.[6] As a general matter, the Producer Price Index is a family of indexes that measures the average change over time in selling prices received by domestic producers of goods and services. PPI measures price change from the perspective of the seller. This contrasts with other metrics, such as the Consumer Price Index (''CPI''), that measure price change from the purchaser's perspective.[7] About 10,000 PPIs for individual products and groups of products are tracked and released each month.[8] PPIs are available for the output of nearly all industries in the goods-producing sectors of the U.S. economy—mining, manufacturing, agriculture, fishing, and forestry—as well as natural gas, electricity, and construction, among others. The PPI program covers approximately 69 percent of the service sector's output, as measured by revenue reported in the 2017 Economic Census.

For purposes of this proposal, the relevant industry-specific PPI is the Data Processing and Related Services PPI (''Data PPI''), which is an industry net-output PPI that measures the average change in selling prices received by companies that provide data processing services.

The Data PPI was introduced in January 2002 by the Bureau of Labor Statistics (''BLS'') as part of an ongoing effort to expand Producer Price Index coverage of the services sector of the U.S. economy and is identified as NAICS—518210 in the North American Industry Classification System.[9] According to the BLS ''[t]he primary output of NAICS 518210 is the provision of electronic data processing services. In the broadest sense, computer services companies help their customers efficiently use technology. The processing services market consists of vendors who use their own computer systems—often utilizing proprietary software—to process customers' transactions and data. Companies that offer processing services collect, organize, and store a customer's transactions and other data for record-keeping purposes. Price movements for the NAICS 518210 index are based on changes in the revenue received by companies that provide data processing services. Each month, companies provide net transaction prices for a specified service. The transaction is an actual contract selected by probability, where the price-determining characteristics are held constant while the service is repriced. The prices used in index calculation are the actual prices billed for the selected service contract.'' [10]

The Exchange believes the Data PPI is an appropriate measure to be considered in the context of the proposed rule change to modify the fee for its connectivity products because the Exchange uses its ''own computer systems'' and ''proprietary software,'' *i.e.,* its own data center and proprietary matching engine software, respectively, to collect, organize, store and report customers' transactions in U.S. equity securities on the Exchange's proprietary trading platform. In other words, the Exchange is in the business of data processing and related services.

For purposes of this proposed rule change, the Exchange examined the Data PPI value for the period from January 2017 to August 2024. The Data PPI had a starting value of 105.6 in January 2017 and an ending value of 116.022 in August 2024, a 10.422% increase. This indicates that companies who are also in the data storage and processing business have generally increased prices for a specified service covered under NAICS 518210 by an average of 10.422% during this period. Based on that percentage change, the Exchange proposes to make a one-time fee increase of only 10%, which reflects an increase covering roughly the entire period since the last price adjustments to these fees were made.

The Exchange further believes the Data PPI is an appropriate measure for purposes of the proposed rule change on the basis that it is a stable metric with limited volatility, unlike other consumer-side inflation metrics. In fact, the Data PPI has not experienced a greater than 2.16% increase for any one calendar year period since Data PPI was

[5] Remote MITCH Wave Ports are for clients co-located at other third-party data centers, through which NASDAQ TotalView ITCH market data is distributed after delivery to those data centers via wireless network.

[6] *See https://fred.stlouisfed.org/series/PCU51825182#0.*

[7] *See https://www.bls.gov/ppi/overview.htm.*

[8] *See Id.*

[9] *NAICS appears in table 5 of the PPI Detailed Report and is available at https://data.bls.gov/timeseries/PCU518210518210.*

[10] *See https://www.bls.gov/ppi/factsheets/producer-price-index-for-the-data-processing-and-related-servicesindustry-naics-518210.htm.*

introduced into the PPI in January 2002. The average calendar year change from January 2002 to December 2023 was .62%, with a cumulative increase of 15.67% over this 21-year period. The Exchange believes the Data PPI is considerably less volatile than other inflation metrics such as CPI, which has had individual calendar-year increases of more than 6.5%, and a cumulative increase of over 73% over the same period.[11]

The Exchange believes the Data PPI, and significant investments into, and enhanced performance of, the Exchange support the reasonableness of the proposed fee increases.[12]

These proposed fee increases will be immediately effective upon filing. However, going forward and until December 1, 2024, the Exchange will waive all fees set forth herein to the extent that such fees exceed the levels that would have been charged for the same products and services purchased during that time period, had such fees been calculated at the rates set forth in SR–BX–2024–033 (*i.e.,* pricing reflective of a 5.5% increase from prior fee levels). This waiver is reasonable, equitable, and not unfairly discriminatory because it will afford all customers in excess of the 30-day prior notice period for fee changes set forth in the Exchange's service terms.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[13] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[14] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

This belief is based on two factors. First, the current fees do not properly reflect the quality of the services and products, as fees for the services and products in question have been static in nominal terms, and therefore falling in real terms due to inflation. Second, the Exchange believes that investments made in enhancing the capacity and speed of Exchange systems increase the performance of the services and products.

The Proposed Rule Change Is Reasonable

As noted above, the Exchange has not increased any of the fees included in the proposal since 2017 or earlier. However, in the years following the last fee increases, the Exchange has made significant investments in upgrades to its connectivity products, services, and facilities, enhancing the quality of its services. In other words, Exchange customers have greatly benefitted, while the Exchange's ability to recoup its investments has been hampered. Between 2017 and 2024, the inflation rate is 3.64% per year, on average, producing a cumulative inflation rate of 28.43%.[15] Using the more targeted inflation number of Data PPI, the cumulative inflation rate was 10.422%. The exchange believes the Data PPI is a reasonable metric to base this fee increase on because it is targeted to producer-side increases in the data processing industry.

Notwithstanding inflation, as noted above, the Exchange has not increased its fees at all for over seven years for the subject services. The proposed fee changes represent a modest increase from the current fees. The Exchange believes the proposed fee increase is reasonable in light of the Exchange's continued expenditure in maintaining a robust technology ecosystem. Furthermore, the Exchange continues to invest in maintaining and enhancing its connectivity products—for the benefit and often at the behest of its customers and global investors. Such enhancements include refreshing all aspects of the technology ecosystem including software, hardware, and network while introducing new and innovative products and expanded and modernized facilities.[16] The goal of the enhancements discussed above, among other things, is to provide faster, higher-capacity, and more modern connectivity products and services. Accordingly, the Exchange continues to expend resources to innovate and modernize technology so that it may benefit its members in offering its connectivity products and services.

The Proposed Fees Are Equitably Allocated and Not Unfairly Discriminatory

The Exchange believes that the proposed fee increases are equitably allocated and not unfairly discriminatory because they would apply to all market participants that choose to purchase connectivity products and services from the Exchange. Any participant that chooses to purchase the Exchange's connectivity products and services would be subject to the same Fee Schedule, regardless of what type of business they operate or the use they plan to make use of the products and services. Additionally, the fee increase would be applied uniformly to market participants without regard to Exchange membership status or the extent of any other business with the Exchange or affiliated entities. The Exchange also believes that the proposal represents an equitable allocation of reasonable dues, fees and other charges because Exchange fees have fallen in real terms during the relevant period. Finally, the Exchange believes that the proposed fee changes are not unfairly discriminatory because the fees would be assessed uniformly across all market participants, in the same manner they are today, that voluntarily purchase the Exchange's connectivity products and services, which would remain available for purchase by all market participants.

These proposed fee increases will be immediately effective upon filing. However, going forward and until December 1, 2024, the Exchange will waive all fees set forth herein to the extent that such fees exceed the levels that would have been charged for the same products and services purchased during that time period, had such fees been calculated at the rates set forth in SR–BX–2024–033 (*i.e.,* pricing reflective of a 5.5% increase from prior fee levels). This waiver is reasonable, equitable, and not unfairly discriminatory because it will afford all customers in excess of the 30-day prior notice period for fee changes set forth in the Exchange's service terms.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed fees will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Intramarket Competition

The Exchange believes that the proposed fees do not put any market

[11] *See https://www.usinflationcalculator.com/inflation/consumer-price-index-and-annual-percent-changesfrom-1913-to-2008/.*

[12] *See supra* discussion of connectivity product and facility improvements. Additionally, other exchanges have filed for increases in certain fees, based in part on comparisons to inflation. See, *e.g.,* Securities Exchange Act Release Nos. 34–100004 (April 22, 2024), 89 FR 32465 (April 26, 2024) (SR–CboeBYX–2024–012); and 34–100398 (June 21, 2024), 89 FR 53676 (June 27, 2024) (SR–BOX–2024–16)l; Securities Exchange Act Release No. 34–100994 (September 10, 2024), 89 FR 75612 (September 16, 2024) (SR–NYSEARCA–2024–79).

[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(4) and (5).

[15] *See https://www.officialdata.org/us/inflation/2017?amount=1.*

[16] *See, e.g.,* Securities Exchange Act Release No. 34–101073 (September 18, 2024), 89 FR 77926 (September 24, 2024) (SR–BX–2024–035 (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Expand [the Exchange's] Co-Location Services).

participants at a relative disadvantage compared to other market participants. As noted above, the fee schedule would continue to apply to all purchasers of the Exchange's connectivity products and services in the same manner as it does today albeit at inflation-adjusted rates for certain fees, and customers may choose whether to purchase these products and services at all. The Exchange also believes that the level of the proposed fees neither favor nor penalize one or more categories of market participants in a manner that would impose an undue burden on competition. Likewise, the proposed fee waiver described above will apply to all purchasers of the Exchange's connectivity products and services in the same manner and therefore will not burden competition among them.

Intermarket Competition

The Exchange believes that the proposed fees do not impose a burden on competition or on other SROs that is not necessary or appropriate. In determining the proposed fees, the Exchange utilized an objective and stable metric with limited volatility. Utilizing Data PPI over a specified period of time is a reasonable means of recouping the Exchange's investment in maintaining and enhancing its connectivity products, services, and facilities. The Exchange believes utilizing Data PPI, a tailored measure of inflation, to increase certain fees for connectivity products and services to recoup the Exchange's investment in maintaining and enhancing such products, services, and its facilities would not impose a burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[17]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–BX–2024–049 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–BX–2024–049. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–BX–2024–049 and should be submitted on or before December 18, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–27758 Filed 11–26–24; 8:45 am]

BILLING CODE 8011–01–P

[17] 15 U.S.C. 78s(b)(3)(A)(ii).

[18] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101677; File No. SR–NYSECHX–2024–32]

Self-Regulatory Organizations; NYSE Chicago, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 7.37

November 21, 2024.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act''),[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on November 7, 2024, the NYSE Chicago, Inc. (''NYSE Chicago'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 7.37 to specify the Exchange's source of data feeds from Investors' Exchange, LLC (''IEX'') for purposes of order handling, order execution, order routing, and regulatory compliance. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries,

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to update and amend the use of data feeds table in Rule 7.37(d), which sets forth on a market-by-market basis the specific securities information processor (''SIP'') and proprietary data feeds that the Exchange utilizes for the handling, execution, and routing of orders, and for performing the regulatory compliance checks related to each of those functions. Specifically, the Exchange proposes to amend the table in Rule 7.37(d) to specify that, with respect to IEX, the Exchange will receive an IEX direct feed as its primary source of data for order handling, order execution, order routing, and regulatory compliance, and will use the SIP Data Feed as its secondary source for data from IEX.

The Exchange proposes to make this change operative in the fourth quarter of 2024, and, in any event, before the end of the first quarter of 2025. The Exchange proposes to announce the implementation date of this change by Trader Update.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[4] in general, and furthers the objectives of Section 6(b)(5),[5] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest. Additionally, the Exchange believes that the proposed rule change is consistent with the Section 6(b)(5) requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes its proposal to update the table in Rule 7.37(d) to include the IEX direct feed will ensure that the Rule correctly identifies and publicly states on a market-by-market basis all of the specific SIP and proprietary data feeds that the Exchange utilizes for the handling, execution, and routing of orders, and for performing the regulatory compliance checks for each of those functions. The proposed rule change also removes impediments to and perfects the mechanism of a free and open market and protects investors and the public interest by providing additional specificity, clarity, and transparency in the Exchange's rules.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Rather, the Exchange believes that the proposal will enhance competition because providing the public and market participants with up-to-date information about the data feeds the Exchange will use for the handling, execution, and routing of orders, as well as for regulatory compliance would enhance transparency and enable investors to better assess the quality of the Exchange's execution and routing services. The Exchange also believes the proposal would enhance competition because it would potentially enhance the performance of its order handling and execution of orders in equity securities by receiving market data directly from IEX. Finally, the proposed rule change would not impact competition between market participants because it will affect all market participants equally.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[6] and Rule 19b–4(f)(6) thereunder.[7] Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[8] and Rule 19b–4(f)(6)(iii) thereunder.[9]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[10] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include file number SR–NYSECHX–2024–32 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NYSECHX–2024–32. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(5).

[6] 15 U.S.C. 78s(b)(3)(A)(iii).

[7] 17 CFR 240.19b–4(f)(6).

[8] 15 U.S.C. 78s(b)(3)(A).

[9] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[10] 15 U.S.C. 78s(b)(2)(B).

Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NYSECHX–2024–32 and should be submitted on or before December 18, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–27746 Filed 11–26–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101700; File No. SR–CboeBYX–2024–042]

Self-Regulatory Organizations; Cboe BYX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fee Schedule Relating to Routing Codes

November 21, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 14, 2024, Cboe BYX Exchange, Inc. (''Exchange'' or ''BYX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BYX Exchange, Inc. (the ''Exchange'' or ''BYX'') proposes to amend its Fee Schedule. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/BYX/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Effective November 1, 2024, the Exchange proposes to amend its BYX Fee Schedule applicable to its equities trading platform.[3] By implementing a remove fee (as opposed to a rebate) for fee code, AA, removing fee code, BJ, and adding EDGA to the list of venues to which orders appended with fee code, PL, are routed.

Fee Codes

The Exchange proposes to implement a remove fee for fee code, AA. The proposed changes are as follows:

• For securities priced above $1.00,[4] fee code AA is appended to orders that are routed to EDGA using the ALLB[5] routing strategy. Currently, orders appended with fee code AA receive a rebate of $0.0018.

The Exchange now proposes to amend fee code, AA, as follows:

• For securities priced above $1.00, fee code AA will continue to be appended to orders that are routed to EDGA using the ALLB routing strategy. However, orders appended with fee code AA will now pay a fee of $0.0030. The Exchange does not propose to add a fee or rebate for removing liquidity for securities priced below $1.00.

The Exchange also proposes to remove fee code, BJ. For securities priced above $1.00,[6] fee code BJ is currently appended to orders that are routed to EDGA using the TRIM[7] or SLIM[8] routing strategies and receive a rebate of $0.0018. However, effective November 1, 2024,[9] EDGA transitioned from an inverted fee model[10] to a maker-taker fee model.[11]

The Exchange also proposes to edit the description of fee code, PL. The BYX Fee Schedule currently describes PL, as a fee code appended to orders that are ''[r]outed to BZX, EDGX, NYSE, NYSE Arca or Nasdaq using RMPL routing strategy.'' The Exchange now proposes to move EDGA to the list of high-cost destinations for the RMPL routing

[11] 17 CFR 200.30–3(a)(12), (59).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Exchange initially filed the proposed fee change on November 1, 2024 (SR–CboeBYX–2024–040). On November 14, 2024, the Exchange withdrew that filing and submitted this filing.

[4] The Exchange notes for securities priced below $1.00, there is no fee or rebate for removing liquidity from EDGA using the ALLB routing strategy.

[5] ALLB is a routing option under which an order checks the System for available shares and is then sent to Cboe BZX Exchange, Inc., Cboe EDGA Exchange, Inc., and/or Cboe EDGX Exchange, Inc. in accordance with the System routing table. If shares remain unexecuted after routing, they are posted on the BYX Book, unless otherwise instructed by the User. *See* Rule 11.13(b)(3)(M).

[6] There is no charge or rebate for securities priced below $1.00.

[7] TRIM is a routing strategy under which an order checks EDGA for available shares if so instructed by the entering User, and then is sent to destinations on the applicable System routing table. *See generally* Rule 11.13(b)(3)(G)(iv).

[8] SLIM is a routing strategy under which an order checks EDGA for available shares if so instructed by the entering User, and then is sent to destinations on the applicable System routing table. *See generally* Rule 11.13(b)(3)(G)(v).

[9] *See* SR–CboeEDGA–2024–042; *see also,* SR–CboeEDGA–2024–045.

[10] The inverted As such, orders that remove liquidity from EDGA will pay a remove fee, rather than receive a rebate. Because Members typically utilize routing options TRIM and SLIM, and fee code BJ, to seek low-cost executions, it does not make sense to maintain fee code, BJ, as Members would not expect to pay a fee for removing liquidity from EDGA. Therefore, the Exchange proposes to discontinue this fee code, as it is no longer necessary, and BYX does not desire to charge such orders a fee for removing liquidity from EDGA.fee model is a pricing structure in which a market, such as an exchange, charges its participants a fee to provide liquidity in securities, and provides a rebate to participants that remove liquidity in securities. *See* SEC Market Structure Advisory Committee, Memorandum on ''Maker-Taker Fees on Equities Exchanges,'' October 20, 2015, available at: *https://www.sec.gov/spotlight/emsac/memo-maker-taker-fees-on-equities-exchanges.pdf.*

[11] The maker-taker fee model is a pricing structure in which a market, such as an exchange, generally pays its members a per share rebate to provide (*i.e.,* ''make'') liquidity in securities and assesses on them a fee to remove (*i.e.,* ''take'') liquidity. *Id.*

strategy that are assigned the PL fee code, by amending the description in the Fee Schedule to read as follow: ''Routed to BZX, EDGX, *EDGA,* NYSE, NYSE Arca or Nasdaq using RMPL routing strategy.'' Previously, orders appended with fee code, PX, utilized routing option, RMPL, which is a midpoint liquidity seeking strategy that first targets low-cost executions at certain lower-cost venues, including EDGA. However, because EDGA is now transitioning to a maker-taker fee model, EDGA will now be assessing a full remove fee of $0.0030 for orders that remove liquidity from EDGA.[12] As such, the Exchange believes that current fee code, PL—which charges a $0.0030 for routing orders to other exchanges—is now the more appropriate fee code to be appended to midpoint liquidity seeking orders that are routed to other major exchanges. Similar to EDGA, the other exchanges targeted by RMPL—NYSE, NYSE Arca, and Nasdaq—also charge a high remove fee to liquidity removing orders.[13]

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[14] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [15] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [16] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers as well as Section 6(b)(4) [17] as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities.

Adjusting fee code AA and removing fee code, BJ, is necessary to reflect the transition of EDGA to a maker-taker fee model, effective November 1, 2024. Prior to the November 1, 2024, orders entered onto BYX, that were appended with fee code, AA, and were routed to EDGA using routing option ALLB, received a rebate of $0.0018 for removing liquidity from the EDGA Book for securities priced at or above $1.00. However, given EDGA's transition to a maker-taker fee model, orders that remove liquidity will now need to pay a liquidity removal fee, rather than receive a rebate. Accordingly, removal of the current $0.00180 rebate associated with fee code, AA, and implementation of a $0.0030 remove fee is appropriate and consistent with the economics of a maker-taker model, as well as the expectations of Members that remove liquidity from EDGA (*i.e.,* Members would expect to pay a fee to remove liquidity). Moreover, the proposed fee is not unfairly discriminatory because it applies to all Members equally, in that all Members will pay the same fee for orders routed to EDGA using the ALLB routing strategy, and appended with fee code, AA.

The Exchange also believes that its removal of fee code, BJ, is reasonable, equitable, and not unfairly discriminatory as it does not change the fees or rebates assessed by the Exchange, but rather updates the BYX Fee Schedule to remove a fee code that the Exchange no longer desires to, nor is required to, offer to its Members. Therefore, the proposed rule change is reasonably designed to update the Fee Schedule to accurately reflect the Exchange's current product offerings and is designed to reduce any potential confusion regarding the routing of orders with fee code, BJ, from BYX to EDGA. Furthermore, as noted above, orders appended with fee code, BJ, entered onto BYX and routed to EDGA using the routing option TRIM or SLIM, previously received a rebate of $0.0018 for removing liquidity from the EDGA Book. However, effective November 1, 2024, EDGA transitioned from an inverted fee model to a maker-taker fee model. As such, orders that remove liquidity from EDGA will pay a remove fee, rather than receive a rebate. Because Members typically utilize routing options TRIM and SLIM, and fee code BJ, to seek low-cost executions, it does not make sense to maintain the BJ fee code, as Members utilizing this fee code would not expect to pay a fee for removing liquidity from EDGA. Therefore, the Exchange proposes to discontinue this fee code, as it is no longer necessary, and BYX does not desire to charge such orders a fee for removing liquidity from EDGA.

Finally, the Exchange believes that moving EDGA to the list of high-cost destinations for the RMPL routing strategy that are assigned the PL fee code, and assessing such orders a fee of $0.0030, is necessary and appropriate. Members appending their orders with the PL fee code already expect to pay a remove fee for removing liquidity from exchanges accessed by RMPL, rather than receive a rebate for removing liquidity as they do with liquidity removing orders appended with the PX fee code. Additionally, the remove fee of $0.0030 per share represents an equitable allocation of reasonable dues, fees, and other charges. The proposed change would enable the Exchange to charge a rate reasonably related to the rate that Cboe Trading, Inc. (''Cboe Trading''), the Exchange's affiliated routing broker-dealer, would be charged for routing orders to destinations described in fee codes PL. As a result, when Cboe Trading is charged a fee when it routes an order which removes liquidity from a destination described in fee codes PL, Cboe Trading will pass through these rates to the Exchange and the Exchange, in turn, will charge the rate under fee codes PL. The proposed fee under fee code, PL, for orders routed pursuant to the RMPL routing strategy would enable the Exchange to equitably allocate its costs among all Members.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule changes will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Given EDGA's transition to a maker-taker fee model, orders that remove liquidity will now need to pay a liquidity removal fee, rather than receive a rebate. Accordingly, removing the current $0.0018 rebate associated with fee code, AA, and implementing a $0.0030 remove fee is appropriate and consistent

[12] *See* SR–CboeEDGA–2024–045.

[13] NYSE Arca charges a removal fee of $0.0030. *See* Section III—Standard Rates—Transactions (applicable when Tier Rates do not apply), Removing Liquidity, pg. 3, available at: *https://www.nyse.com/publicdocs/nyse/markets/nyse-arca/NYSE_Arca_Marketplace_Fees.pdf;* NYSE charges a removal fee of $0.0030 for orders that remove midpoint liquidity. *See* NYSE Stock Exchange Price List, ''Equity per Share Charge—per transaction—MPL orders that remove liquidity from the NYSE (Adding Tier Credits do not apply) and with no Retail Modifier, as defined in Rule 13 (''Retail Modifier'')), pg. 5, available at *https://www.nyse.com/publicdocs/nyse/markets/nyse/NYSE_Price_List.pdf;* Nasdaq charges a removal fee of $0.0030. *See* Fees to Remove Liquidity, Shares Executed at or above $1.00, available at: *https://www.nasdaqtrader.com/Trader.aspx?id=PriceListTrading2.*

[14] 15 U.S.C. 78f(b).

[15] 15 U.S.C. 78f(b)(5).

[16] *Id.*

[17] 15 U.S.C. 78f(b)(4).

with the economics of a maker-taker model, as well as the expectations of Members that remove liquidity from EDGA (*i.e.,* Members would expect to pay a fee to remove liquidity).

Moreover, moving EDGA to the list of high-cost destinations for the RMPL routing strategy that are assigned the PL fee code simply reflects the fact that orders routed to EDGA that remove liquidity will now—just as they do on other exchanges accessed with the PL fee code—pay a remove fee instead of receiving a rebate. In addition, the BJ fee code was typically appended to orders utilizing the TRIM or SLIM strategies, which are designed to seek low-cost executions. Given EDGA's transition to a maker-taker fee model, though, removers of liquidity will now pay a remove fee. As such, it is appropriate to remove the BJ fee code as Member's utilizing this fee code would expect to receive a rebate and not expect to pay a fee. Accordingly, these proposed changes are necessary and appropriate in order to align Members' expectations with the economics of EDGA's new maker-taker fee model and will not have any impact on competition.

Additionally, moving EDGA from fee code, PX, to fee code is PL, will not have any impact on competition. Rather, it is necessary and appropriate given EDGA's transition to a maker-taker fee model. Users of the PL fee code already expect to pay fees for removing liquidity from exchanges, whereas users of the PX fee code would expect lower-cost executions for removing liquidity from exchanges, including EDGA.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [18] and paragraph (f) of Rule 19b–4 [19] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–CboeBYX–2024–042 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–CboeBYX–2024–042. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–CboeBYX–2024–042 and should be submitted on or before December 18, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

Sherry R. Haywood,

Assistant Secretary.

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[18] 15 U.S.C. 78s(b)(3)(A).

[19] 17 CFR 240.19b–4(f).

[20] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101686; File No. SR–MRX–2024–43]

Self-Regulatory Organizations; Nasdaq MRX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend its Fees for Connectivity and Co-location Services

November 21, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 8, 2024, Nasdaq MRX, LLC (''MRX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's fees for connectivity and co-location services, as described further below.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/mrx/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the Exchange's fees relating to connectivity and co-location services.[3] Specifically, the Exchange proposes to raise its fees for connectivity and co-location services in General 8 as well as certain fees related to its Testing Facilities in Options 7, Section 7 by 10%, with certain exceptions.

General 8, Section 1 includes the Exchange's fees that relate to connectivity, including fees for cabinets, external telco/inter-cabinet connectivity fees, fees for connectivity to the Exchange, fees for connectivity to third party services, fees for market data connectivity, fees for cabinet power install, and fees for additional charges and services. General 8, Section 2 includes the Exchange's fees for direct connectivity services, including fees for direct circuit connection to the Exchange, fees for direct circuit connection to third party services, and fees for point of presence connectivity. With the exception of the Exchange's GPS Antenna fees and the Cabinet Proximity Option Fee for cabinets with power density >10kW,[4] the Exchange proposes to increase its fees throughout General 8 by 10%.

In addition to increasing fees in General 8, the Exchange also proposes to increase certain fees in Options 7, Section 7, which relate to the Testing Facility. Options 7, Section 7 provides that subscribers to the Testing Facility located in Carteret, New Jersey shall pay a fee of $1,000 per hand-off, per month for connection to the Testing Facility. The hand-off fee includes either a 1Gb or 10Gb switch port and a cross connect to the Testing Facility. In addition, Options 7, Section 7 provides that subscribers shall also pay a one-time installation fee of $1,000 per hand-off. The Exchange proposes to increase these aforementioned fees by 10% to require that subscribers to the Testing Facility shall pay a fee of $1,100 per hand-off, per month for connection to the Testing Facility and a one-time installation fee of $1,100 per hand-off.

The proposed increases in fees would enable the Exchange to maintain and improve its market technology and services to remain competitive with its peers. Over the years, customer demand for more sophisticated, higher-throughput, lower-latency, and higher-power connectivity solutions has increased. The Exchange continues to invest in maintaining, improving, and enhancing its connectivity and co-location products, services, and facilities—for the benefit and often at the behest of its customers. Such enhancements include refreshing hardware and expanding Nasdaq's existing co-location facility to offer customers additional space and power. Nevertheless, and with the exception of fees that were established as part of a new service in 2017 (and have remained unchanged since their adoption), the Exchange has not increased any of the fees included in the proposal since prior to 2017, and many of the fees date back to between 2010 and 2014. For each of the connectivity products and services that pre-date 2017, inflation (as measured using the ''Data PPI'' metric described below) has been between roughly 15–17%, and in no instance has such inflation been less than 10%. Nevertheless, the Exchange proposes to increase its fees only with respect to the 10% inflation that has occurred since 2017.

As discussed below, the Exchange proposes to adjust its fees by an industry- and product-specific inflationary measure. It is reasonable and consistent with the Act for the Exchange to recoup its investments, at least in part, by adjusting its fees. Continuing to operate at fees frozen at 2010–2017 levels impacts the Exchange's ability to enhance its offerings and the interests of market participants and investors.

The fee increases the Exchange proposes are based on an industry-specific Producer Price Index (''PPI''), which is a tailored measure of inflation.[5] As a general matter, the Producer Price Index is a family of indexes that measures the average change over time in selling prices received by domestic producers of goods and services. PPI measures price change from the perspective of the seller. This contrasts with other metrics, such as the Consumer Price Index (''CPI''), that measure price change from the purchaser's perspective.[6] About 10,000 PPIs for individual products and groups of products are tracked and released each month.[7] PPIs are available for the output of nearly all industries in the goods-producing sectors of the U.S. economy—mining, manufacturing, agriculture, fishing, and forestry—as well as natural gas, electricity, and construction, among others. The PPI program covers approximately 69 percent of the service sector's output, as measured by revenue reported in the 2017 Economic Census.

For purposes of this proposal, the relevant industry-specific PPI is the Data Processing and Related Services PPI (''Data PPI''), which is an industry net-output PPI that measures the average change in selling prices received by companies that provide data processing services.

The Data PPI was introduced in January 2002 by the Bureau of Labor Statistics (''BLS'') as part of an ongoing effort to expand Producer Price Index coverage of the services sector of the U.S. economy and is identified as NAICS—518210 in the North American Industry Classification System.[8] According to the BLS ''[t]he primary output of NAICS 518210 is the provision of electronic data processing services. In the broadest sense, computer services companies help their customers efficiently use technology. The processing services market consists of vendors who use their own computer systems—often utilizing proprietary software—to process customers' transactions and data. Companies that offer processing services collect, organize, and store a customer's transactions and other data for record-keeping purposes. Price movements for the NAICS 518210 index are based on changes in the revenue received by companies that provide data processing

[3] The Exchange initially filed the proposed pricing change on March 1, 2024 (SR–MRX–2024–04). On April 29, 2024, the Exchange withdrew that filing and submitted SR–MRX–2024–10. On June 27, 2024, the Exchange withdrew SR–MRX–2024–10 and submitted SR–MRX–2024–18. The Exchange withdrew SR–MRX–2024–18 and replaced it with SR–MRX–2024–34 on September 10, 2024. On October 11, 2024, The Exchange replaced SR–MRX–2024–34 with SR–MRX–2024–41. This instant filing replaces SR–MRX–2024–41.

[4] The Exchange proposes to exclude the GPS Antenna fees from the proposed fee increase because, unlike the other fees in General 8, the Exchange recently increased its GPS Antenna fees. *See* Securities Exchange Act Release No. 34–99130 (December 11, 2023), 88 FR 87009 (December 15, 2023) (SR–MRX–2023–24). The Exchange also proposes to exclude the Cabinet Proximity Option Fee for cabinets with power density >10kW from the proposed fee increase because the Exchange recently established such fee. *See* Securities Exchange Act Release No. 34–100200 (May 21, 2024), 89 FR 46183 (May 28, 2024) (SR–MRX–2024–12). Similarly, the Exchange proposes to exclude from the proposed fee increase those fees that the Exchange recently established for services in its new NY11–4 expansion facility. *See* Securities Exchange Act Release No. 34–101269 (October 7, 2024), 89 FR 82657 (October 11, 2024) (SR–MRX–2024–37).

[5] *See https://fred.stlouisfed.org/series/PCU51825182#0.*

[6] *See https://www.bls.gov/ppi/overview.htm.*

[7] *See Id.*

[8] *NAICS appears in table 5 of the PPI Detailed Report and is available at https://data.bls.gov/timeseries/PCU518210518210.*

services. Each month, companies provide net transaction prices for a specified service. The transaction is an actual contract selected by probability, where the price-determining characteristics are held constant while the service is repriced. The prices used in index calculation are the actual prices billed for the selected service contract.'' [9]

The Exchange believes the Data PPI is an appropriate measure to be considered in the context of the proposed rule change to modify the fee for its connectivity products because the Exchange uses its ''own computer systems'' and ''proprietary software,'' *i.e.,* its own data center and proprietary matching engine software, respectively, to collect, organize, store and report customers' transactions in U.S. equity securities on the Exchange's proprietary trading platform. In other words, the Exchange is in the business of data processing and related services.

For purposes of this proposed rule change, the Exchange examined the Data PPI value for the period from January 2017 to August 2024. The Data PPI had a starting value of 105.6 in January 2017 and an ending value of 116.022 in August 2024, a 10.422% increase. This indicates that companies who are also in the data storage and processing business have generally increased prices for a specified service covered under NAICS 518210 by an average of 10.422% during this period. Based on that percentage change, the Exchange proposes to make a one-time fee increase of only 10%, which reflects an increase covering roughly the entire period since the last price adjustments to these fees were made.

The Exchange further believes the Data PPI is an appropriate measure for purposes of the proposed rule change on the basis that it is a stable metric with limited volatility, unlike other consumer-side inflation metrics. In fact, the Data PPI has not experienced a greater than 2.16% increase for any one calendar year period since Data PPI was introduced into the PPI in January 2002. The average calendar year change from January 2002 to December 2023 was .62%, with a cumulative increase of 15.67% over this 21-year period. The Exchange believes the Data PPI is considerably less volatile than other inflation metrics such as CPI, which has had individual calendar-year increases of more than 6.5%, and a cumulative increase of over 73% over the same period.[10]

The Exchange believes the Data PPI, and significant investments into, and enhanced performance of, the Exchange support the reasonableness of the proposed fee increases.[11]

These proposed fee increases will be immediately effective upon filing. However, going forward and until December 1, 2024, the Exchange will waive all fees set forth herein to the extent that such fees exceed the levels that would have been charged for the same products and services purchased during that time period, had such fees been calculated at the rates set forth in SR–MRX–2024–34 (*i.e.,* pricing reflective of a 5.5% increase from prior fee levels). This waiver is reasonable, equitable, and not unfairly discriminatory because it will afford all customers in excess of the 30-day prior notice period for fee changes set forth in the Exchange's service terms.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[12] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[13] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

This belief is based on two factors. First, the current fees do not properly reflect the quality of the services and products, as fees for the services and products in question have been static in nominal terms, and therefore falling in real terms due to inflation. Second, the Exchange believes that investments made in enhancing the capacity and speed of Exchange systems increase the performance of the services and products.

The Proposed Rule Change Is Reasonable

As noted above, the Exchange has not increased any of the fees included in the proposal since 2017 or earlier. However, in the years following the last fee increases, the Exchange has made significant investments in upgrades to its connectivity products, services, and facilities, enhancing the quality of its services. In other words, Exchange customers have greatly benefitted, while the Exchange's ability to recoup its investments has been hampered. Between 2017 and 2024, the inflation rate is 3.64% per year, on average, producing a cumulative inflation rate of 28.43%.[14] Using the more targeted inflation number of Data PPI, the cumulative inflation rate was 10.422%. The exchange believes the Data PPI is a reasonable metric to base this fee increase on because it is targeted to producer-side increases in the data processing industry.

Notwithstanding inflation, as noted above, the Exchange has not increased its fees at all for over seven years for the subject services. The proposed fee changes represent a modest increase from the current fees. The Exchange believes the proposed fee increase is reasonable in light of the Exchange's continued expenditure in maintaining a robust technology ecosystem. Furthermore, the Exchange continues to invest in maintaining and enhancing its connectivity products—for the benefit and often at the behest of its customers and global investors. Such enhancements include refreshing all aspects of the technology ecosystem including software, hardware, and network while introducing new and innovative products and expanded and modernized facilities.[15] The goal of the enhancements discussed above, among other things, is to provide faster, higher-capacity, and more modern connectivity products and services. Accordingly, the Exchange continues to expend resources to innovate and modernize technology so that it may benefit its members in offering its connectivity products and services.

The Proposed Fees Are Equitably Allocated and Not Unfairly Discriminatory

The Exchange believes that the proposed fee increases are equitably

[9] *See https://www.bls.gov/ppi/factsheets/producer-price-index-for-the-data-processing-and-related-servicesindustry-naics-518210.htm.*

[10] *See https://www.usinflationcalculator.com/inflation/consumer-price-index-and-annual-percent-changesfrom-1913-to-2008/.*

[11] *See supra* discussion of connectivity product and facility improvements. Additionally, other exchanges have filed for increases in certain fees, based in part on comparisons to inflation. See, *e.g.,* Securities Exchange Act Release Nos. 34–100004 (April 22, 2024), 89 FR 32465 (April 26, 2024) (SR–CboeBYX–2024–012); and 34–100398 (June 21, 2024), 89 FR 53676 (June 27, 2024) (SR–BOX–2024–16)l; Securities Exchange Act Release No. 34–100994 (September 10, 2024), 89 FR 75612 (September 16, 2024) (SR–NYSEARCA–2024–79).

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(4) and (5).

[14] *See https://www.officialdata.org/us/inflation/2017?amount=1.*

[15] *See, e.g.,* Securities Exchange Act Release No. 34–101077 (September 18, 2024), 89 FR 77904 (September 24, 2024) (SR–MRX–2024–36 (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Expand [the Exchange's] Co-Location Services)).

allocated and not unfairly discriminatory because they would apply to all market participants that choose to purchase connectivity products and services from the Exchange. Any participant that chooses to purchase the Exchange's connectivity products and services would be subject to the same Fee Schedule, regardless of what type of business they operate or the use they plan to make use of the products and services. Additionally, the fee increase would be applied uniformly to market participants without regard to Exchange membership status or the extent of any other business with the Exchange or affiliated entities. The Exchange also believes that the proposal represents an equitable allocation of reasonable dues, fees and other charges because Exchange fees have fallen in real terms during the relevant period. Finally, the Exchange believes that the proposed fee changes are not unfairly discriminatory because the fees would be assessed uniformly across all market participants, in the same manner they are today, that voluntarily purchase the Exchange's connectivity products and services, which would remain available for purchase by all market participants.

These proposed fee increases will be immediately effective upon filing. However, going forward and until December 1, 2024, the Exchange will waive all fees set forth herein to the extent that such fees exceed the levels that would have been charged for the same products and services purchased during that time period, had such fees been calculated at the rates set forth in SR–MRX–2024–34 (*i.e.,* pricing reflective of a 5.5% increase from prior fee levels). This waiver is reasonable, equitable, and not unfairly discriminatory because it will afford all customers in excess of the 30-day prior notice period for fee changes set forth in the Exchange's service terms.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed fees will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Intramarket Competition

The Exchange believes that the proposed fees do not put any market participants at a relative disadvantage compared to other market participants. As noted above, the fee schedule would continue to apply to all purchasers of the Exchange's connectivity products and services in the same manner as it does today albeit at inflation-adjusted rates for certain fees, and customers may choose whether to purchase these products and services at all. The Exchange also believes that the level of the proposed fees neither favor nor penalize one or more categories of market participants in a manner that would impose an undue burden on competition. Likewise, the proposed fee waiver described above will apply to all purchasers of the Exchange's connectivity products and services in the same manner and therefore will not burden competition among them.

Intermarket Competition

The Exchange believes that the proposed fees do not impose a burden on competition or on other SROs that is not necessary or appropriate. In determining the proposed fees, the Exchange utilized an objective and stable metric with limited volatility. Utilizing Data PPI over a specified period of time is a reasonable means of recouping the Exchange's investment in maintaining and enhancing its connectivity products, services, and facilities. The Exchange believes utilizing Data PPI, a tailored measure of inflation, to increase certain fees for connectivity products and services to recoup the Exchange's investment in maintaining and enhancing such products, services, and its facilities would not impose a burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[16] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include file number SR–MRX–2024–43 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–MRX–2024–43. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–MRX–2024–43 and should be submitted on or before December 18, 2024.

[16] 15 U.S.C. 78s(b)(3)(A)(ii).

[17] 17 CFR 200.30–3(a)(12).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–27755 Filed 11–26–24; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101685; File Nos. SR–DTC–2024–003; SR–FICC–2024–006; SR–NSCC–2024–003]

Self-Regulatory Organizations; The Depository Trust Company; Fixed Income Clearing Corporation; National Securities Clearing Corporation; Order Approving Proposed Rule Change To Amend the Clearing Agency Risk Management Framework

November 21, 2024.

I. Introduction

On March 11, 2024, The Depository Trust Company (''DTC''), Fixed Income Clearing Corporation (''FICC''), and National Securities Clearing Corporation (''NSCC,'' each a ''Clearing Agency,'' and collectively, the ''Clearing Agencies''), filed with the Securities and Exchange Commission (''Commission'') proposed rule changes SR–DTC–2024–003, SR–FICC–2024–006, and SR–NSCC–2024–003, respectively, pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder (the ''Proposed Rule Changes'').[2] The Proposed Rule Changes were published for comment in the **Federal Register** on March 26, 2024.[3] The Commission has received comments on the changes proposed.[4] For the reasons discussed below, the Commission is approving the Proposed Rule Changes.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 99802 (Mar. 20, 2024), 89 FR 21118 (Mar. 26, 2024) (File No. SR–DTC–2024–003) (''DTC Notice of Filing''); Securities Exchange Act Release No. 99805 (Mar. 20, 2024), 89 FR 21068 (Mar. 26, 2024) (File No. SR–FICC–2024–006) (''FICC Notice of Filing''); Securities Exchange Act Release No. 99803 (Mar. 20, 2024), 89 FR 21091 (Mar. 26, 2024) (File No. SR–NSCC–2024–003) (''NSCC Notice of Filing'').

[4] Specifically, the Commission received comments on the FICC Notice of Filing, and the comments are available at *https://www.sec.gov/comments/sr-ficc-2024-006/srficc2024006.htm.* The comments generally relate to issues raised in other FICC proposed rule changes that are not relevant to the Notices of Filing. See, Securities Exchange Act Release Nos. 99817 (SR–FICC–2024–005) and 99844 (SR–FICC–2024–007). The Commission considers the relevant comments related to the FICC Notice of Filing in its analysis at Section IV *infra.*

II. Background

On December 13, 2023, the Commission adopted rules under the Act to amend the standards applicable to covered clearing agencies providing central counterparty services for transactions in U.S. Treasury securities to require policies and procedures be reasonably designed to ensure that the covered clearing agency has appropriate means to facilitate access to clearance and settlement services of all eligible secondary market transactions in U.S. Treasury securities, including those of indirect participants.[5] The adopted rules also require that these policies and procedures be reviewed annually by the board of directors of such covered clearing agencies for U.S. Treasury securities.[6] Currently, FICC is the only Clearing Agency providing clearance and settlement services to the U.S. Treasury securities market.

To address the new requirements, the Clearing Agencies propose to amend their Clearing Agency Risk Management Framework (''Framework).[7] Specifically, the Proposed Rule Changes would add a new section to the Framework regarding ''Solicitation of Participant and Stakeholder Views''. This subsection would: (i) describe generally Clearing Agency participant and industry stakeholder outreach in the development and evaluation of new programs or risk management practices, and (ii) provide for the annual review of FICC's Government Securities Division (''GSD'') access models by FICC's Board of Directors. The proposal would also make other conforming and clean up changes to the text of the Framework, as described below.

III. Description of the Proposed Rule Changes

A. Subsection 3.4.1 General Solicitation of Views

The Clearing Agencies state that they routinely solicit their participants' and other industry stakeholders' views when developing and evaluating products, services, or risk management practices so they may best meet the industry's needs.[8] To codify this practice, the proposal would add a new subsection to the Framework (entitled ''General Solicitation of Views''), which identifies several ways that the Clearing Agencies may seek the views of participants and stakeholders. Such methods would include targeted outreach to firms expected to be impacted by a proposal, widely distributed surveys, ad hoc forums, and standing advisory councils assembled to consider issues relevant to a proposal. This list of outreach methods is illustrative, not exhaustive.

The subsection would also identify the industry stakeholders that may participate in such advisory councils, including for example, representatives from transfer agents, liquidity providers, market infrastructures, institutional and retail investors, customers of the Clearing Agencies' participants, securities issuers, and securities holders. The Clearing Agencies state that the proposed changes in subsection 3.4.1 do not create any obligation for the Clearing Agencies to conduct such outreach in any particular circumstances.[9]

B. Subsection 3.4.2 Required Solicitation of Views—Annual Review of GSD Access Models

The Clearing Agencies propose adding a new subsection to the Framework (entitled ''Required Solicitation of Views—Annual Review of GSD Access Models'') in connection with the recently adopted requirement in Rule 17ad–22(e)(18)(iv)(C) that the board of directors of a covered clearing agency annually review the policies and procedures that the covered clearing agency uses to ensure that they have appropriate means to facilitate access to clearance and settlement services of all eligible secondary market transactions in U.S. Treasury securities, including those of indirect participants.[10] To assist the board in their review of GSD access models, the Proposed Rule Changes would establish an advisory council comprised of participants, their customers, and other industry stakeholders. This advisory council review of GSD's access models would be escalated to the FICC Board of Directors, or a committee thereof, with its annual review of GSD's access models, which

[5] *See* Standards for Covered Clearing Agencies for U.S. Treasury Securities and Application of the Broker-Dealer Customer Protection Rule with Respect to U.S. Treasury Securities, Exchange Act Release No. 99149 (Feb. 15, 2023), 88 FR 13872 (Jan. 16, 2024) (S7–23–22) (''Treasury Clearing Adopting Release'').

[6] 17 CFR 240.17ad–22(e)(18)(iv)(C).

[7] The Framework provides an outline for, among other things, how each of the Clearing Agencies comprehensively manages the risks, including the legal, credit, liquidity, operational, general business, investment, custody, and other risks, that arise in or are borne by it.

[8] *See* DTC Notice of Filing, *supra* note 3, 89 FR at 21119; FICC Notice of Filing, *supra* note 3, 89 FR at 21069; and NSCC Notice of Filing, *supra* note 3, 89 FR at 21091.

[9] *See* DTC Notice of Filing, *supra* note 3, 89 FR at 21119; FICC Notice of Filing, *supra* note 3, 89 FR at 21069; and NSCC Notice of Filing, *supra* note 3, 89 FR at 21092.

[10] 17 CFR 240.17ad–22(e)(18)(iv)(C).

would also be required by this new subsection.

FICC's goal in the annual review of FICC/GSD's access models is to determine whether the GSD Clearing Rules and any other written policies and procedures are reasonably designed to ensure appropriate and flexible means to facilitate access to clearance and settlement of all eligible secondary market transactions in U.S. Treasury securities, including those of indirect participants.[11] In furtherance of this goal, the new subsection would require that the annual review include the following: (1) document any instance in which FICC treats transactions differently based on either the identity of the submitting participant, the fact that an indirect participant is a party to the transaction, the method of execution, or any other way, and confirm that any variation in treatment is both necessary and appropriate to meet the minimum standards regarding, among other things, operations, governance, and risk management identified in the Standards for Covered Clearing Agencies; (2) consider whether to enable GSD's Netting Members, as defined in the GSD Rules,[12] to submit eligible transactions for clearance and settlement that have been executed by two indirect participants of FICC/GSD (''done-away''); (3) consider the volumes and proportion of the markets that are being centrally cleared through different access models in determining whether FICC/GSD's access models are meeting the needs of the market; and (4) consider whether it is appropriate to develop and propose an additional category or categories of Netting Members to the GSD Rules to reflect the types of legal entities that applied to be a Netting Member over the prior 12 months and did not fit into one of the existing Netting Member categories.[13]

C. Other Conforming and Clean Up Changes

The proposal would make other conforming and clean up changes to the Framework. The Clearing Agencies would amend Section 1 of the Framework to: (1) include the annual review of GSD's access models in the list of regulatory requirements that are addressed in the Framework, and (2) update the description of the contents of Section 3 of the Framework to include the solicitation of participant and stakeholder views and annual review of GSD's access models as part of the Clearing Agencies' management of risks.

The Clearing Agencies would also remove the defined term ''Management Committee'' wherever referenced and replace it with ''senior management committee'' while maintaining the current makeup and responsibilities of the current Management Committee, as described in the Framework. The Clearing Agencies state that the proposed change would allow the Framework to continue to be accurate notwithstanding any future name changes to the committee.[14]

Other minor grammatical and clean up changes would also be made to the Framework.

IV. Discussion and Commission Findings

Section 19(b)(2)(C) of the Act [15] directs the Commission to approve a proposed rule change of a self-regulatory organization if it finds that such proposed rule change is consistent with the requirements of the Act and rules and regulations thereunder applicable to such organization. After carefully considering the Proposed Rule Changes, the Commission finds that the Proposed Rule Changes are consistent with the requirements of the Act and the rules and regulations thereunder applicable to the Clearing Agencies. In particular, the Commission finds that the Proposed Rule Changes are consistent with Section 17A(b)(3)(F) [16] of the Act and Rule 17Ad–22(e)(18)(iv)(C),[17] each promulgated under the Act.

A. Section 17A(b)(3)(F) of the Act

Section 17A(b)(3)(F) of the Act requires, in part, that the rules of a registered clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions and assure the safeguarding of securities and funds which are in their custody or control or for which they are responsible.[18]

As described above in Section III.A, the Clearing Agencies routinely solicit their participants' and other industry stakeholders' views. The Proposed Rule Changes would codify that the Clearing Agencies use this practice, which should help ensure that the Clearing Agencies have mechanisms in place to be informed of the views of their participants and other industry stakeholders. By allowing specifically for formal engagement and transparency on their risk management practices, the Proposed Rule Changes should continue to encourage communication and provide a formal mechanism to help the Clearing Agencies identify and evaluate any unintended consequences a proposal or practice may have on its direct and indirect participants and obtain recommendations on how to meet its goals through alternative approaches. In addition, as described in Section III.B, the Proposed Rule Changes would establish an annual advisory council for FICC's GSD to assist the FICC Board of Directors, or a committee thereof, in its required annual review of GSD access models, and the Proposed Rule Changes would also identify several things that the advisory council would have to do as part of its review. Adopting this advisory council and a plan for its work, as well as requiring annual review by the FICC Board of Directors, should help FICC work to meet its regulatory obligations to establish, implement, maintain and enforce written policies and procedures reasonably designed to ensure that it has appropriate means to facilitate access, including for indirect participants, to its clearance and settlement services by providing a method by which FICC can be informed by its participants and other industry stakeholders as to access issues. This change should help ensure that FICC solicits and considers such views when making decisions about how to structure its access models, which should, in turn, help further continued prompt and accurate clearance and settlement in the U.S. Treasury market, consistent with Section 17A(b)(3)(F) of the Act.[19]

Finally, the proposed conforming and clean-up changes should help to ensure that the Framework is clear and accurate. The risk management functions described in the Framework allow the Clearing Agencies to continue their critical operations and services, and better understanding of the Framework should help promote the prompt and accurate clearance and settlement of securities transactions,

[11] *See* DTC Notice of Filing, *supra* note 3, 89 FR at 21119; FICC Notice of Filing, *supra* note 3, 89 FR at 21069; and NSCC Notice of Filing, *supra* note 3, 89 FR at 21092.

[12] *See* Fixed Income Clearing Corporation Government Securities Division Rulebook, Rule 1 (defining Netting Member and associated terms), *available at https://www.dtcc.com/~/media/files/downloads/legal/rules/ficc_gov_rules.pdf.*

[13] In a separate proposed rule change, FICC proposed to add a framework to consider an applicant who does not meet the eligibility requirements of any existing categories. *See* Securities Exchange Act Release No. 99817 (Mar. 21, 2024), 89 FR 21362, 21373 (Mar. 27, 2024) (File No. SR–FICC–2024–005).

[14] *See* DTC Notice of Filing, *supra* note 3, 89 FR at 21120; FICC Notice of Filing, *supra* note 3, 89 FR at 21070; and NSCC Notice of Filing, *supra* note 3, at 3.

[15] 15 U.S.C. 78s(b)(2)(C).

[16] 15 U.S.C. 78q–1(b)(3)(F).

[17] 17 CFR 240.17ad–22(e)(18)(iv)(C).

[18] *See supra* note 13.

[19] 15 U.S.C. 78q–1(b)(3)(F).

consistent with Section 17A(b)(3)(F) of the Act.[20]

Accordingly, and for the reasons stated above, the Commission finds that the Proposed Rule Changes are consistent with Section 17A(b)(3)(F) of the Act.

B. Section 17Ad–22(e)(18)(iv)(C) of the Act

Section 17Ad–22(e)(18)(iv)(C) under the Act requires, among other things, that a covered clearing agency serving the U.S. Treasury market, like FICC, establish, implement, maintain, and enforce written policies and procedures reasonably designed to ensure that the covered clearing agency has appropriate means to facilitate access to clearance and settlement services of all eligible secondary market transactions in U.S. Treasury securities, including those of indirect participants, and that the board of directors for the covered clearing agency, like FICC, annually review such policies and procedures.[21] The Proposed Rule Changes, as described in Section III.B above, would establish an advisory council and framework for that council's work and would provide for annual review by the FICC Board of Directors as to FICC's policies and procedures regarding access to its clearance and settlement services.

One commenter addressed certain aspects of this proposal. Specifically, the commenter states that FICC's rules ''should provide that indirect participants will be allotted at least 50% of the representation on the council.'' [22] The Commission agrees that indirect participant representation on the proposed council is important. Under the Proposed Rule Changes, the advisory council would include representatives not only from FICC participants, but also their customers, that is, indirect participants who rely on FICC's services to access FICC's clearance and settlement services. Though not required, the use of an advisory council is consistent with Rule 17ad–22(e)(18)(iv)(C), and that rule does not mandate the particular composition of the advisory council that FICC has chosen to establish.

The Commission recently adopted Rule 17ad–25(j) [23] which requires each registered clearing agency to establish, implement, maintain, and enforce written policies and procedures reasonably designed to solicit, consider, and document its consideration of the views of participants and other relevant stakeholders. The Commission therefore has given clearing agencies discretion in the design and structure of stakeholder outreach.[24] The Commission also stated in the Rule 17ad–25(j) final rule release that such ''other relevant stakeholders'' generally would include investors, customers of clearing agency participants, and securities issuers.[25]

Pursuant to the Proposed Rule Changes, FICC would include indirect participants on its advisory council. The Commission supports the inclusion of indirect participants and encourages FICC to solicit views from a variety of indirect participants who may have differing needs.

The commenter further stated that FICC should, ''explicitly describe how and to what extent the feedback and recommendations made by the indirect participant members on the council (or indirect participants at large) will be considered and/or incorporated into the review process and potential changes to the access models.'' [26] Within the Proposed Rule Changes, FICC has outlined specific points of consideration, and specific data to document and analyze in furtherance of the annual review by the Board of Directors, or a committee thereof, of GSD access models as noted in Section III.B above. In addition, pursuant to the Proposed Rule Changes, the advisory council's review would be escalated to the FICC Board of Directors, or a committee thereof, to assist in their annual review. Rule 17ad–22(e)(18)(iv)(C) does not require the use of an advisory council.

Accordingly, the Commission finds that the Proposed Rule Changes are consistent with the requirements of Rule 17ad–22(e)(18)(iv)(C).[27]

V. Conclusion

On the basis of the foregoing, the Commission finds that the Proposed Rule Change is consistent with the requirements of the Act and in particular with the requirements of Section 17A of the Act [28] and the rules and regulations promulgated thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act [29] that proposed rule changes SR–DTC–2024–003, SR–FICC–2024–006, and SR–NSCC–2024–003 be, and hereby are, *approved*.[30]

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[31]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–27754 Filed 11–26–24; 8:45 am]

BILLING CODE 8011–01–P

[20] 15 U.S.C. 78q–1(b)(3)(F).

[21] 17 CFR 240.17ad–22(e)(18)(iv)(C).

[22] Letter from Jiri Krol, Deputy CEO, Global Head of Government Affairs, Alternative Investment Management Association, at 8 (Apr. 23, 2024), *available at https://www.sec.gov/comments/sr-ficc-2024-006/srficc2024006.htm* (''AIMA Letter'').

[23] 17 CFR 240.17ad–25(j).

[24] Clearing Agency Governance and Conflicts of Interest, Securities Exchange Act Release No. 98959 (Nov. 16, 2023), 88 FR 84454, 84483 (Dec. 5, 2023).

[25] *See id.*

[26] AIMA Letter, *supra* note 22, at 8.

[27] 17 CFR 240.17ad–22(e)(18)(iv)(C).

[28] 15 U.S.C. 78q–1.

[29] 15 U.S.C. 78s(b)(2).

[30] In approving the Proposed Rule Changes, the Commission considered their impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[31] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101693; File No. SR–NASDAQ–2024–068]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Deadline for a Listed Company To Notify Nasdaq of a Reverse Stock Split

November 21, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 8, 2024, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to modify its listing standards related to notification and disclosure of reverse stock splits to the Exchange. The proposed rule change will become operative on January 30, 2025.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/nasdaq/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On June 21, 2023, Nasdaq filed with the Commission a proposed rule change related to notification and disclosure of reverse stock splits.[3] On November 1, 2023, the Commission approved the proposed rule changes.[4] On March 1, 2024, Nasdaq adopted an additional change to the rule and Company Event Notification Form to further clarify the requirements.[5] Nasdaq is now proposing to amend the deadline for a company to notify Nasdaq of a reverse stock split from 5 business days to 10 calendar days in order to conform to the requirements of SEC Rule 10b–17 of the Act.[6]

Specifically, Rule 10b–17(a)(2) and (b) of the Act, require issuers to provide notice to FINRA (formerly the National Association of Securities Dealers, Inc.) no later than 10 calendar days prior to the date of record to participate in a stock split or reverse stock split, unless the impacted security is traded on a national securities exchange with a substantially comparable requirement to those set forth in Rule 10b–17(b)(1).[7]

Currently, Rule 5250(e)(7) and IM–5250–3 require a company conducting a reverse stock split to notify Nasdaq about certain details of the reverse stock split by submitting a complete Company Event Notification Form and a draft of the disclosure required by Rule 5250(b)(4) at least 5 business days (no later than 12:00 p.m. ET) prior to the anticipated market effective date, which includes all the information required by Rule 10b–17 applicable to reverse stock splits.

It has come to Nasdaq's attention that Nasdaq's current rule may not be considered substantially comparable to the 10 calendar-day prior notice required in Rule 10b–17 of the Act. Accordingly, Nasdaq is proposing to amend the deadline for a company to notify Nasdaq of a reverse stock split from no later than 12:00 p.m. ET 5 business days to 10 calendar days prior to the anticipated market effective date of the reverse stock split to ensure that Rule 5250(e)(7) and IM–5250–3 are substantially comparable to Rule 10b–17 and, therefore, that companies are compliant with Rule 10b–17 when they give notice under those rules.[8] Nasdaq is not amending the requirement to provide public disclosure under Rule 5250(b)(4) at least 2 business days (no later than 12:00 p.m. ET) prior to the anticipated market effective date. Nasdaq still believes that this timeframe provides sufficient notice to the public about reverse stock splits.[9]

Nasdaq is also submitting an updated Company Event Notification Form as *Exhibit 3* to the rule filing. Nasdaq is making conforming changes to the Form to reflect that the deadline for submission is 10 calendar days, rather than 5 business days.

In order to provide companies that have already planned action for a reverse stock split under the current rule's timeframe with the ability to effect their reverse stock split under that schedule, the proposed rule change will become operative on January 30, 2025.[10] Nasdaq believes that this delayed operative date will allow sufficient time for market participants to adjust to the new time frame. For example, a company may have already scheduled a shareholder meeting or submitted a preliminary or final proxy statement to the Commission with a view towards effecting a reverse stock split based on the currently required five-day notice period. Nasdaq believes this delayed operative date will reduce potential confusion for companies and investors about the transition and allow companies to appropriately plan for the change.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[11] in general, and furthers the objectives of Section 6(b)(5) of the Act,[12] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, by aligning its rules related to notification of reverse stock splits with the notification requirements of Rule 10b–17 of the Act.

The proposal amends Rule 5250(e)(7) and IM–5250–3 to require a company to submit a complete Company Event Notification Form and a draft of the disclosure required by Rule 5250(b)(4) at least 10 calendar days (no later than 12:00 p.m. ET) prior to the anticipated market effective date, rather than 5 business days, and provides conforming updates to the Company Event Notification Form. Nasdaq believes that this will align Nasdaq's rules with the requirements of Rule 10b–17 under the Act, and will thereby help promote clarity, transparency and consistency for market participants and companies. Nasdaq also believes that the delayed operative date of the proposed rule change is consistent with Section 6(b)(5) of the Act in that it will allow sufficient time for market participants to adjust to the new time frame and will thereby help to reduce potential confusion for companies and investors.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed change is designed to align an existing rule and related Company Event Notification Form with the requirements of Rule 10b–17 of the Act and, therefore, Nasdaq believes that the proposed change will not impose a burden on competition.

[3] *See* Securities Exchange Act Release No. 98014 (July 28, 2023), 88 FR 51376 (August 3, 2023) (proposing SR–Nasdaq–2023–025).

[4] *See* Securities Exchange Act Release No. 98843 (November 1, 2023), 88 FR 76867 (November 7, 2023) (approving SR–Nasdaq–2023–025).

[5] *See* Securities Exchange Act Release No. 99734 (March 14, 2024), 89 FR 19905 (March 20, 2024).

[6] 17 CFR 240.10b–17.

[7] 17 CFR 240.10b–17(a)(2), (b)(1) and (b)(3).

[8] For example, if a company desires to effect a reverse stock split with a market effective date of Monday, September 23, the company would have to provide Nasdaq with a draft of the disclosure required by proposed Rule 5250(b)(4) and a complete Company Event Notification Form by 12:00 p.m. ET on Friday, September 13, and provide the public disclosure by 12:00 p.m. ET by Thursday, September 19. Note that this example presumes that there are no holidays during these dates. If a company withdraws and re-submits a Company Event Notification Form, the 10 calendar day period would be measured from the date the company re-submitted the form (rather than the date of the first submission).

[9] *See supra* note 3.

[10] For example, a company may have already scheduled a shareholder meeting or submitted a preliminary or final proxy statement to the Commission with a view towards effecting a reverse stock split during a compliance period under the Nasdaq Listing Rules. The additional time to provide 10 calendar days advance notice of the reverse stock split, instead of the currently required five business-day notice period, could prevent the company from regaining compliance during the compliance period.

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act [13] and subparagraph (f)(6) of Rule 19b–4 thereunder.[14]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–NASDAQ–2024–068 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NASDAQ–2024–068. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NASDAQ–2024–068 and should be submitted on or before December 18, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–27761 Filed 11–26–24; 8:45 am]

BILLING CODE 8011–01–P

[13] 15 U.S.C. 78s(b)(3)(A)(iii).

[14] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[15] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101684; File No. SR–OCC–2024–014]

Self-Regulatory Organizations; The Options Clearing Corporation; Notice of Designation of Longer Period for Commission Action on Proposed Rule Change, as Modified by Partial Amendment No. 1, by the Options Clearing Corporation Concerning Its Process for Adjusting Certain Parameters in Its Proprietary System for Calculating Margin Requirements During Periods When the Products It Clears and the Markets It Serves Experience High Volatility

November 21, 2024.

On October 1, 2024, the Options Clearing Corporation (''OCC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change SR–OCC–2024–014, pursuant to Section 19(b) of the Securities Exchange Act of 1934 (''Exchange Act'') [1] and Rule 19b–4 [2] thereunder, to codify OCC's process for adjusting certain parameters in its proprietary system for calculating margin requirements during periods when the products OCC clears and the markets it serves experience high volatility.[3] The proposed rule change, as modified by Partial Amendment no. 1 (hereinafter, the ''Proposed Rule Change''), was published for public comment in the **Federal Register** on October 9, 2024.[4] The Commission has received no comments regarding the Proposed Rule Change.

Section 19(b)(2)(i) of the Exchange Act [5] provides that, within 45 days of the publication of notice of the filing of a proposed rule change, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved unless the Commission extends the period within which it must act as provided in Section 19(b)(2)(ii) of the Exchange Act.[6] Section 19(b)(2)(ii) of the Exchange Act allows the Commission to designate a longer period for review (up to 90 days from the publication of notice of the filing of a proposed rule change) if the Commission finds such longer period to be appropriate and publishes

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Notice of Filing *infra* note 4, at 89 FR 81958.

[4] Securities Exchange Act Release No. 101246 (Oct. 3, 2024), 89 FR 81958 (Oct. 9, 2024) (File No. SR–OCC–2024–014) (''Notice of Filing'').

[5] 15 U.S.C. 78s(b)(2)(i).

[6] 15 U.S.C. 78 s(b)(2)(ii).

its reasons for so finding, or as to which the self-regulatory organization consents.[7]

The 45th day after publication of the Notice of Filing is November 23, 2024. In order to provide the Commission with sufficient time to consider the Proposed Rule Change, the Commission finds that it is appropriate to designate a longer period within which to take action on the Proposed Rule Change and therefore is extending this 45-day time period.

Accordingly, the Commission, pursuant to Section 19(b)(2) of the Exchange Act,[8] designates January 7, 2025, as the date by which the Commission shall either approve, disapprove, or institute proceedings to determine whether to disapprove proposed rule change SR–OCC–2024–014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–27753 Filed 11–26–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101683; File No. SR–NYSEARCA–2024–96]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 7.37–E

November 21, 2024.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act''),[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on November 7, 2024, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 7.37–E to specify the Exchange's source of data feeds from Long-Term Stock Exchange, Inc. (''LTSE'') for purposes of order handling, order execution, order routing, and regulatory compliance. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to update and amend the use of data feeds table in Rule 7.37–E(d), which sets forth on a market-by-market basis the specific securities information processor (''SIP'') and proprietary data feeds that the Exchange utilizes for the handling, execution, and routing of orders, and for performing the regulatory compliance checks related to each of those functions. Specifically, the Exchange proposes to amend the table in Rule 7.37–E(d) to specify that, with respect to LTSE, the Exchange will receive a LTSE direct feed as its primary source of data for order handling, order execution, order routing, and regulatory compliance, and will use the SIP Data Feed as its secondary source for data from LTSE.

The Exchange proposes to make this change operative in the fourth quarter of 2024, and, in any event, before the end of the first quarter of 2025. The Exchange proposes to announce the implementation date of this change by Trader Update.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[4] in general, and furthers the objectives of Section 6(b)(5),[5] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest. Additionally, the Exchange believes that the proposed rule change is consistent with the Section 6(b)(5) requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes its proposal to update the table in Rule 7.37(e) to include the LTSE direct feed will ensure that the Rule correctly identifies and publicly states on a market-by-market basis all of the specific SIP and proprietary data feeds that the Exchange utilizes for the handling, execution, and routing of orders, and for performing the regulatory compliance checks for each of those functions. The proposed rule change also removes impediments to and perfects the mechanism of a free and open market and protects investors and the public interest by providing additional specificity, clarity, and transparency in the Exchange's rules.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Rather, the Exchange believes that the proposal will enhance competition because providing the public and market participants with up-to-date information about the data feeds the Exchange will use for the handling, execution, and routing of orders, as well as for regulatory compliance would enhance transparency and enable investors to better assess the quality of the Exchange's execution and routing services. The Exchange also believes the proposal would enhance competition because it would potentially enhance the performance of its order handling and execution of orders in equity securities by receiving market data directly from LTSE. Finally, the proposed rule change would not impact competition between market participants because it will affect all market participants equally.

[7] *Id.*

[8] *Id.*

[9] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(5).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[6] and Rule 19b–4(f)(6) thereunder.[7] Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[8] and Rule 19b–4(f)(6)(iii) thereunder.[9]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[10] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–NYSEARCA–2024–96 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NYSEARCA–2024–96. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NYSEARCA–2024–96 and should be submitted on or before December 18, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–27752 Filed 11–26–24; 8:45 am]

BILLING CODE 8011–01–P

[6] 15 U.S.C. 78s(b)(3)(A)(iii).

[7] 17 CFR 240.19b–4(f)(6).

[8] 15 U.S.C. 78s(b)(3)(A).

[9] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[10] 15 U.S.C. 78s(b)(2)(B).

[11] 17 CFR 200.30–3(a)(12), (59).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101682; File No. SR–NYSENat–2024–30]

Self-Regulatory Organizations; NYSE National, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 7.37

November 21, 2024.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act''),[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on November 7, 2024, NYSE National, Inc. (''NYSE National'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 7.37 to specify the Exchange's source of data feeds from Long-Term Stock Exchange, Inc. (''LTSE'') for purposes of order handling, order execution, order routing, and regulatory compliance. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to update and amend the use of data feeds table in Rule 7.37(d), which sets forth on a market-by-market basis the specific securities information processor (''SIP'') and proprietary data feeds that the Exchange utilizes for the handling, execution, and routing of orders, and for performing the regulatory compliance checks related to each of those functions. Specifically, the Exchange proposes to amend the table in Rule 7.37(d) to specify that, with respect to LTSE, the Exchange will receive a LTSE direct feed as its primary source of data for order handling, order execution, order routing, and regulatory compliance, and will use the SIP Data Feed as its secondary source for data from LTSE.

The Exchange proposes to make this change operative in the fourth quarter of 2024, and, in any event, before the end of the first quarter of 2025. The Exchange proposes to announce the implementation date of this change by Trader Update.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[4] in general, and furthers the objectives of Section 6(b)(5),[5] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest. Additionally, the Exchange believes that the proposed rule change is consistent with the Section 6(b)(5) requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes its proposal to update the table in Rule 7.37(e) to include the LTSE direct feed will ensure that the Rule correctly identifies and publicly states on a market-by-market basis all of the specific SIP and proprietary data feeds that the Exchange utilizes for the handling, execution, and routing of orders, and for performing the regulatory compliance checks for each of those functions. The proposed rule change also removes impediments to and perfects the mechanism of a free and open market and protects investors and the public interest by providing additional specificity, clarity, and transparency in the Exchange's rules.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Rather, the Exchange believes that the proposal will enhance competition because providing the public and market participants with up-to-date information about the data feeds the Exchange will use for the handling, execution, and routing of orders, as well as for regulatory compliance would enhance transparency and enable investors to better assess the quality of the Exchange's execution and routing services. The Exchange also believes the proposal would enhance competition because it would potentially enhance the performance of its order handling and execution of orders in equity securities by receiving market data directly from LTSE. Finally, the proposed rule change would not impact competition between market participants because it will affect all market participants equally.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[6] and Rule 19b–4(f)(6) thereunder.[7] Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[8] and Rule 19b–4(f)(6)(iii) thereunder.[9]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[10] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–NYSENat–2024–30 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NYSENat–2024–30. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(5).

[6] 15 U.S.C. 78s(b)(3)(A)(iii).

[7] 17 CFR 240.19b–4(f)(6).

[8] 15 U.S.C. 78s(b)(3)(A).

[9] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[10] 15 U.S.C. 78s(b)(2)(B).

public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NYSENat–2024–30 and should be submitted on or before December 18, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–27751 Filed 11–26–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101691; File No. SR–Phlx–2024–57]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Fees for Connectivity and Co-Location Services

November 21, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 8, 2024, Nasdaq PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's fees for connectivity and co-location services, as described further below.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/phlx/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the Exchange's fees relating to connectivity and co-location services.[3] Specifically, the Exchange proposes to raise its fees for connectivity and co-location services in General 8 as well as certain fees related to its Testing Facilities in Equity 7, Section 3 by 10%, with certain exceptions.

General 8, Section 1 includes the Exchange's fees that relate to connectivity, including fees for cabinets, external telco/inter-cabinet connectivity fees, fees for connectivity to the Exchange, fees for connectivity to third party services, fees for market data connectivity, fees for cabinet power install, and fees for additional charges and services. General 8, Section 2 includes the Exchange's fees for direct connectivity services, including fees for direct circuit connection to the Exchange, fees for direct circuit connection to third party services, and fees for point of presence connectivity. With the exception of the Exchange's GPS Antenna fees and the Cabinet Proximity Option Fee for cabinets with power density >10kW,[4] the Exchange proposes to increase its fees throughout General 8 by 10%.

In addition to increasing fees in General 8, the Exchange also proposes to increase certain fees in Equity 7, Section 3, which relate to the Testing Facility. Equity 7, Section 3 provides that subscribers to the Testing Facility located in Carteret, New Jersey shall pay a fee of $1,000 per hand-off, per month for connection to the Testing Facility. The hand-off fee includes either a 1Gb or 10Gb switch port and a cross connect to the Testing Facility. In addition, Equity 7, Section 3 provides that subscribers shall also pay a one-time installation fee of $1,000 per hand-off. The Exchange proposes to increase these aforementioned fees by 10% to require that subscribers to the Testing Facility shall pay a fee of $1,100 per hand-off, per month for connection to the Testing Facility and a one-time installation fee of $1,100 per hand-off.

The proposed increases in fees would enable the Exchange to maintain and improve its market technology and services to remain competitive with its peers. Over the years, customer demand for more sophisticated, higher-throughput, lower-latency, and higher-power connectivity solutions has increased. The Exchange continues to invest in maintaining, improving, and enhancing its connectivity and co-location products, services, and facilities—for the benefit and often at the behest of its customers. Such enhancements include refreshing hardware and expanding Nasdaq's existing co-location facility to offer customers additional space and power. Nevertheless, and with the exception of fees that were established as part of a new service in 2017 (and have remained unchanged since their adoption), the Exchange has not increased any of the fees included in the proposal since prior to 2017, and many of the fees date back to between 2010 and 2014. For each of

[11] 17 CFR 200.30–3(a)(12), (59).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Exchange initially filed the proposed pricing change on March 1, 2024 (SR–PHLX–2024–08). On April 29, 2024, the Exchange withdrew that filing and submitted SR–Phlx–2024–019. The Exchange withdrew SR–PHLX–2024–019 and replaced it with SR–PHLX–2024–27. The instant filing replaces SR–PHLX–2024–027, which was withdrawn on August 23, 2024. The Exchange withdrew SR–PHLX–2024–07 and replaced it with SR–PHLX–2024–45 on September 10, 2024. On October 11, 2024, the Exchange replaced SR–PHLX–2024–45 with SR–PHLX–2024–52. The instant filing replaces SR–PHLX–2024–52.

[4] The Exchange proposes to exclude the GPS Antenna fees from the proposed fee increase because, unlike the other fees in General 8, the Exchange recently increased its GPS Antenna fees. *See* Securities Exchange Act Release No. 34–99125 (December 8, 2023), 88 FR 86705 (December 14, 2023) (SR–Phlx–2023–53). The Exchange also proposes to exclude the Cabinet Proximity Option Fee for cabinets with power density >10kW from the proposed fee increase because the Exchange recently established such fee. *See* Securities Exchange Act Release No. 34–100197 (May 21, 2024), 89 FR 46185 (May 28, 2024) (SR–Phlx–2024–23). Similarly, the Exchange proposes to exclude from the proposed fee increase those fees that the Exchange recently established for services in its new NY11–4 expansion facility. *See* Securities Exchange Act Release No. 34–101268 (October 7, 2024), 89 FR 82661 (October 11, 2024) (SR–PHLX–2024–49).

the connectivity products and services that pre-date 2017, inflation (as measured using the ''Data PPI'' metric described below) has been between roughly 15–17%, and in no instance has such inflation been less than 10%. Nevertheless, the Exchange proposes to increase its fees only with respect to the 10% inflation that has occurred since 2017.

As discussed below, the Exchange proposes to adjust its fees by an industry- and product-specific inflationary measure. It is reasonable and consistent with the Act for the Exchange to recoup its investments, at least in part, by adjusting its fees. Continuing to operate at fees frozen at 2010–2017 levels impacts the Exchange's ability to enhance its offerings and the interests of market participants and investors.

The fee increases the Exchange proposes are based on an industry-specific Producer Price Index (''PPI''), which is a tailored measure of inflation.[5] As a general matter, the Producer Price Index is a family of indexes that measures the average change over time in selling prices received by domestic producers of goods and services. PPI measures price change from the perspective of the seller. This contrasts with other metrics, such as the Consumer Price Index (''CPI''), that measure price change from the purchaser's perspective.[6] About 10,000 PPIs for individual products and groups of products are tracked and released each month.[7] PPIs are available for the output of nearly all industries in the goods-producing sectors of the U.S. economy—mining, manufacturing, agriculture, fishing, and forestry—as well as natural gas, electricity, and construction, among others. The PPI program covers approximately 69 percent of the service sector's output, as measured by revenue reported in the 2017 Economic Census.

For purposes of this proposal, the relevant industry-specific PPI is the Data Processing and Related Services PPI (''Data PPI''), which is an industry net-output PPI that measures the average change in selling prices received by companies that provide data processing services.

The Data PPI was introduced in January 2002 by the Bureau of Labor Statistics (''BLS'') as part of an ongoing effort to expand Producer Price Index coverage of the services sector of the U.S. economy and is identified as NAICS–518210 in the North American Industry Classification System.[8] According to the BLS ''[t]he primary output of NAICS 518210 is the provision of electronic data processing services. In the broadest sense, computer services companies help their customers efficiently use technology. The processing services market consists of vendors who use their own computer systems—often utilizing proprietary software—to process customers' transactions and data. Companies that offer processing services collect, organize, and store a customer's transactions and other data for record-keeping purposes. Price movements for the NAICS 518210 index are based on changes in the revenue received by companies that provide data processing services. Each month, companies provide net transaction prices for a specified service. The transaction is an actual contract selected by probability, where the price-determining characteristics are held constant while the service is repriced. The prices used in index calculation are the actual prices billed for the selected service contract.'' [9]

The Exchange believes the Data PPI is an appropriate measure to be considered in the context of the proposed rule change to modify the fee for its connectivity products because the Exchange uses its ''own computer systems'' and ''proprietary software,'' *i.e.,* its own data center and proprietary matching engine software, respectively, to collect, organize, store and report customers' transactions in U.S. equity securities on the Exchange's proprietary trading platform. In other words, the Exchange is in the business of data processing and related services.

For purposes of this proposed rule change, the Exchange examined the Data PPI value for the period from January 2017 to August 2024. The Data PPI had a starting value of 105.6 in January 2017 and an ending value of 116.022 in August 2024, a 10.422% increase. This indicates that companies who are also in the data storage and processing business have generally increased prices for a specified service covered under NAICS 518210 by an average of 10.422% during this period. Based on that percentage change, the Exchange proposes to make a one-time fee increase of only 10%, which reflects an increase covering roughly the entire period since the last price adjustments to these fees were made.

The Exchange further believes the Data PPI is an appropriate measure for purposes of the proposed rule change on the basis that it is a stable metric with limited volatility, unlike other consumer-side inflation metrics. In fact, the Data PPI has not experienced a greater than 2.16% increase for any one calendar year period since Data PPI was introduced into the PPI in January 2002. The average calendar year change from January 2002 to December 2023 was .62%, with a cumulative increase of 15.67% over this 21-year period. The Exchange believes the Data PPI is considerably less volatile than other inflation metrics such as CPI, which has had individual calendar-year increases of more than 6.5%, and a cumulative increase of over 73% over the same period.[10]

The Exchange believes the Data PPI, and significant investments into, and enhanced performance of, the Exchange support the reasonableness of the proposed fee increases.[11]

These proposed fee increases will be immediately effective upon filing. However, going forward and until December 1, 2024, the Exchange will waive all fees set forth herein to the extent that such fees exceed the levels that would have been charged for the same products and services purchased during that time period, had such fees been calculated at the rates set forth in SR–PHLX–2024–45 (*i.e.,* pricing reflective of a 5.5% increase from prior fee levels). This waiver is reasonable, equitable, and not unfairly discriminatory because it will afford all customers in excess of the 30-day prior notice period for fee changes set forth in the Exchange's service terms.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[12] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[13] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges

[5] *See https://fred.stlouisfed.org/series/PCU51825182#0.*

[6] *See https://www.bls.gov/ppi/overview.htm.*

[7] *See Id.*

[8] *NAICS appears in table 5 of the PPI Detailed Report and is available at https://data.bls.gov/timeseries/PCU518210518210.*

[9] *See https://www.bls.gov/ppi/factsheets/producer-price-index-for-the-data-processing-and-related-servicesindustry-naics-518210.htm.*

[10] *See https://www.usinflationcalculator.com/inflation/consumer-price-index-and-annual-percent-changesfrom-1913-to-2008/.*

[11] *See supra* discussion of connectivity product and facility improvements. Additionally, other exchanges have filed for increases in certain fees, based in part on comparisons to inflation. See, *e.g.,* Securities Exchange Act Release Nos. 34–100004 (April 22, 2024), 89 FR 32465 (April 26, 2024) (SR–CboeBYX–2024–012); and 34–100398 (June 21, 2024), 89 FR 53676 (June 27, 2024) (SR–BOX–2024–16)l; Securities Exchange Act Release No. 34–100994 (September 10, 2024), 89 FR 75612 (September 16, 2024) (SR–NYSEARCA–2024–79).

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(4) and (5).

among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

This belief is based on two factors. First, the current fees do not properly reflect the quality of the services and products, as fees for the services and products in question have been static in nominal terms, and therefore falling in real terms due to inflation. Second, the Exchange believes that investments made in enhancing the capacity and speed of Exchange systems increase the performance of the services and products.

The Proposed Rule Change Is Reasonable

As noted above, the Exchange has not increased any of the fees included in the proposal since 2017 or earlier. However, in the years following the last fee increases, the Exchange has made significant investments in upgrades to its connectivity products, services, and facilities, enhancing the quality of its services. In other words, Exchange customers have greatly benefitted, while the Exchange's ability to recoup its investments has been hampered. Between 2017 and 2024, the inflation rate is 3.64% per year, on average, producing a cumulative inflation rate of 28.43%.[14] Using the more targeted inflation number of Data PPI, the cumulative inflation rate was 10.422%. The exchange believes the Data PPI is a reasonable metric to base this fee increase on because it is targeted to producer-side increases in the data processing industry.

Notwithstanding inflation, as noted above, the Exchange has not increased its fees at all for over seven years for the subject services. The proposed fee changes represent a modest increase from the current fees. The Exchange believes the proposed fee increase is reasonable in light of the Exchange's continued expenditure in maintaining a robust technology ecosystem. Furthermore, the Exchange continues to invest in maintaining and enhancing its connectivity products—for the benefit and often at the behest of its customers and global investors. Such enhancements include refreshing all aspects of the technology ecosystem including software, hardware, and network while introducing new and innovative products and expanded and modernized facilities.[15] The goal of the enhancements discussed above, among other things, is to provide faster, higher-capacity, and more modern connectivity products and services. Accordingly, the Exchange continues to expend resources to innovate and modernize technology so that it may benefit its members in offering its connectivity products and services.

The Proposed Fees Are Equitably Allocated and Not Unfairly Discriminatory

The Exchange believes that the proposed fee increases are equitably allocated and not unfairly discriminatory because they would apply to all market participants that choose to purchase connectivity products and services from the Exchange. Any participant that chooses to purchase the Exchange's connectivity products and services would be subject to the same Fee Schedule, regardless of what type of business they operate or the use they plan to make use of the products and services. Additionally, the fee increase would be applied uniformly to market participants without regard to Exchange membership status or the extent of any other business with the Exchange or affiliated entities. The Exchange also believes that the proposal represents an equitable allocation of reasonable dues, fees and other charges because Exchange fees have fallen in real terms during the relevant period. Finally, the Exchange believes that the proposed fee changes are not unfairly discriminatory because the fees would be assessed uniformly across all market participants, in the same manner they are today, that voluntarily purchase the Exchange's connectivity products and services, which would remain available for purchase by all market participants.

These proposed fee increases will be immediately effective upon filing. However, going forward and until December 1, 2024, the Exchange will waive all fees set forth herein to the extent that such fees exceed the levels that would have been charged for the same products and services purchased during that time period, had such fees been calculated at the rates set forth in SR–PHLX–2024–45 (*i.e.,* pricing reflective of a 5.5% increase from prior fee levels). This waiver is reasonable, equitable, and not unfairly discriminatory because it will afford all customers in excess of the 30-day prior notice period for fee changes set forth in the Exchange's service terms.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed fees will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Intramarket Competition

The Exchange believes that the proposed fees do not put any market participants at a relative disadvantage compared to other market participants. As noted above, the fee schedule would continue to apply to all purchasers of the Exchange's connectivity products and services in the same manner as it does today albeit at inflation-adjusted rates for certain fees, and customers may choose whether to purchase these products and services at all. The Exchange also believes that the level of the proposed fees neither favor nor penalize one or more categories of market participants in a manner that would impose an undue burden on competition. Likewise, the proposed fee waiver described above will apply to all purchasers of the Exchange's connectivity products and services in the same manner and therefore will not burden competition among them.

Intermarket Competition

The Exchange believes that the proposed fees do not impose a burden on competition or on other SROs that is not necessary or appropriate. In determining the proposed fees, the Exchange utilized an objective and stable metric with limited volatility. Utilizing Data PPI over a specified period of time is a reasonable means of recouping the Exchange's investment in maintaining and enhancing its connectivity products, services, and facilities. The Exchange believes utilizing Data PPI, a tailored measure of inflation, to increase certain fees for connectivity products and services to recoup the Exchange's investment in maintaining and enhancing such products, services, and its facilities would not impose a burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

[14] *See https://www.officialdata.org/us/inflation/2017?amount=1.*

[15] *See, e.g.,* Securities Exchange Act Release No.34–101079 (September 18, 2024), 89 FR 77931 (September 24, 2024) (SR–PHLX–2024–47 (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Expand [the Exchange's] Co-Location Services).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[16]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–Phlx–2024–57 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–Phlx–2024–57. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–Phlx–2024–57 and should be submitted on or before December 18, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Sherry R. Haywood,

Assistant Secretary.

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BILLING CODE 8011–01–P

[16] 15 U.S.C. 78s(b)(3)(A)(ii).

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101679; File No. SR–NYSE–2024–74]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 7.37

November 21, 2024.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act''),[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on November 7, 2024, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 7.37 to specify the Exchange's source of data feeds from Investors' Exchange, LLC (''IEX'') for purposes of order handling, order execution, order routing, and regulatory compliance. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to update and amend the use of data feeds table in Rule 7.37(e), which sets forth on a market-by-market basis the specific securities information processor (''SIP'') and proprietary data feeds that the Exchange utilizes for the handling, execution, and routing of orders, and for performing the regulatory compliance checks related to each of those functions. Specifically, the Exchange proposes to amend the table in Rule 7.37(e) to specify that, with respect to IEX, the Exchange will receive an IEX direct feed as its primary source of data for order handling, order execution, order routing, and regulatory compliance, and will use the SIP Data Feed as its secondary source for data from IEX.

The Exchange proposes to make this change operative in the fourth quarter of 2024, and, in any event, before the end of the first quarter of 2025. The Exchange proposes to announce the implementation date of this change by Trader Update.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[4] in general, and furthers the objectives of Section 6(b)(5),[5] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(5).

remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest. Additionally, the Exchange believes that the proposed rule change is consistent with the Section 6(b)(5) requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes its proposal to update the table in Rule 7.37(e) to include the IEX direct feed will ensure that the Rule correctly identifies and publicly states on a market-by-market basis all of the specific SIP and proprietary data feeds that the Exchange utilizes for the handling, execution, and routing of orders, and for performing the regulatory compliance checks for each of those functions. The proposed rule change also removes impediments to and perfects the mechanism of a free and open market and protects investors and the public interest by providing additional specificity, clarity, and transparency in the Exchange's rules.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Rather, the Exchange believes that the proposal will enhance competition because providing the public and market participants with up-to-date information about the data feeds the Exchange will use for the handling, execution, and routing of orders, as well as for regulatory compliance would enhance transparency and enable investors to better assess the quality of the Exchange's execution and routing services. The Exchange also believes the proposal would enhance competition because it would potentially enhance the performance of its order handling and execution of orders in equity securities by receiving market data directly from IEX. Finally, the proposed rule change would not impact competition between market participants because it will affect all market participants equally.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[6] and Rule 19b–4(f)(6) thereunder.[7] Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[8] and Rule 19b–4(f)(6)(iii) thereunder.[9]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[10] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–NYSE–2024–74 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NYSE–2024–74. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NYSE–2024–74 and should be submitted on or before December 18, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–27748 Filed 11–26–24; 8:45 am]

BILLING CODE 8011–01–P

[6] 15 U.S.C. 78s(b)(3)(A)(iii).

[7] 17 CFR 240.19b–4(f)(6).

[8] 15 U.S.C. 78s(b)(3)(A).

[9] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[10] 15 U.S.C. 78s(b)(2)(B).

[11] 17 CFR 200.30–3(a)(12), (59).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101680; File No. SR–NYSENAT–2024–29]

Self-Regulatory Organizations; NYSE National, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 7.37

November 21, 2024.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the

[1] 15 U.S.C. 78s(b)(1).

''Act''),[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on November 7, 2024, NYSE National, Inc. (''NYSE National'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 7.37 to specify the Exchange's source of data feeds from Investors' Exchange, LLC (''IEX'') for purposes of order handling, order execution, order routing, and regulatory compliance. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to update and amend the use of data feeds table in Rule 7.37(d), which sets forth on a market-by-market basis the specific securities information processor (''SIP'') and proprietary data feeds that the Exchange utilizes for the handling, execution, and routing of orders, and for performing the regulatory compliance checks related to each of those functions. Specifically, the Exchange proposes to amend the table in Rule 7.37(d) to specify that, with respect to IEX, the Exchange will receive an IEX direct feed as its primary source of data for order handling, order execution, order routing, and regulatory compliance, and will use the SIP Data Feed as its secondary source for data from IEX.

The Exchange proposes to make this change operative in the fourth quarter of 2024, and, in any event, before the end of the first quarter of 2025. The Exchange proposes to announce the implementation date of this change by Trader Update.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[4] in general, and furthers the objectives of Section 6(b)(5),[5] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest. Additionally, the Exchange believes that the proposed rule change is consistent with the Section 6(b)(5) requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes its proposal to update the table in Rule 7.37(d) to include the IEX direct feed will ensure that the Rule correctly identifies and publicly states on a market-by-market basis all of the specific SIP and proprietary data feeds that the Exchange utilizes for the handling, execution, and routing of orders, and for performing the regulatory compliance checks for each of those functions. The proposed rule change also removes impediments to and perfects the mechanism of a free and open market and protects investors and the public interest by providing additional specificity, clarity, and transparency in the Exchange's rules.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Rather, the Exchange believes that the proposal will enhance competition because providing the public and market participants with up-to-date information about the data feeds the Exchange will use for the handling, execution, and routing of orders, as well as for regulatory compliance would enhance transparency and enable investors to better assess the quality of the Exchange's execution and routing services. The Exchange also believes the proposal would enhance competition because it would potentially enhance the performance of its order handling and execution of orders in equity securities by receiving market data directly from IEX. Finally, the proposed rule change would not impact competition between market participants because it will affect all market participants equally.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[6] and Rule 19b–4(f)(6) thereunder.[7] Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[8] and Rule 19b–4(f)(6)(iii) thereunder.[9]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(5).

[6] 15 U.S.C. 78s(b)(3)(A)(iii).

[7] 17 CFR 240.19b–4(f)(6).

[8] 15 U.S.C. 78s(b)(3)(A).

[9] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

under Section 19(b)(2)(B) [10] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–NYSENAT–2024–29 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NYSENAT–2024–29. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NYSENAT–2024–29 and should be submitted on or before December 18, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–27749 Filed 11–26–24; 8:45 am]

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[10] 15 U.S.C. 78s(b)(2)(B).

[11] 17 CFR 200.30–3(a)(12), (59).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101676; File No. SR–NYSEAMER–2024–72]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Change To Harmonize NYSE American Rule 4530

November 21, 2024.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on November 12, 2024, NYSE American LLC (''NYSE American'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to harmonize NYSE American Rule 4530 (Reporting Requirements) with certain changes by the Financial Industry Regulatory Authority, Inc. (''FINRA'') to FINRA Rule 4530. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to harmonize NYSE American Rule 4530 (Reporting Requirements) with certain changes by FINRA to FINRA Rule 4530.[4]

Background and Proposed Rule Change

NYSE American Rule 4530 requires member organizations to promptly report to the Exchange specified events, such as statutory disqualifications and quarterly statistical and summary information regarding written customer complaints. The Exchange adopted the text of FINRA Rule 4530 in 2011 to replace comparable provisions in its legacy reporting Rule 351.[5]

In 2013, FINRA amended Rule 4530(e) to provide an exception from the reporting requirement for information disclosed on the Form U4 (Uniform Application for Securities Industry Registration or Transfer) in order to avoid duplicative reporting.[6] In addition, in 2013, FINRA added Supplementary Material .10 to FINRA Rule 4530 to provide that, for purposes of FINRA Rules 4530(a)(1)(A), (C) and (D) only, members are not required to report findings and actions by FINRA.[7]

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] This proposed change aligns with NYSE Rule 4530, which was recently updated to conform with FINRA 4530 regarding Reporting Requirements. *See* Securities Exchange Act Release No. 100168 (May 17, 2024), 89 FR 45712 (May 23, 2024) (SR–NYSE–2024–28). *See also* NYSE Rule 4530.

[5] *See* Securities Exchange Act Release No. 64784 (June 30, 2011), 76 FR 39947 (July 7, 2011) (SR–NYSEAMEX–2011–42). FINRA Rule 4530, adopted in 2010, was modeled after NYSE American Rule 351(a)-(d) and NASD Rule 3070. *See* Securities Exchange Act Release No. 63260 (November 5, 2010), 75 FR 69508 (November 12, 2010) (SR–FINRA–2010–034). *See also* Securities Exchange Act Release No. 64560 (May 27, 2011), 76 FR 32246 (June 3, 2011) (SR–FINRA–2011–024).

[6] *See* Securities Exchange Act Release No. 68701 (January 18, 2013), 78 FR 5532 (January 25, 2013) (SR–FINRA–2013–006) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to FINRA Rule 4530 (Reporting Requirements)).

[7] *See id.* FINRA Rule 4530(a)(1)(A) requires a member to report external findings regarding the member or an associated person. FINRA Rules 4530(a)(1)(C) and (D) require a member to report regulatory actions against the member or an associated person. FINRA Rules 4530(a)(1)(A), (C) and (D) do not expressly exclude findings and actions by FINRA. *See generally id.* NYSE American Rules 4530(a)(1)(A), (C) and (D) are virtually identical to the FINRA rules.

In 2015, FINRA again amended FINRA Rule 4530 to provide an exception from the reporting requirements of paragraph (a)(1)(H) of the rule for dealings with a member or associated person subject to statutory disqualification, if that member or associated person has been approved (or is otherwise permitted pursuant to FINRA rules and the federal securities laws) to be a member or to be associated with a member.[8]

The Exchange proposes to incorporate each of these amendments into NYSE American Rule 4530, as follows.

NYSE American Rule 4530(a)(1)(H)

NYSE American Rule 4530(a)(1)(H) requires member organizations to promptly report whenever the member organization or an associated person of the member organization is subject to a ''statutory disqualification'' as defined in the Act.[9] The rule also requires a member organization to report whenever the member organization or an associated person thereof is involved in the sale of any financial instrument, the provision of any investment advice or the financing of any such activities with any person that is subject to a ''statutory disqualification'' as defined in the Act. The report must include the name of the person subject to the statutory disqualification and details concerning the disqualification.

The Exchange proposes, consistent with current FINRA Rule 4530(a)(1)(H), to exclude activities with a disqualified member or associated person that has been approved (or is otherwise permitted pursuant to FINRA rules and the federal securities laws) to be a member organization or associated with a member organization. To effectuate this change, the Exchange proposes to add the following deletions (bracketed) and additions (italicized) to NYSE American Rule 4530(a)(1)(H):

(H) is *(i) subject to a ''statutory disqualification'' as that term is defined in the Exchange Act*[,] or [is]*(ii)* involved in the sale of any financial instrument, the provision of any investment advice or the financing of any such activities with any person [who]*that* is[,] subject to a ''statutory disqualification'' as that term is defined in the Exchange Act*, provided, however, that this requirement shall not apply to activities with a member organization or an associated person that has been approved (or is otherwise permitted pursuant to Exchange rules and the federal securities laws) to be a member organization or to be associated with a member organization.* The report shall include the name of the person subject to the statutory disqualification and details concerning the disqualification; or

With the exception of conforming changes reflecting the Exchange's membership. the proposed text is identical to FINRA's counterpart rule.

NYSE American Rule 4530(e)

NYSE American Rule 4530(e) currently provides that a member organization is not required to report a specified event under the rule if it reports that event on the Form U5 (Uniform Termination Notice for Securities Industry Registration), consistent with the requirements of that form. The exception does not extend to the reporting of quarterly statistical and summary customer complaint information under the rule. In order to eliminate duplicative reporting of information disclosed on a Form U4, and consistent with FINRA's current rule, the Exchange proposes to provide a similar exception for certain specified events reported on the Form U4. To effectuate this change, the Exchange proposes to add the following deletions (bracketed) and additions (italicized) to NYSE American Rule 4530(e):

(e) Nothing contained in this Rule shall eliminate, reduce or otherwise abrogate the responsibilities of a member organization or person associated with a member organization to promptly disclose required information on the Forms BD, U4 or U5, as applicable, to make any other required filings or to respond to the Exchange with respect to any customer complaint, examination or inquiry. In addition, member organizations are required to comply with the reporting obligations under paragraphs (a), (b) and (d) of this Rule, regardless of whether the information is reported or disclosed pursuant to any other rule or requirement, including the requirements of the Form[s] BD [or U4]. However, a member organization need not report an event otherwise required to be reported under *(1) paragraph (a)(1) of this Rule if the member organization discloses the event on the Form U4, consistent with the requirements of that form, and indicates, in such manner and format that the Exchange may require, that such disclosure satisfies the requirements of paragraph (a)(1) of this Rule, as applicable; or (2)* paragraphs (a) or (b) of this Rule if the member organization discloses the event on the Form U5, consistent with the requirements of that form.

With the exception of conforming changes reflecting the Exchange's membership, the proposed text is identical to FINRA's counterpart rule.

NYSE American Rule 4530, Supplementary Material .11

Finally, the Exchange proposes to adopt the text of FINRA Rule 4530, Supplementary Material .10, as new NYSE American Rule 4530, Supplementary Material .11.

NYSE American Rule 4530(a)(1)(A) requires a member organization to report that the member organization or an associated person has been found to have violated any securities-, insurance-, commodities-, financial- or investment-related laws, rules, regulations or standards of conduct of any domestic or foreign regulatory body, self-regulatory organization or business or professional organization.

NYSE American Rule 4530(a)(1)(C) requires a member organization to report that the member organization or an associated person thereof has been named as a defendant or respondent in any proceeding brought by a domestic or foreign regulatory body or self-regulatory organization alleging the violation of any provision of the Act, or of any other federal, state or foreign securities, insurance or commodities statute, or of any rule or regulation thereunder, or of any provision of the by-laws, rules or similar governing instruments of any securities, insurance or commodities domestic or foreign regulatory body or self-regulatory organization.

Finally, NYSE American Rule 4530(a)(1)(D) requires a member organization to report that the member organization or associated person thereof has been denied registration or is expelled, enjoined, directed to cease and desist, suspended or otherwise disciplined by any securities, insurance or commodities industry domestic or foreign regulatory body or self-regulatory organization or is denied membership or continued membership in any such self-regulatory organization; or is barred from becoming associated with any member organization of any such self-regulatory organization.

Since NYSE American Rules 4530(a)(1)(A), (C) and (D) do not expressly exclude findings and actions by the Exchange or FINRA, the Exchange proposes to add the following new Supplementary Material .11 to NYSE American Rule 4530 (additions italicized):

.11 For purposes of paragraphs (a)(1)(A), (C) and (D) of this Rule only, member organizations are not required to report findings and actions by the Exchange or by FINRA.

With the exception of adding findings and actions by the Exchange, the proposed Supplementary Material .11 to NYSE American Rule 4530 is identical to FINRA Rule 4530.10.

[8] *See* Securities Exchange Act Release No. 74953 (May 13, 2015), 80 FR 28740 (May 19, 2015) (SR–FINRA–2015–011) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to the Reporting Requirements of FINRA Rule 4530(a)(1)(H)).

[9] *See* 15 U.S.C. 78c(a)(39).

Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[10] in general, and furthers the objectives of Section 6(b)(5),[11] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule changes support the objectives of the Act by eliminating unnecessary reporting of information to the Exchange and allowing the Exchange to use its resources more efficiently. The Exchange believes that harmonizing Exchange rules modeled on FINRA's rules would result in less burdensome and more efficient regulatory compliance without compromising the regulatory information available to the Exchange. As previously noted, except for changes reflecting the Exchange's membership, the proposed additional text for NYSE American Rule 4530 is identical to the text in FINRA Rule 4530. As such, the proposed rule change would facilitate rule harmonization among self-regulatory organizations with respect to the reporting requirements, thereby fostering cooperation and coordination with persons engaged in facilitating transactions in securities and will remove impediments to and perfect the mechanism of a free and open market and a national market system.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not intended to address competitive issues but rather would reduce potential compliance burdens on member organizations by eliminating potentially duplicative information under NYSE American Rule 4530. Specifically, the proposed rule change would reduce potential compliance burdens on firms by eliminating the requirements under NYSE American Rule 4530(a)(1)(H) to report to the Exchange each instance where a member organization or an associated person is involved in a financial activity with a disqualified member organization or associated person that has been approved or is otherwise permitted to be a member organization or associated with a member organization. Similarly, the proposed amendment to NYSE American Rule 4530(e) to provide an exception for information disclosed on the Form U4 will eliminate the burden on member organizations of having to report the same event twice. Finally, the addition of Supplementary Material .11 to NYSE American Rule 4530 eliminates the burden on member organizations of having to report findings and actions by the Exchange or by FINRA for purposes of NYSE American Rules 4530(a)(1)(A), (C) and (D).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[12] and Rule 19b–4(f)(6) thereunder.[13] Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[14]

A proposed rule change filed under Rule 19b–4(f)(6)[15] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[16] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[17] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include file number SR–NYSEAMER–2024–72 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NYSEAMER–2024–72. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(5).

[12] 15 U.S.C. 78s(b)(3)(A)(iii).

[13] 17 CFR 240.19b–4(f)(6).

[14] Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[15] 17 CFR 240.19b–4(f)(6).

[16] 17 CFR 240.19b–4(f)(6)(iii).

[17] 15 U.S.C. 78s(b)(2)(B).

a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NYSEAMER–2024–72 and should be submitted on or before December 18, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–27745 Filed 11–26–24; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101681; File No. SR–NYSEARCA–2024–95]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 7.37–E

November 21, 2024.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act''),[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on November 18, 2024, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 7.37–E to specify the Exchange's source of data feeds from Investors' Exchange, LLC (''IEX'') for purposes of order handling, order execution, order routing, and regulatory compliance. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to update and amend the use of data feeds table in Rule 7.37–E(d), which sets forth on a market-by-market basis the specific securities information processor (''SIP'') and proprietary data feeds that the Exchange utilizes for the handling, execution, and routing of orders, and for performing the regulatory compliance checks related to each of those functions. Specifically, the Exchange proposes to amend the table in Rule 7.37–E(d) to specify that, with respect to IEX, the Exchange will receive an IEX direct feed as its primary source of data for order handling, order execution, order routing, and regulatory compliance, and will use the SIP Data Feed as its secondary source for data from IEX.

The Exchange proposes to make this change operative in the fourth quarter of 2024, and, in any event, before the end of the first quarter of 2025. The Exchange proposes to announce the implementation date of this change by Trader Update.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[4] in general, and furthers the objectives of Section 6(b)(5),[5] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest. Additionally, the Exchange believes that the proposed rule change is consistent with the Section 6(b)(5) requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes its proposal to update the table in Rule 7.37–E(d) to include the IEX direct feed will ensure that the Rule correctly identifies and publicly states on a market-by-market basis all of the specific SIP and proprietary data feeds that the Exchange utilizes for the handling, execution, and routing of orders, and for performing the regulatory compliance checks for each of those functions. The proposed rule change also removes impediments to and perfects the mechanism of a free and open market and protects investors and the public interest by providing additional specificity, clarity, and transparency in the Exchange's rules.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Rather, the Exchange believes that the proposal will enhance competition because providing the public and market participants with up-to-date information about the data feeds the Exchange will use for the handling, execution, and routing of orders, as well as for regulatory compliance would enhance transparency and enable investors to better assess the quality of the Exchange's execution and routing services. The Exchange also believes the proposal would enhance competition because it would potentially enhance the performance of its order handling and execution of orders in equity securities by receiving market data directly from IEX. Finally, the proposed rule change would not impact competition between market participants because it will affect all market participants equally.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section

[18] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(5).

19(b)(3)(A)(iii) of the Act[6] and Rule 19b–4(f)(6) thereunder.[7] Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[8] and Rule 19b–4(f)(6)(iii) thereunder.[9]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[10] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments:

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include file number SR–NYSEARCA–2024–95 on the subject line.

Paper Comments:

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NYSEARCA–2024–95. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NYSEARCA–2024–95 and should be submitted on or before December 18, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–27750 Filed 11–26–24; 8:45 am]

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[6] 15 U.S.C. 78s(b)(3)(A)(iii).

[7] 17 CFR 240.19b–4(f)(6).

[8] 15 U.S.C. 78s(b)(3)(A).

[9] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[10] 15 U.S.C. 78s(b)(2)(B).

[11] 17 CFR 200.30–3(a)(12), (59).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101678; File No. SR–NYSEAMER–2024–69]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Change To Amend Rule 7.37E

November 21, 2024.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act''),[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on November 7, 2024, NYSE American LLC (''NYSE American'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 7.37E to specify the Exchange's source of data feeds from Investors' Exchange, LLC (''IEX'') for purposes of order handling, order execution, order routing, and regulatory compliance. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to update and amend the use of data feeds table in Rule 7.37E(d), which sets forth on a market-by-market basis the specific securities information processor (''SIP'') and proprietary data feeds that the Exchange utilizes for the handling, execution, and routing of orders, and for performing the regulatory compliance checks related to each of those functions. Specifically, the Exchange proposes to amend the table in Rule 7.37E(d) to specify that, with respect to IEX, the Exchange will receive an IEX direct feed as its primary source of data for order handling, order execution, order routing, and regulatory compliance, and will use the SIP Data Feed as its secondary source for data from IEX.

The Exchange proposes to make this change operative in the fourth quarter of 2024, and, in any event, before the end of the first quarter of 2025. The Exchange proposes to announce the implementation date of this change by Trader Update.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[4] in general, and furthers the objectives of Section 6(b)(5),[5] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest. Additionally, the Exchange believes that the proposed rule change is consistent with the Section 6(b)(5) requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes its proposal to update the table in Rule 7.37E(d) to include the IEX direct feed will ensure that the Rule correctly identifies and publicly states on a market-by-market basis all of the specific SIP and proprietary data feeds that the Exchange utilizes for the handling, execution, and routing of orders, and for performing the regulatory compliance checks for each of those functions. The proposed rule change also removes impediments to and perfects the mechanism of a free and open market and protects investors and the public interest by providing additional specificity, clarity, and transparency in the Exchange's rules.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Rather, the Exchange believes that the proposal will enhance competition because providing the public and market participants with up-to-date information about the data feeds the Exchange will use for the handling, execution, and routing of orders, as well as for regulatory compliance would enhance transparency and enable investors to better assess the quality of the Exchange's execution and routing services. The Exchange also believes the proposal would enhance competition because it would potentially enhance the performance of its order handling and execution of orders in equity securities by receiving market data directly from IEX. Finally, the proposed rule change would not impact competition between market participants because it will affect all market participants equally.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[6] and Rule 19b–4(f)(6) thereunder.[7] Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[8] and Rule 19b–4(f)(6)(iii) thereunder.[9]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[10] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–NYSEAMER–2024–69 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NYSEAMER–2024–69. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NYSEAMER–2024–69 and should be submitted on or before December 18, 2024.

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(5).

[6] 15 U.S.C. 78s(b)(3)(A)(iii).

[7] 17 CFR 240.19b–4(f)(6).

[8] 15 U.S.C. 78s(b)(3)(A).

[9] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[10] 15 U.S.C. 78s(b)(2)(B).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–27747 Filed 11–26–24; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101696; File No. SR–FINRA–2024–019]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Adjust FINRA Fees To Provide Sustainable Funding for FINRA's Regulatory Mission

November 21, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 8, 2024, the Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by FINRA. FINRA has designated the proposed rule change as ''establishing or changing a due, fee or other charge'' under Section 19(b)(3)(A)(ii) of the Act[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposal effective upon receipt of this filing by the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

FINRA is proposing to adjust FINRA fees to provide sustainable funding for FINRA's regulatory mission.

The text of the proposed rule change is available on FINRA's website at *http://www.finra.org,* at the principal office of FINRA and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. FINRA has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Overview

FINRA is submitting this proposed rule change to increase the revenues that FINRA, as a not-for-profit self-regulatory organization (''SRO''), relies upon to fund its regulatory mission. Over the past year, FINRA has publicly stated many times its need to file a fee change this year to increase its fees. Over the past several years, FINRA has experienced significant expense growth resulting from rising technology costs related to capital investments seeking long-term efficiency gains for both FINRA and the industry, rising cloud hosting costs, ongoing disaster recovery and cybersecurity requirements, and elevated wage inflation and essential headcount increases necessitated by the growing breadth and complexity of FINRA's responsibilities.

To sustain FINRA's regulatory capabilities, FINRA proposes to increase fees related to FINRA's core regulatory functions as well as select fees related to the use of FINRA programs and services. The proposal is designed to closely align FINRA's revenues with its costs while preserving the historical equitable allocation of fees among FINRA members. In parallel, FINRA continues to implement operational improvements to ensure FINRA's operations are effective and efficient.

Implementation of the proposed rule change would take place over several years, with a minority of fees going into effect in 2025, most fees implemented in 2026 or later, and several fees phased in over several years between 2025 and 2029.

Thus, under the proposed rule change, FINRA would aim to collect more than 90 percent of the revenue it seeks to raise in 2026 or later. FINRA is submitting the proposed rule change now to provide members with sufficient advance notice of the proposed fee changes for annual budgeting and financial planning purposes. The proposed rule change is intended to provide sustainable longer-term funding, in a manner consistent with FINRA's public Financial Guiding Principles (''Guiding Principles''),[5] to enable FINRA to continue fulfilling its regulatory mission.

FINRA's Current Fee Structure

As a not-for-profit SRO, FINRA receives no taxpayer funding and instead relies on a mix of fees that are intended to cover the overall costs of FINRA's operations. The majority of FINRA's funding is derived from three regulatory fees: the Gross Income Assessment (GIA), Trading Activity Fee (TAF), and Personnel Assessment (PA). These fees, respectively, reflect one of the three critical components driving FINRA's regulatory costs with respect to a particular member: (1) the size of the firm measured by firm revenue, (2) the firm's trading activity, and (3) the number and role of persons registered with the firm. FINRA also employs use-based fees for specific services it provides to members and the public in support of its regulatory mission. Several use-based fees, including registration fees, qualification examination fees, and continuing education fees, among others, align with a critical component of FINRA's regulatory costs (*i.e.,* the number and role of registered persons at a firm). As such, FINRA considers those use-based fees part of its ''core'' regulatory fees.

In addition, FINRA employs other use-based fees for certain services it provides to members and the public. Examples include fees associated with: reviewing public offering filings; reviewing communications with the public; and operating the FINRA Dispute Resolution Services (''DRS'') arbitration forum. As FINRA has explained previously,[6] when applying use-based fees, FINRA takes into account three associated types of costs: direct costs for the program associated with the use-based fee, such as program development and operating expenses, and reinvestments and enhancements; indirect costs for the program, including supporting services necessary for the program's associated regulatory activity; and a contribution to FINRA's overall regulatory operations, which promotes its mission of investor protection.[7] Thus, taken together, core regulatory

[11] 17 CFR 200.30–3(a)(12), (59).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

[5] *See* FINRA's Financial Guiding Principles, *https://www.finra.org/sites/default/files/finra_financial_guiding_principles_0.pdf.*

[6] *See* Securities Exchange Act Release No. 90176 (October 14, 2020), 85 FR 66592 (October 20, 2020) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2020–032).

[7] *See supra* note 6.

fees and other use-based fees allow FINRA to fund its regulatory mission.[8]

FINRA has explained that numerous operations and services must be funded by general revenue sources, which include both core regulatory and other use-based fees.[9] There are several reasons for this. For instance, it is not feasible to associate a direct affiliated revenue stream for each of FINRA's programs (*e.g.,* examinations of members do not have an associated revenue stream). Similarly, there is no one consistent driver of costs of a particular regulatory program. Even where one cost driver may, at times, align with a particular revenue stream (*e.g.,* as trading activity increases, certain Market Regulation costs may increase), the relationship may not hold at other times. For example, novel trading patterns in single or multiple securities may not be associated with significant volume but may require comparatively larger efforts in terms of regulatory oversight. Likewise, periods of intense market volatility may influence regulatory costs independent of the change in trading volume.

Further, in light of FINRA's diverse membership of firms that vary greatly in size and business model, it is not feasible to develop a comprehensive pricing structure that precisely accounts for the particular costs associated with each member.[10] Rather, FINRA's current fee structure is designed to ensure sufficient funding to meet all of its regulatory obligations in a manner that equitably allocates fees among FINRA members, notwithstanding the fluctuations in different revenue streams and cost drivers that are naturally expected to occur over time. The Commission has historically agreed that this overall cost-based pricing structure ''is reasonable in that it achieves a generally equitable impact across FINRA's membership and correlates the fees assessed to the regulatory services provided by FINRA.'' [11] FINRA continues to believe that this approved approach to overall pricing is the most reasonable and equitable way to provide sufficient funding to meet its regulatory obligations as a not-for-profit SRO with broad, diverse membership.

As set out in the Guiding Principles, FINRA targets break-even cash flows as a means to appropriately fund its mission of protecting investors and promoting market integrity while facilitating vibrant capital markets. Careful expense management is another key element of the Guiding Principles. The Guiding Principles also explain the extent to which FINRA relies on its financial reserves—originally derived from the sale of Nasdaq—to help support its regulatory mission.[12] The Guiding Principles also describe how FINRA uses fine monies—which are not included in FINRA's operating budget—to promote compliance and improve markets.[13]

FINRA's most recent comprehensive fee increase included increases to core regulatory fees from 2022 through 2024.[14] Looking ahead, FINRA projects that its current fees will not keep pace with its projected future expenses in light of the continued growth in the breadth and complexity of FINRA's regulatory obligations, described in detail below. As FINRA noted recently in its 2024 Annual Budget Summary, based on the current fee structure (inclusive of the fee adjustments made from 2022 through 2024), FINRA projects it will recognize an operating loss in 2024, with a drawdown on its financial reserves of approximately $100 million.[15] FINRA estimates that, absent any action, its reserve balance will fall below its Board-approved target level of one-year of operating costs by 2027. As described in more detail below, FINRA has carefully managed its expenses; however, careful expense management cannot suffice as a sustainable financial strategy in the long term, particularly in the context of rising systemic costs and FINRA's increasing regulatory responsibilities.

Background

Over the past several years, FINRA's regulatory and oversight responsibilities have grown significantly, and FINRA anticipates that they will continue to grow over the rest of this decade, requiring investments in technology and increased headcount. Simultaneously, FINRA has experienced substantial systemic expense growth resulting from, among other things, elevated wage inflation and increased operating costs related to technology.[16] Several factors have contributed to these areas of growth, including: continued increases in the volume and complexity of member activity; new investment products, services, and market participants under FINRA's purview; the continuing evolution of market structure and trading patterns; and the SEC's adoption of significant new rules that require implementation by FINRA and its expanded member oversight.

For example, FINRA has made substantial investments to supervise or comply with new and amended SEC rules, such as amendments to Disclosure

[8] In addition to the services FINRA provides in furtherance of its regulatory mission, FINRA also provides certain services on a contract basis to third parties. These contract service fees represent approximately 8% of FINRA's total revenues. Importantly, these revenues pay in full for the services rendered under the contracts, and FINRA's costs to perform these services are not funded with any of the regulatory revenue discussed in this filing.

[9] *See supra* note 6.

[10] *See supra* note 6.

[11] *See* Securities Exchange Act Release No. 61042 (November 20, 2009), 74 FR 62616, 62620 (November 30, 2009) (Order Approving File No. SR–FINRA–2009–057).

[12] *See supra* note 5. Information about FINRA's financial reserves is provided each year in FINRA's published annual financial reports. *See* FINRA Financial Reports and Policies, available at *https://www.finra.org/about/annual-reports.* FINRA strives to maintain an appropriate level of reserves, which the FINRA Board of Governors has determined to be at least one year of expenditures.

[13] While fine monies are not included in FINRA's annual operating budget, they are included in cash flow projections. For purposes of its projections, FINRA assumed a conservative amount of fine money for future years based on historical fine money receipt. When FINRA imposes fines, the amounts are based on the facts and circumstances of the misconduct and are guided by the principles set forth in FINRA's Sanction Guidelines that are similar in nature—fines are not based on revenue considerations, and FINRA does not establish any minimum amount of fines that must be collected for purposes of the annual operating budget. Fines collected are accounted for separately, and the use of these monies is subject to special governance procedures and restrictions on use, as set forth in our Guiding Principles. *See supra* note 5. In accordance with the Guiding Principles, FINRA issues a separate annual report detailing use of fine monies as approved by the FINRA Board of Governors. *See, e.g.,* Report of Use of 2023 Fine Monies (June 14, 2024), available at *https://www.finra.org/about/annual-reports/report-use-2023-fine-monies.*

[14] *See supra* note 6.

[15] *See* FINRA 2024 Annual Budget Summary, *https://www.finra.org/sites/default/files/2024-06/FINRA-2024-Annual-Budget-Summary.pdf,* at 2. This potential loss is in line with FINRA's previous multiyear strategic planning for financial sustainability, which contemplates a series of annual losses in order to reduce the size of FINRA's reserves. As discussed in the Guiding Principles, FINRA has relied on its financial reserves, which were originally derived from the sale of Nasdaq, to help support its regulatory mission. *See also* Funding FINRA's Mission, available at *https://www.finra.org/media-center/blog/funding-finras-mission.*

FINRA has made reasonably conservative assumptions using a variety of information points, including historical data and anticipated trends. If FINRA's structural financial deficit is materially reduced during this period, or if key assumptions change materially, FINRA would consider various modifications as appropriate. For example, FINRA has used rebates to support its commitment to reasonable, cost-based fee assessments in instances where revenues significantly exceed expenditures. These rebates are approved by the FINRA Board of Governors. A number of factors must be considered when determining whether to provide rebates, including the amount of excess revenue for the year, whether budget projections anticipate near-term revenue shortfalls, and the number of firms that would be eligible to receive rebates. FINRA makes information about these factors transparent to the public each year.

[16] FINRA's technology costs, for example, have risen by approximately 11% per year over the last five years.

of Order Execution Information, Regulation M, Shortening the Securities Transaction Settlement Cycle, Regulation Best Interest, Market Data Infrastructure, and Minimum Pricing Increments, Access Fees, and Transparency of Better Priced Orders. FINRA must also be prepared to implement and supervise significant potential new and amended rules that the SEC has proposed, including Regulation S–P, Conflicts of Interest Associated with the Use of Predictive Data Analytics, Regulation Systems Compliance and Integrity, Cybersecurity Risk Management, Regulation Best Execution, and the Order Competition Rule. Furthermore, FINRA is investing in preparation for its expanded role in the oversight of a broader range of market participants under several SEC rulemakings. For example, the SEC has narrowed the exemption for certain exchange members under Exchange Act Rule 15b9–1, further defined ''as part of a regular business'' [17] in the definitions of ''dealer'' and ''government securities dealer'' under the Exchange Act, and proposed to amend the definition of ''exchange'' under Exchange Act Rule 3b–16 and amend Regulation ATS.

FINRA is also investing to enable continued effective oversight over evolving trading patterns, such as the significant growth in retail trading, growth in smaller and fractional share trading, and increased trading outside of regular trading hours. These and other market developments, together with the evolution of new and evolving products such as securities with crypto asset components and short-dated options products, require increased oversight by FINRA staff.

FINRA is committed to a culture of continuous improvement, with a rigorous focus on carefully managing costs and identifying new efficiency opportunities, where consistent with its mission. FINRA has exercised prudent expense control and managed costs through various initiatives and technology investments that have helped to enhance efficiency and effectiveness. Beginning with the FINRA360 [18] initiative, which launched a comprehensive self-evaluation and organizational improvement exercise in 2017 to ensure that FINRA was maximizing its effectiveness, FINRA has implemented a number of enhancements including: enforcement program consolidation; new external transparency tools; the launch of the Small Firm Helpline; increased examiner training; creation of an Innovation Outreach Initiative; and the development of a program to evaluate and integrate advances in data analytics.

FINRA continues to invest in technology to better serve its mission and to improve FINRA's ability to communicate with members. For example, FINRA completed a multi-year digital platform upgrade that improved system interfaces, including essential registration and disclosure systems used by members.[19] FINRA also continues to build on its early use of cloud computing in regulation, and invested in an Advanced Analytics Program that supports risk identification and other regulatory efforts. In the interest of regulatory efficiency, FINRA also recently discontinued a program requiring the reporting of prescribed data by certain members based on availability of data from alternative sources, resulting in millions of dollars in cost savings benefits to members.[20]

Further, cost savings have been accomplished in recent years through supplementary expense reduction initiatives, including conducting a comprehensive efficiency review of FINRA's core business lines; establishing a framework for improving measurement of FINRA's key performance results; voluntary retirement/incentive programs in 2020 and 2024; and strategic reductions in FINRA's corporate real estate footprint.

Given this context, and despite the significant increase in the breadth and complexity of FINRA's regulatory responsibilities, FINRA's expense growth rate from 2013 through 2023 has been significantly lower than that of the broader financial services industry. Specifically, FINRA's costs increased by 41% cumulatively during this period compared with 129% for the industry.[21] Similarly, FINRA's total compensation costs rose by 31% on a cumulative basis during this period as compared with a 50% increase for the average U.S. financial services employee.[22] FINRA's restrained expense growth is the result of careful management of both compensation costs, the largest driver of FINRA's budget, and non-compensation costs, such as technology and real estate.

Notwithstanding these efforts, as discussed, FINRA projects that its current fees will not keep pace with its projected future expenses. FINRA therefore proposes to increase its fees as described below.

Proposal

The proposed rule change would raise FINRA's core regulatory fees [23] as well as select use-based fees [24] that fund various FINRA services and programs. Consistent with the Guiding Principles, the proposed rule change would more effectively allow FINRA to balance its cash flow sources, operating expenses and capital expenditures, and stabilize its financial reserves by 2029. As discussed above, a minority of proposed fee increases would go into effect in 2025, while most fees would be implemented in 2026 or later, and several fees would be phased in over several years between 2025 and 2029.[25] The following table summarizes the proposed timeline for implementing each fee increase: [26]

[17] The updated definition covers additional market participants engaged in liquidity-providing activities that generally would require SRO membership.

[18] Detailed information about the FINRA360 initiative is available at *https://www.finra.org/about/finra-360.*

[19] Detailed information about FINRA's ''Digital Experience Transformation'' is available at *https://www.finra.org/filing-reporting/dxt.* FINRA built the capabilities of the Digital Experience Transformation initiative in consultation with the industry, and FINRA's investment is estimated to save the industry more than $200 million annually in time and direct costs.

[20] *See Regulatory Notice* 23–17 (October 2023).

[21] Based on FOCUS reporting.

[22] FINRA total compensation represents business compensation, excluding technology. Average U.S. employee wage growth represents Finance and Business Services wage growth supplied by the Bureau of Labor Statistics and Federal Reserve Bank of Atlanta. *See* Current Population Survey, Bureau of Labor Statistics, and Federal Reserve Bank of Atlanta Calculations at *https://www.atlantafed.org/chcs/wage-growth-tracker.*

[23] For ease of reference in this filing, FINRA refers to the following core regulatory fees: GIA; TAF; PA; Branch Office Fees; Registration; Qualification Examination; Continuing Education Regulatory Element Reporting; Late Disclosure; System Processing; and Renewal Late Fee.

[24] For ease of reference in this filing, FINRA refers to the following select use-based fees: Corporate Financing Private Placement Review; Corporate Financing Public Offering Review; Advertising Regulation Review; DRS Arbitration; and Regulation T and Exchange Act Rule 15c3–3(n) Requests for Extension of Time. The proposed fee increase will apply to filings or submissions related to these use-based services on or after the effective date.

[25] FINRA considered feedback from members of FINRA's advisory committees and other industry consultations that emphasized the importance of advance notice of fee increases to permit member firms to better plan for the proposed package of fee increases over multiple budget cycles. FINRA also considered stakeholder feedback that one-time increases for certain fees help reduce the administrative burdens on members.

[26] Fees listed in chronological order of initial implementation. Unless specified otherwise in the table above, the proposed fee increase would take effect on January 1 of the year stated. This table does not include proposed conforming amendments to two fees that impact funding portal members.

FEE IMPLEMENTATION SCHEDULE

Fee	Implementation schedule
Advertising Regulation Review	2025.
DRS Arbitration	2025.
Regulation T and Exchange Act Rule 15c3–3(n) Requests for Extension of Time	2025.
Corporate Financing Private Placement Review	2025 (Q3).
Corporate Financing Public Offering Review	2025 (Q3)–2029.
Branch Office Fees	2026, 2028.
Continuing Education Regulatory Element	2026.
Late Disclosure	2026.
Qualification Examination	2026.
System Processing	2026, 2028.
GIA	2026–2028.
TAF	2026–2029.
PA	2026–2029.
Registration	2028.
Renewal Late Fee	2028.

Taken together, the proposed rule change is projected to generate additional revenue of between $40 million and $160 million each year compared to the previous year from 2025 through 2029. The amount of the increase varies each year due to the phased implementation schedule described above. Cumulatively, the proposed rule change would increase FINRA's annual fee revenues by an estimated $450 million (once fully implemented in 2029) as compared to the annual fee revenues that would have existed in the absence of the proposed rule change. As such, the proposed rule change is calibrated to cover FINRA's projected budget deficit and achieve a balanced budget by 2029.[27] This approach will retain FINRA's reserve balance at its target level based on FINRA's projected revenue and costs,[28] while providing members advance notice of fee increases, phasing some of the increases over multiple years, and maintaining an equitable allocation of fees among FINRA members. As discussed further below, under the proposed rule change, the current proportion of fees borne by FINRA members based on firm size and business model, respectively, would remain stable through 2029.[29]

In total, the proposed fee changes will result in a compounded annualized growth rate (''CAGR'') of 5.3% across total FINRA fees between 2025 and 2029.[30] Excluding specific fees typically passed on by members,[31] the CAGR between 2025 and 2029 is projected to be 4.8% for FINRA members. Further, assuming that the majority, if not all, of TAF is also passed directly through to investors, the fee increase CAGR falls to the 3% to 4% range for FINRA members.[32] During the same period, FINRA reasonably anticipates that its future expenses will grow at a CAGR of 5.9%, with a portion of such expense growth covered by anticipated cash flow sources other than the proposed fee increases. FINRA's fees will continue to represent a small dollar proportion of industry revenues as reported in FOCUS reports. FINRA estimates that FINRA's total fees when the proposed fee increases are fully implemented would represent approximately 0.31% of recent industry revenues by 2029.[33]

In sum, the proposed rule change is designed to collect the targeted revenue amount needed to address FINRA's projected budget deficit through a combination of core regulatory and select use-based fees that yield an equitable overall fee increase across member size and type. The proposed rule change is thus designed to preserve the same SEC-approved, equitable fee allocation across members that FINRA has maintained for years by minimizing the change to distribution of fees across members.

Each specific fee in the proposed rule change is described below.

Core Regulatory Fees

Gross Income Assessment

The GIA is a core regulatory fee designed to correlate to one of the three critical components of FINRA's regulatory costs—the size of a firm (based on revenue). Accordingly, the GIA is based on a firm's annual gross revenue,[34] employing a graduated seven-tier rate structure that has applied since 2008.[35]

[27] As discussed below, Chart 2, attached in Exhibit 3, available on FINRA's website at *http://www.finra.org,* demonstrates the difference between FINRA's projected cash flow sources and cash flow uses through 2029, absent the proposed rule change.

[28] Anticipated costs would not include potential costs associated with new services that may be initiated or approved in the future. FINRA may submit separate fee filings to cover program costs for new services. FINRA notes this proposed rule change does not include fees associated with the Consolidated Audit Trail (''CAT'') or the Securities Lending and Transparency Engine (''SLATE''), both of which are subject to separate proposed rule changes with the Commission. *See, e.g.,* Securities Exchange Act Release No. 100920 (September 4, 2024), 89 FR 73457 (September 10, 2024) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2024–011); Securities Exchange Act Release No. 100920 (September 4, 2024), 89 FR 73457 (September 10, 2024) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2024–012). Similarly, FINRA notes that program costs associated with the reporting of transactions in U.S. Treasury Securities (''Treasuries'') are not included in the targeted amount sought by this proposal; currently, Treasuries transactions are exempted from both TRACE transaction reporting fees and from the TAF. *See* Securities Exchange Act Release No. 79116 (October 18, 2016), 81 FR 73167, 73176 (October 24, 2016) (Order Approving File No. SR–FINRA–2016–027).

[29] *See* Exhibit 3, Charts 5 and 6.

[30] The CAGR provides a geometric average of the change in fees over the implementation period. It is particularly useful for comparing growth rates from various sets of data over the same multi-year period.

[31] Some of the fees discussed in this filing are or would be absorbed by non-members, including Corporate Financing review fees for public offerings and private placements, which are generally passed through to issuers, and a portion of DRS fees that are paid directly by customers.

[32] Many members identify that they pass through TAF to customers. Assuming 65% of TAF is passed to non-members, the fee increase CAGR to membership falls to 3.9%. If 100% of TAF is passed through, the fee increase CAGR to FINRA's membership falls to 3.1%.

[33] Industry revenue projections for 2029 are based on historical FOCUS revenue growth of 8.5% (2013–2023).

[34] Section 2 of Schedule A to the FINRA By-Laws defines gross revenue for assessment purposes as total income as reported on FOCUS form Part II or IIA, excluding commodities income.

[35] The applicable GIA rate applies on a marginal basis to annual gross revenues that exceed each applicable threshold. While the GIA rate structure has not changed since 2008, FINRA made modifications to the method of GIA calculation

Section 1(c) of Schedule A to the FINRA By-Laws sets forth the GIA. The current rates, which reflect the fee adjustments made from 2022 through 2024, are as follows:

(1) $1,200.00 on annual gross revenue up to $1 million;

(2) 0.1732% of annual gross revenue greater than $1 million up to $25 million;

(3) 0.3705% of annual gross revenue greater than $25 million up to $50 million;

(4) 0.0738% of annual gross revenue greater than $50 million up to $100 million;

(5) 0.0520% of annual gross revenue greater than $100 million up to $5 billion;

(6) 0.0566% of annual gross revenue greater than $5 billion up to $25 billion; and

(7) 0.1219% of annual gross revenue greater than $25 billion.

Thus, for example, under the current rates, for a member with annual gross revenue of $30 billion, the GIA would be calculated as follows: the first $1 million at the Tier 1 rate ($1,200), plus the next $24 million at the Tier 2 rate (0.1732%), plus the next $25 million at the Tier 3 rate (0.3705%), plus the next $50 million at the Tier 4 rate (0.0738%), plus the next $4.9 billion at the Tier 5 rate (0.0520%), plus the next $20 billion at the Tier 6 rate (0.0566%), plus the final $5 billion at the Tier 7 rate (0.1219%), for a total assessment of $20,135,293.

FINRA is proposing the following changes to its GIA tier rates from 2026 through 2028.[36]

GIA—Proposed Implementation

Tier (revenue)	2024 (current)	2025 (no change)	2026	2027	2028	2029
$0 to $1 million	$1,200	$1,200	$1,200	$1,200	$1,200	$1,200
Greater than $1 million up to $25 million	0.1732%	0.1732%	0.1827%	0.2056%	0.2280%	0.2280%
Greater than $25 million up to $50 million	0.3705%	0.3705%	0.3909%	0.4397%	0.4877%	0.4877%
Greater than $50 million up to $100 million	0.0738%	0.0738%	0.0779%	0.0876%	0.0972%	0.0972%
Greater than $100 million up to $5 billion	0.0520%	0.0520%	0.0549%	0.0618%	0.0685%	0.0685%
Greater than $5 billion up to $25 billion	0.0566%	0.0566%	0.0597%	0.0672%	0.0745%	0.0745%
Greater than $25 billion	0.1219%	0.1219%	0.1286%	0.1447%	0.1604%	0.1604%

Thus, for example, under the new rates once fully implemented in 2029, for a member with annual gross revenue of $30 billion, the GIA would be calculated as follows: the first $1 million at the Tier 1 rate ($1,200), plus the next $24 million at the Tier 2 rate (0.2280%), plus the next $25 million at the Tier 3 rate (0.4877%), plus the next $50 million at the Tier 4 rate (0.0972%), plus the next $4.9 billion at the Tier 5 rate (0.0685%), plus the next $20 billion at the Tier 6 rate (0.0745%), plus the final $5 billion at the Tier 7 rate (0.1604%), for a total assessment of $26,502,945.

When the proposed GIA rates are fully implemented, they are designed to generate an additional $80 million in annual revenue by 2029. The proposed GIA increase preserves the existing seven-tier structure and calculation method while raising each tier proportionately. With these proposed increases, the GIA structure would continue to reflect the costs associated with performing regulatory responsibilities across FINRA's diverse population of members. Notably, the proposed rule change would not increase the flat $1,200 fee for members with revenues of $1 million or less. Maintaining this fee level for the smallest members preserves FINRA's existing approach to cost distribution between members of varying sizes.

Further, FINRA seeks to preserve the historical proportionality across fees associated with the three main components of FINRA's regulatory costs—the size of the firm measured by firm revenue, the firm's trading activity, and the number and role of persons registered with the firm—with the aim of collecting a generally comparable amount of revenue from fees associated with each of these components once the proposed rule change is fully implemented. To that end, the proposed rule change would increase the GIA at a reduced rate relative to the other core regulatory fees. This is because, for 2024, GIA revenues exceeded projections due to record aggregate industry revenues. As a result, FINRA has proposed to phase in the proposed increases to the GIA more gradually, and at a reduced rate, relative to the other core regulatory fees to help preserve historical proportionality across these fees and achieve a generally comparable revenue distribution. FINRA believes this proportional approach to fee increases will provide member firms a greater degree of certainty and predictability, as it seeks to maintain consistency with FINRA's existing equitable fee distribution. FINRA further believes its proportional approach reduces the potential for unintended impacts on the services provided by member firms, and the business models they adopt, that could arise from significant changes to fee distribution.

Trading Activity Fee

The TAF is a core regulatory fee designed to correlate to a critical component of FINRA's regulatory costs—the trading activity of a firm.

under the structure in 2009 and 2014, and increased the GIA rate between 2022 and 2024. In 2009, the Commission approved a GIA calculation modification designed to mitigate year-to-year revenue volatility by assessing members the greater of a GIA calculated based on the firm's annual gross revenue from the preceding calendar year, or a GIA averaged over the prior three years. *See* Order Approving SR–FINRA–2009–057, *supra* note 11, 74 FR 62616, 62617. In 2014, FINRA refined the GIA calculation method to provide limited relief for smaller member firms from unintended effects of the 2009 calculation change; as a result of the 2014 change, firms that have annual gross revenue of $25 million or less pay the GIA based on preceding year revenue without looking to a three-year average. *See* Securities Exchange Act Release No. 73632 (November 18, 2014), 79 FR 69937 (November 24, 2014) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2014–046). In 2020, FINRA proposed changes to the GIA tier rates, which went into effect between 2022 and 2024. *See* Order Approving SR–FINRA–2020–032, *supra* note 6, 85 FR 66592.

[36] FINRA notes the Exhibit 5 to this proposed rule change, available on FINRA's website at *http://www.finra.org,* is marked to show the changes as they are proposed to take effect each year, as described in this filing. Specifically, Exhibit 5A and 5B shows the proposed changes that would take effect in 2025, Exhibit 5C shows the proposed changes that would take effect in 2026, Exhibit 5D shows the proposed changes that would take effect in 2027, Exhibit 5E shows the proposed changes that would take effect in 2028, and Exhibit 5F shows the proposed changes that would take effect in 2029.

FINRA initially adopted the TAF in 2002, modeled on the Commission's transaction-based Section 31 fee.[37] The TAF is generally assessed on the sale of all exchange-listed securities wherever executed (except debt securities that are not TRACE-Eligible Securities), over-the-counter equity securities, security futures, TRACE-Eligible Securities (provided that the transaction is a Reportable TRACE Transaction), and all municipal securities subject to Municipal Securities Rulemaking Board reporting requirements.[38] The current TAF rates, which reflect the fee adjustments made from 2022 through 2024, are:

(1) $0.000166 per share for each sale of a covered equity security, with a maximum charge of $8.30 per trade;

(2) $0.00279 per contract for each sale of an option;

(3) $0.00011 per contract for each round turn transaction of a security future, provided there is a minimum charge of $0.014 per round turn transaction;

(4) $0.00105 per bond for each sale of a covered TRACE-Eligible Security (other than an Asset-Backed Security) and/or municipal security, with a maximum charge of $1.05 per trade; and

(5) $0.00000105 times the value, as reported to TRACE, of a sale of an Asset-Backed Security, with a maximum charge of $1.05 per trade.[39]

FINRA is proposing the following changes to its TAF rates between 2026 and 2029:

TAF—Proposed Implementation

Security type	2024 (current)	2025 (no change)	2026	2027	2028	2029
Covered Equity Security.	$0.000166 per share (up to $8.30 max per trade).	$0.000166 per share (up to $8.30 max per trade).	$0.000195 per share (up to $9.79 max per trade).	$0.000232 per share (up to $11.61 max per trade).	$0.000240 per share (up to $12.05 max per trade).	$0.000249 per share (up to $12.50 max per trade).
Options	$0.00279 per contract.	$0.00279 per contract.	$0.00329 per contract.	$0.00390 per contract.	$0.00404 per contract.	$0.00420 per contract.
Security Future	$0.00011 per contract (with $0.014 minimum per round turn transaction).	$0.00011 per contract (with $0.014 minimum per round turn transaction).	$0.000135 per contract (with $0.016 minimum per round turn transaction).	$0.00016 per contract (with $0.019 minimum per round turn transaction).	$0.000166 per contract (with $0.020 minimum per round turn transaction).	$0.000172 per contract (with $0.021 minimum per round turn transaction).
TRACE-Eligible Security (Other than Asset-Backed Security) or municipal security.	$0.00105 per bond (up to $1.05 max per trade).	$0.00105 per bond (up to $1.05 max per trade).	$0.00124 per bond (up to $1.24 max per trade).	$0.00147 per bond (up to $1.47 max per trade).	$0.00153 per bond (up to $1.53 max per trade).	$0.00158 per bond (up to $1.58 max per trade).
TRACE-Eligible Asset-Backed Security.	$0.00000105 times reported value (up to $1.05 max per trade).	$0.00000105 times reported value (up to $1.05 max per trade).	$0.00000124 times reported value (up to $1.24 max per trade).	$0.00000147 times reported value (up to $1.47 max per trade).	$0.00000153 times reported value (up to $1.53 max per trade).	$0.00000158 times reported value (up to $1.58 max per trade).

When the new TAF rates are fully implemented, they are designed to generate an additional $186 million in annual revenue by 2029. The proposed TAF changes reflect proportional increases in the amount raised for each security type—meaning there is no anticipated change in the percentage of overall TAF revenue collected from transactions in each security type—phased in incrementally over the delayed four-year implementation period. Accordingly, while TAF revenues are largely derived from transactions in equity securities, like the SEC's Section 31 fee, this proposed rule change is intended to preserve the current distribution of TAF fees among security types.

The aggregate TAF increases would generate more revenue relative to the other core regulatory fees to preserve the historical proportionality among the core regulatory fees associated with firm trading activity and the other main components of FINRA's regulatory costs—the size of the firms measured by firm revenue and the number and role of persons registered with the firm—while seeking to collect a generally comparable amount of revenue from fees associated with each component. This is consistent with the proportional approach to fee increases discussed throughout this filing, which seeks to maintain consistency with FINRA's existing equitable fee distribution.

Personnel Assessment

The PA is a core regulatory fee designed to correlate to the third critical component of FINRA's regulatory costs—the number and role of registered persons at a firm. The PA currently is assessed on a three-tiered rate structure: members with one to five registered representatives and principals are assessed $210 for each such registered person (''Reps'' in the table below); there is a $200 charge for each of the next 20 registered persons (between 6 and 25); and a $190 charge for each additional registered person beyond 25 registered persons.

Section 1(e) of Schedule A to the FINRA By-Laws sets forth the PA. These rates last increased between 2022 and 2024.[40] FINRA is proposing the following increases to its PA tier rates between 2026 and 2029:

[37] *See* Securities Exchange Act Release No. 46416 (August 23, 2002), 67 FR 55901 (August 30, 2002) (Notice of Filing and Immediate Effectiveness of File No. SR–NASD–2002–98).

[38] Certain types of transactions are excluded from the TAF (*e.g.,* primary market transactions, proprietary transactions executed by a member on a national securities exchange in the member's capacity as an exchange specialist or market maker, transactions effected by a proprietary trading firm on an exchange of which such firm is a member, and transactions in U.S. Treasury Securities). *See* FINRA By-Laws, Schedule A, Section 1(b)(2) (providing full list of transactions exempt from the TAF). This proposed rule change would not change the scope of any current TAF exemptions.

[39] If the execution price for a covered security is less than the TAF rate ($0.000166 for covered equity securities, $0.00279 for covered options contracts, or $0.014 for a security future) on a per share, per contract, or round turn transaction basis, then no fee is assessed.

[40] *See* Order Approving SR–FINRA–2020–032, *supra* note 6, 85 FR 66592.

PA—PROPOSED IMPLEMENTATION

Tier (number of reps)	2024	2025 (no change)	2026	2027	2028	2029
Reps 0–5	$210	$210	$245	$260	$270	$295
Reps 6–25	200	200	235	250	260	285
Reps 26 and greater	190	190	225	240	250	275

When the proposed PA rates are fully implemented, they are designed to generate an additional $52 million in annual revenue by 2029. The proposed PA increases, together with the proposed increases to the use-based fees aligned with the number and role of registered persons at a firm discussed below, are calibrated to preserve the historical proportionality among the core regulatory fees associated with the three main components of FINRA's regulatory costs and collect a generally comparable amount of revenue from fees associated with each component. This is consistent with the proportional approach to fee increases discussed throughout this filing, which seeks to maintain consistency with FINRA's existing equitable fee distribution.

Branch Office Fees

FINRA members are assessed regulatory fees for registered branch offices. These fees are related to firm size and structure. Section 4(a) of Schedule A to the FINRA By-Laws includes a branch office registration fee and a branch office system processing fee upon the initial registration of each branch office as defined in the By-Laws. The initial branch office registration fee is waived for the first branch office registered by a member. In addition, each member is assessed an annual registration fee for each branch office registered by the member. This fee has a tiered regressive rate structure that assesses a per branch office annual registration fee depending on the number of branch offices the firm has. Currently, each member is assessed an annual registration fee of: (1) $175, for each of the first 250 branch offices registered by the member; (2) $150, for each of branch offices 251 to 500 registered by the member; (3) $125, for each of branch offices 501 to 1,000 registered by the member; (4) $100, for each of branch offices 1,001 to 2,000 registered by the member; and (5) $75, for every branch office greater than 2,000 registered by the member. For one branch office per member per year, the annual branch office registration fee and annual branch office system processing fee is waived.

FINRA has not increased the branch office registration fee since 2013.[41] FINRA is proposing to retain the tiered regressive rate structure, but increase the branch office registration fee in 2026 as follows:

BRANCH OFFICE REGISTRATION FEES—PROPOSED IMPLEMENTATION

Fee	2024 (current)	2025 (no change)	2026	2027	2028	2029
FINRA Branch Registration Fee	$75	$75	$105	$105	$105	$105
Annual Registration Fee 1–250 branch offices registered by the member	175	175	245	245	245	245
Annual Registration Fee 251–500 branch offices registered by the member	150	150	210	210	210	210
Annual Registration Fee 501–1000 branch offices registered by the member	125	125	175	175	175	175
Annual Registration Fee 1001–2000 branch offices registered by the member	100	100	140	140	140	140
Annual Registration Fee 2001+ branch offices registered by the member	75	75	105	105	105	105

When the proposed branch office registration fee changes are fully implemented, they are designed to generate $7 million in annual revenue by 2029.[42] The proposed rule change would retain the same tiered regressive rate structure that assesses a per branch office annual registration fee depending on the number of branch offices of the firm, but would raise the fee associated with each range of branch office numbers. FINRA would continue to waive, for one branch office per member per year, payment of the annual registration fee, but increase the amount of the waiver from $175 to $245 to match the new rates.

FINRA has not increased the branch office system processing fee since 2022.[43] FINRA is proposing to increase the branch office system processing fee in 2028 as follows:

[41] *See Regulatory Notice* 12–32 (June 2012).

[42] The projected revenue from the proposed increased Branch Office Fees assumes that the number of branch offices will remain at 2024 levels through 2029. Due to the COVID–19 pandemic, FINRA had provided regulatory relief including a temporary suspension of the requirements to maintain updated Form U4 information regarding the office of employment address for registered persons who temporarily relocated due to the pandemic, and the requirement to submit branch office applications on Form BR for any newly opened temporary office locations or space-sharing arrangements. *See Regulatory Notice* 20–08 (March 2020). In mid-2024, that relief ended and FINRA implemented new Rule 3110.19, which exempts from branch office registration a residential supervisory location (or RSL). An RSL is a private residence at which an associated person engages in specified supervisory activities, subject to certain safeguards and limitations. *See Regulatory Notice* 24–02 (January 2024). FINRA believes its assumptions are reasonable given the recency of these changes. As noted, if key assumptions change materially, FINRA would consider various modifications as appropriate, including rebates, for example. *See supra* note 15.

[43] *See supra* note 6.

BRANCH OFFICE SYSTEM PROCESSING FEE—PROPOSED IMPLEMENTATION

Fee	2024 (current)	2025 (no change)	2026 (no change)	2027 (no change)	2028	2029
Branch Office System Processing Fee (initial and annual)	$75	$75	$75	$75	$105	$105

When the proposed branch office system processing fee change is fully implemented, it is designed to generate $4 million in annual revenue by 2029.[44] FINRA would continue to waive, for one branch office per member per year, payment of the annual branch office system processing fee, but increase the amount of the waiver from $75 to $105 to match the new rates. FINRA believes these proposed increases to the branch office fees, which relate to firm size and structure, are consistent with the proportional approach to fee increases discussed throughout this filing.

Registration Fees

Registration fees are registered person-level fees that, while use-based, also correlate to the third critical component of FINRA's regulatory costs—the number and role of registered persons at a firm. Section 4 of Schedule A to the FINRA By-Laws establishes fees connected to FINRA's operation of the Central Registration Depository (''Web CRD®'' or ''CRD system''), the central licensing and registration system that FINRA operates for the benefit of FINRA, the SEC, other SROs, state securities regulators, and broker-dealer firms. The CRD system contains the registration records of broker-dealer firms and their associated individuals including their qualification, employment, and disclosure histories; it also facilitates the processing of, among other things, form filings and facilitates the making of fingerprint results available to the appropriate authorized recipients.[45] The CRD system enables individuals and firms seeking registration with multiple states and SROs to do so by submitting a single form and fee payment.[46]

FINRA last increased associated registration fees between 2022 and 2024.[47] FINRA has explained that these fees are important to fund activities that help ensure the integrity of information in the CRD system—information critical to FINRA and other regulators, as well as to investors through BrokerCheck—and to support FINRA's overall regulatory mission.[48] FINRA is proposing to increase certain registration fees [49] in 2028 as follows:

REGISTRATION FEES—PROPOSED IMPLEMENTATION

Fee	2024 (current)	2025 (no change)	2026 (no change)	2027 (no change)	2028	2029
Initial/Transfer Registration Form U4 filing[50]	$125	$125	$125	$125	$175	$175.
Termination U5 filing	$50 (plus $100 if late filed).	$50 (plus $100 if late filed).	$50 (plus $100 if late filed).	$50 (plus $100 if late filed).	$70 (plus $140 if late filed).	$70 (plus $140 if late filed).
Disclosure review[51]	$155	$155	$155	$155	$215	$215.
Electronic Fingerprinting[52]	$20[53]	$20[54]	$20	$20	$28	$28.
Non-Electronic Fingerprinting[55]	$30	$30	$30	$30	$42	$42.
Fingerprinting Processed Through Another SRO.	$30	$30	$30	$30	$42	$42.

When these proposed registration fee changes are fully implemented, they are designed to generate an additional $10 million in annual revenue by 2029.

Renewal Late Fee

Members renew their registrations with FINRA, other SROs and states/jurisdictions during the annual renewal program. Section 4(b)(8) of Schedule A to the FINRA By-Laws sets forth the renewal late fee, which applies if a member fails to timely pay the amount

[44] *See supra* note 42.

[45] Specified information reported to the CRD system is displayed in BrokerCheck®, an electronic system that provides the public with information on the professional background, business practices, and conduct of FINRA members and their associated persons. Investors use BrokerCheck to help make informed choices about the individuals and firms with which they currently conduct or are considering conducting business.

[46] FINRA outsources fingerprint processing to Sterling Identity (''Sterling''), an FBI-approved channeler that processes fingerprints for members on FINRA's behalf. This provides for a more efficient and streamlined process with fewer fingerprint rejections, secure electronic transmission of FBI results, and significantly reduced turn-around times. Sterling assesses and collects all fees for fingerprint collection and processing, including the FBI fee.

[47] *See* Order Approving SR–FINRA–2020–032, *supra* note 6, 85 FR 66592.

[48] *See* Securities Exchange Act Release No. 67247 (June 25, 2012), 77 FR 38866 (June 29, 2012) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2012–030).

[49] FINRA also proposes conforming changes to Section 15(g) of Schedule A to the FINRA By-Laws to align this proposed fee change with the same fees for Funding Portal members.

[50] This fee applies for each initial or transfer Uniform Application for Securities Industry Registration or Transfer (''Form U4'') filed by a member in the CRD system to register an individual. Section 4(b)(1) of Schedule A includes a discount in cases where a member is transferring the registrations of individuals in connection with the acquisition of all or part of another member's business. The discount ranges from 10 to 50 percent, based on the number of registered personnel being transferred. While FINRA is proposing to increase the registration fee, it is not proposing to make any changes to the discount schedule.

[51] This fee applies for the additional processing of each initial or amended Form U4, Form U5, or Form BD that includes the initial reporting, amendment, or certification of one or more disclosure events or proceedings.

[52] This fee applies for processing and posting to the CRD system each set of fingerprints submitted electronically by a member to FINRA, plus any other charge that may be imposed by the United States Department of Justice for processing each set of fingerprints.

[53] In 2024, the fee for funding portal members that submit fingerprints electronically is $15. *See* Section 15(g) of Schedule A to FINRA By-Laws.

[54] As discussed below, FINRA proposes a conforming change in 2025 to Section 15(g) of Schedule A to the FINRA By-Laws to align the fee for funding portal members that submit fingerprints electronically with the same fee charged to broker-dealer members.

[55] This fee applies for processing and posting to the CRD system each set of fingerprints submitted in non-electronic format by a member to FINRA, plus any other charge that may be imposed by the United States Department of Justice for processing each set of fingerprints.

indicated on its preliminary annual renewal statement.[56] Where this late fee applies, FINRA includes it as part of the final statement. Currently, this fee is the greater of 10 percent of the member's final annual renewal assessment or $100, with a maximum charge of $5,000. FINRA has not increased the renewal late fee since it was established in 2002.[57]

FINRA is proposing to increase the renewal late fee in 2028 as follows:

RENEWAL LATE FEE—PROPOSED IMPLEMENTATION

[The Renewal Late Fee is 10 percent of a member's cumulative final renewal statement with the following minimums and maximums]

Fee	2024 (current)	2025 (no change)	2026 (no change)	2027 (no change)	2028	2029
The minimum late fee FINRA will assess is	$100	$100	$100	$100	$140	$140
The maximum late fee FINRA will assess is	5,000	5,000	5,000	5,000	7,000	7,000

FINRA notes that it collects all applicable renewal fees on behalf of itself and participating regulators, which enables members to submit their total renewal payment to FINRA instead of to each regulator. Among other reasons noted, FINRA believes this proposed fee increase would further encourage members to submit such fees on time. When the proposed renewal late fee changes are fully implemented, they are designed to generate an additional $100,000 in annual revenue by 2029.

Late Disclosure Fee

Related to the registration functions described above, FINRA charges a fee for each day that a new disclosure event or a change in the status of a previously reported disclosure event is not timely filed on an initial or amended Form U5 or an amended Form U4. Section 4(h) of Schedule A to the FINRA By-Laws sets forth the late disclosure fee. This fee is assessed starting on the day following the last date on which the event or change in status was required to be reported.

Timely and complete reporting of all information required by the FINRA By-Laws and rules, as well as the federal securities laws, is critical to investor protection. The SEC, FINRA, other SROs and state securities regulators use the information to make licensing and registration decisions, among other things. FINRA also publishes information in FINRA BrokerCheck, which investors use for researching the professional backgrounds of firms and brokers.

FINRA has not increased the late disclosure fee since 2013.[58] Currently, disclosures filed more than 60 days following the last date on which the event was required to be reported under FINRA rules account for 50 percent of volume and 78 percent of revenues related to late filing fees.

FINRA is proposing to increase the late disclosure fee[59] in 2026 as follows:

LATE DISCLOSURE FEE—PROPOSED IMPLEMENTATION

Fee	2024 (current)	2025 (no change)	2026	2027	2028	2029
First Day	$100	$100	$100	$100	$100	$100
Subsequent Days	25	25	40	40	40	40
Maximum Fee	1,575	1,575	2,460	2,460	2,460	2,460

FINRA believes this proposed fee increase would further encourage firms to file timely and complete initial Forms U4 and U5 and amendments to these forms, while also generating additional revenue as part of the overall proposal to increase fees to fund FINRA's regulatory mission. When the proposed late disclosure fee changes are fully implemented, they are designed to generate an additional $3 million in annual revenue by 2029.[60]

System Processing Fee

FINRA currently assesses an annual system processing fee for each of the member's registered persons. Like the registration fees described above, this fee correlates to the third critical component of FINRA's regulatory costs—the number and role of registered persons at a firm. Section 4(b)(7) of Schedule A to the FINRA By-Laws sets forth the system processing fee. Under the current fee structure, a flat $70 fee applies to each registered person of a member. Many registered persons are registered with one or more securities regulators (*i.e.,* with jurisdictions as a broker-dealer agent and with SROs as a representative or principal).[61] The median number of other SROs and jurisdictions with which each registered person of a member is registered, in addition to their FINRA registration, is 11, with an average of 20.

FINRA's costs and resources allocated to processing this information for members' registered persons depends, in part, on the number of securities regulators with which each registered person is registered (whether as a broker-dealer agent with one or more

[56] Members receive a preliminary annual renewal statement that reflects approved registrations at the time the statement is generated. The statement also includes a date by which members must make full payment available to FINRA.

[57] *See* Securities Exchange Act Release No. 46466 (September 6, 2002), 67 FR 58092 (September 13, 2002) (Notice of Filing and Immediate Effectiveness of File No. SR–NASD–2002–100).

[58] *See Regulatory Notice* 12–32, *supra* note 41.

[59] FINRA also proposes conforming changes to Section 15(e) of Schedule A to the FINRA By-Laws to align this proposed fee change with the same fee for Funding Portal members.

[60] Projected revenue from the proposed increased Late Disclosure Fees assumes approximately 53% late filings based on the historical average (2018–2023) and is based on other reasonably conservative assumptions using a variety of information points, including historical data and anticipated trends. *See supra* note 15.

[61] The term broker-dealer agent (or AG) is the designation used in Form U4 to identify a person who has been approved to sell securities in a particular jurisdiction.

jurisdictions or as a representative or principal with one or more SROs). To account for this variability, FINRA proposes to replace the current flat fee structure with a tiered rate structure in 2026 as described below. In addition, FINRA proposes to increase the proposed tiers in 2028. These proposed changes are summarized as follows:

SYSTEM PROCESSING FEE—PROPOSED IMPLEMENTATION

Number of securities regulators with which each registered person of a member is registered, excluding registration as an investment adviser representative	2024 (current)	2025 (no change)	2026	2027 (no change)	2028	2029 (no change)
1–5	$70	$70	$70	$70	$100	$100
6–20	70	70	95	95	125	125
21–40	70	70	110	110	140	140
41+	70	70	125	125	155	155

The fee would be calculated based on the total number of securities regulators with which each registered person of a member is registered (whether as a broker-dealer agent with one or more jurisdictions or as a representative or principal with one or more SROs). A registered person's registration as an investment adviser representative would not be considered.

FINRA believes this use-based fee will support FINRA's overall regulatory mission while reflecting the resources FINRA allocates to its securities licensing and registration operations for registered persons of members. Further, as noted above, this fee relates to the number and role of registered persons at a firm, which is one of the three critical components of FINRA's regulatory costs.

FINRA proposes to implement the proposed tiered rate structure in 2026. To allow members additional time to adjust and plan, FINRA proposes to defer implementation of proposed increases to this fee until 2028. When this proposed rule change, including implementation of the tiered structure and the proposed increase are fully implemented, it is designed to generate an additional $31 million in annual revenue by 2029.

Qualification Examination Fees

Like registration fees, qualification examination fees are registered person-level fees that, while use-based, also correlate to the third critical component of FINRA's regulatory costs—the number and role of registered persons at a firm. Section 4(c) of Schedule A to the FINRA By-Laws sets forth the fees associated with the qualification examinations that FINRA administers. Persons engaged in the investment banking or securities business of a FINRA member who function as principals or representatives are required to register with FINRA in each category of registration appropriate to their functions. Such individuals must pass an appropriate qualification examination or obtain a waiver before their registration can become effective. These qualification examinations cover a broad range of subjects regarding financial markets and products, individual responsibilities, securities industry rules, and regulatory structure.

FINRA develops, maintains, and delivers all qualification examinations for individuals who are registered or seeking registration with FINRA.[62] FINRA last increased its examination fees between 2022 and 2024.[63] FINRA is proposing to increase its examination fees in 2026 as follows:

QUALIFICATION EXAMINATION FEES—PROPOSED IMPLEMENTATION

Examination number and name	2024 (current)	2025 (no change)	2026	2027	2028	2029
Securities Industry Essentials (SIE) Examination	$80	$80	$100	$100	$100	$100
Series 4: Registered Options Principal Examination	155	155	200	200	200	200
Series 6: Investment Company Products and Variable Contracts Representative Examination	75	75	100	100	100	100
Series 7: General Securities Representative Examination	300	300	395	395	395	395
Series 9: General Securities Sales Supervisor Examination—Options Module	130	130	175	175	175	175
Series 10: General Securities Sales Supervisor Examination—General Module	175	175	235	235	235	235
Series 14: Compliance Official Examination	350	350	450	450	450	450
Series 16: Supervisory Analyst Examination	245	245	325	325	325	325
Series 22: Direct Participation Programs Representative Examination	60	60	100	100	100	100
Series 23: General Securities Principal Examination—Sales Supervisor Module	105	105	135	135	135	135

[62] FINRA also administers and delivers examinations sponsored (*i.e.,* developed) by the Municipal Securities Rulemaking Board (''MSRB'') and other SROs, the North American Securities Administrators Association, and the Federal Deposit Insurance Corporation. The fees charged for these examinations are set according to contracts with the examination sponsors, and FINRA is not proposing any changes to fees associated with those examinations at this time.

[63] *See* Order Approving SR–FINRA–2020–032, *supra* note 6, 85 FR 66592.

QUALIFICATION EXAMINATION FEES—PROPOSED IMPLEMENTATION—Continued

Examination number and name	2024 (current)	2025 (no change)	2026	2027	2028	2029
Series 24: General Securities Principal Examination	175	175	235	235	235	235
Series 26: Investment Company Products and Variable Contracts Principal Examination	150	150	200	200	200	200
Series 27: Financial and Operations Principal Examination	175	175	235	235	235	235
Series 28: Introducing Broker-Dealer Financial and Operations Principal Examination	150	150	195	195	195	195
Series 39: Direct Participation Programs Principal Examination	100	100	200	200	200	200
Series 57: Securities Trader Examination	80	80	105	105	105	105
Series 79: Investment Banking Representative Examination	300	300	395	395	395	395
Series 82: Private Securities Offering Representative Examination	60	60	100	100	100	100
Series 86: Research Analyst Examination—Analysis	225	225	295	295	295	295
Series 87: Research Analyst Examination—Regulatory	150	150	195	195	195	195
Series 99: Operations Professional Examination	60	60	100	100	100	100

FINRA is proposing a one-time fee increase across examinations in 2026 designed to generate an additional $14 million in revenue across all examinations by 2029. In addition, FINRA has determined the amount of each examination fee increase based on the frequency with which the examination is administered, as well as the average fee per hour of examination length. Examinations that are administered more frequently or are longer in duration typically require more effort and cost to develop, maintain, and update. As a result, FINRA is generally proposing greater increases for those examinations, and smaller increases for others to preserve the broad and equitable distribution of proposed fee increases, as discussed throughout this filing.

Continuing Education Regulatory Element Fee

Continuing education fees are also registered person-level fees that, while use-based, correlate to the third critical component of FINRA's regulatory costs—the number and role of registered persons at a firm. In conjunction with other SROs and the Securities Industry/Regulatory Council on Continuing Education, FINRA administers the continuing education (CE) program for the securities industry.[64] The Regulatory Element of the CE program provides training on significant rule changes and other regulatory developments relevant to each registration category. Registered persons must complete the Regulatory Element annually by December 31 for each registration that they hold.[65]

Section 4(f) of Schedule A to the FINRA By-Laws sets forth the fees associated with the Regulatory Element requirement. FINRA has not increased the fee for the web-based delivery of the Regulatory Element since it was established in 2015.[66] FINRA is proposing to increase the Regulatory Element fee in 2026 as follows:

CONTINUING EDUCATION FEE—PROPOSED IMPLEMENTATION

Fee	2024 (current)	2025 (no change)	2026	2027	2028	2029
Continuing Education	$18	$18	$25	$25	$25	$25

When the proposed regulatory element fee rate is fully implemented, it is designed to generate an additional $4 million in annual revenue by 2029.

Select Use-Based Fees

Corporate Financing Private Placement Review Fee

FINRA Rule 5122 (Private Placements of Securities Issued by Members) imposes requirements regarding disclosure, filing, and use of offering proceeds for members that sell a private placement of securities issued by a member or a control entity, subject to various exemptions. Pursuant to FINRA Rule 5122, members that offer or sell their own securities or those of a control

[64] *See* FINRA Rule 1240.

[65] *See* FINRA Rule 1240; *see also* Securities Exchange Act Release No. 93097 (September 21, 2021), 86 FR 53358 (September 27, 2021) (Order Approving File No. SR–FINRA–2021–015).

[66] *See* Securities Exchange Act Release No. 75581 (July 31, 2015), 80 FR 47018 (August 6, 2015) (Order Approving File No. SR–FINRA–2015–015). After FINRA adopted amendments to require registered persons to complete the Regulatory Element of CE annually rather than every three years, FINRA revised the Regulatory Element fee from a $55 fee paid once every three years, to an $18 fee paid annually. *See* Securities Exchange Act Release No. 93928 (January 7, 2022), 87 FR 2193, 2194 (January 13, 2022) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2021–034). Thus, the Regulatory Element fee has not substantially changed since 2015.

entity must file with FINRA's Corporate Financing Department (''Corporate Financing'') a private placement memorandum, term sheet or other offering document and any retail communication that promotes or recommends the member private offering at or prior to the first time the documents are provided to any prospective investor.

Its companion rule, FINRA Rule 5123 (Private Placement of Securities), requires members that sell any other type of private placement to file with Corporate Financing a copy of any private placement memorandum, term sheet or other offering document, and any retail communication that promotes or recommends the private placement. Such filing must occur within 15 calendar days of the first sale, subject to various exemptions.

FINRA has historically performed the review of such filings at no cost since the program was created approximately 15 years ago.[67] This program requires substantial resources, and the volume of filings has increased significantly in recent years.[68] FINRA thus proposes to establish the following fees related to private placement review in July 2025 as follows:

CORPORATE FINANCING PRIVATE PLACEMENT REVIEW FEE—PROPOSED IMPLEMENTATION

Private placements (offerings >$25M)	2024 (current)	2025 (effective 7/1/25) (million)	2026 (million)	2027 (million)	2028 (million)	2029 (million)
Flat Fee	$0	$300	$300	$300	$300	$300
% of Offering	0%	0.008%	0.008%	0.008%	0.008%	0.008%
Offering Cap	$0	$500	$500	$500	$500	$500

The proposed fee is designed to be similar to the current fee for public offering reviews. Like the public offering review fee, this proposed fee would consist of both a flat fee and a percentage of the maximum offering proceeds. However, to reduce the impact on smaller issuers and broker-dealers, FINRA proposes to apply this fee only to private placement offerings of greater than $25 million and to cap the fee at $40,300 (0.008% of $500,000,000 offering + $300 flat fee). In general, FINRA believes that such fees would be paid for by, or passed through to, issuers.[69] This proposed new use-based fee is structured to take into account associated types of costs, including the substantial resources such reviews require.[70] When the proposed new fee for private placement review is fully implemented, it is designed to generate $6 million in annual revenue by 2029.

Corporate Financing Public Offering Review Fee

Corporate Financing reviews the underwriting terms and arrangements of proposed public offerings of securities for compliance with the requirements of FINRA Rule 5110 (Corporate Financing Rule—Underwriting Terms and Arrangements). Pursuant to Rule 5110, no member firm or person associated with a member firm may participate in a public offering subject to the rule, or to FINRA Rules 5121 (Public Offerings of Securities With Conflicts of Interest) and 2310 (Direct Participation Programs), unless the documents and information specified in the rule have been filed with and reviewed by Corporate Financing. The documents Corporate Financing reviews include registration statements, underwriting agreements, engagement letters and other relevant supporting documentation for public offerings. Corporate Financing's review is complementary to the SEC's registration process, which covers a larger set of filings than FINRA's program.[71]

Section 7 of Schedule A to the FINRA By-Laws sets forth the fees associated with filing documents pursuant to the Corporate Financing Rule. It currently provides for a flat fee of $500 plus .015% of the proposed maximum aggregate offering price or other applicable value of all securities registered on an SEC registration statement or included on any other type of offering document (where not filed with the SEC), with a cap of $225,500; or a fee of $225,500 for an offering of securities filed with the SEC and offered pursuant to Securities Act Rule 415 by a Well-Known Seasoned Issuer (''WKSI'') as defined in Securities Act Rule 405. The fee associated with any amendment or other change to the documents initially filed with Corporate Financing is also subject to the current $225,500 cap. FINRA has not raised the fee cap since 2012.[72]

FINRA is proposing to increase and modify the fee cap beginning in July 2025 as follows:

[67] FINRA Rule 5122 became effective on June 17, 2009; FINRA Rule 5123 became effective on December 3, 2012.

[68] *See Regulatory Notice* 23–08 (May 2023) (''In recent years, the unregistered offering market outpaced the public market. . . . In 2021, for example, members submitted over 3,800 unique filings for private placements pursuant to FINRA Rules 5122 and 5123, which require filings for private placements generally sold to individuals, in comparison to roughly 2,000 submissions in 2013.'').

[69] FINRA's belief is informed by its experience with the public offering fee, described below, and based on discussions with FINRA advisory committees and other industry participants.

[70] As discussed above, when applying use-based fees, FINRA takes into account direct costs for the program, indirect costs for the program, and a contribution to FINRA's overall regulatory operations. *See supra* note 7 and accompanying text.

[71] The SEC's current filing fee rate for filings made pursuant to Sections 6(b) of the Securities Act of 1933 and Sections 13(e) and 14(g) of the Exchange Act is $147.60 per $1,000,000. *See https://www.sec.gov/edgar/filer/filing-fees/filing-fee-rate.*

[72] *See* Securities Exchange Act Release No. 67241 (June 22, 2012), 77 FR 38698 (June 28, 2012) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2012–029); *see also Regulatory Notice* 12–32 (June 2012).

CORPORATE FINANCING PUBLIC OFFERING REVIEW FEE CAP—PROPOSED IMPLEMENTATION

IPO	2024 (current)	2025 (effective 7/1/25)	2026	2027	2028	2029
Non-WKSI	$225,000	$1,125,000	$1,125,000	$1,125,000	$1,125,000	$1,125,000
WKSI	225,000	270,000	324,000	389,000	467,000	560,000

This proposed rule change would raise the fee cap to $1,125,000, which would account for the significant growth in the size of offerings since the cap was last raised in 2012. However, for WKSIs, the cap would be raised to $560,000 over a period of five years. FINRA notes that raising the caps would also create more consistency with the SEC IPO review fee, which has no cap.[73] FINRA projects that increasing the cap as proposed would capture 81% of the incremental revenues if there were no cap while bounding the impact on WKSIs whose offerings tend to be less resource intensive for Corporate Financing to review. FINRA believes such fees are and would continue to be paid for by, or passed through to, issuers.[74] When the proposed fee increase is fully implemented, it is designed to generate an additional $31 million in annual revenue by 2029.[75]

Advertising Regulation Review Fee

One way that FINRA protects investors is by having its Advertising Regulation Department review specified broker-dealers' communications for compliance with FINRA's communications with the public rules, and similar rules of[76] the SEC, MSRB and Securities Investor Protection Corporation. FINRA rules require that member communications be based on principles of fair dealing and good faith, be fair and balanced, and provide a sound basis for evaluating the facts in regard to any particular security or type of security, industry or service. Among other things, FINRA rules prohibit member firm communications from including false, exaggerated, unwarranted or misleading statements or claims.

Section 13 of Schedule A to the FINRA By-Laws sets forth the fees associated with review of communications filed with FINRA. Despite rising costs to administer the Advertising Regulation Department review program, FINRA has not increased these fees since 2012.[77] FINRA is proposing an increase to the regular review charge in 2025 as follows:

ADVERTISING REGULATION REVIEW—PROPOSED IMPLEMENTATION

Fee	2024 (current)	2025	2026	2027	2028	2029
Regular Review Charge (non-expedited)	$125	$300	$300	$300	$300	$300

When the proposed fee increase is fully implemented, it is designed to generate an additional $11 million in annual revenue by 2029.[78] Under the proposed rule change, the $600 expedited fee would not change.

Dispute Resolution Services Arbitration Fees

DRS operates the largest securities arbitration forum in the United States, to assist in the resolution of disputes involving customers, members and associated persons. As discussed in turn below, FINRA proposes to raise the (1) hearing session fees, (2) filing fees, (3) member surcharge, and (4) member process fee, as set forth in the Code of Arbitration Procedure for Customer Disputes (''Customer Code'') and Code of Arbitration Procedure for Industry Disputes (''Industry Code'') (together, the ''Codes'').[79]

FINRA believes that the cost of arbitration should be borne by the users of the forum, without imposing a significant barrier to public customers who bring arbitration claims to the forum. Thus, the current DRS arbitration fees are designed to be borne 85 percent by members and 15 percent by customers.[80] The proposed rule change would maintain that pricing structure. It would also maintain a sliding scale fee structure in which the member surcharge and process fees increase across the board, while the hearing session fees and filing fees increase more for higher value claims. Taken together, the proposed increase in DRS' arbitration fees would aim to partially recover increasing costs to operate the forum, without placing an undue burden on users of the forum, particularly customers or claimants with small claims. When the proposed DRS arbitration fee increases are fully implemented, they are designed to generate an additional $10 million in annual revenue by 2029.

Hearing Session Fees

Under FINRA Rules 12902 and 13902, hearing session fees are charged for each hearing session based on the amount in dispute. In the award, the panel determines the amount of each hearing session fee that each party must pay. The arbitrators may apportion the fees in any manner, including assessing the entire amount against one party.[81]

FINRA proposes to raise hearing session fees in 2025 as follows:

[73] *See supra* note 71.

[74] *See supra* note 69.

[75] The proposed rule change would remove the language ''on an automatically effective Form S–3 or F–3 registration statement'' because WKSIs may use other registration forms. *See, e.g.,* Securities Offering Reform for Closed-End Investment Companies, Investment Company Act Release No. 33836 (April 8, 2020), 85 FR 33290 (June 1, 2020).

[76] *See generally* FINRA Rule 2200 Series. FINRA also will review communications filed voluntarily.

[77] *See* Securities Exchange Act Release No. 67239 (June 22, 2012), 77 FR 38692 (June 28, 2012) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2012–028).

[78] FINRA currently charges a $10 fee for the review of each printed page or web page in excess of 10 pages, and for each minute of tape reviewed in excess of 10 minutes of video or audio media. This would not change under the proposed rule change.

[79] The Customer Code is the FINRA Rule 12000 Series; the Industry Code is the FINRA Rule 13000 Series. The proposed fee increases described, below, would be implemented in both Codes.

[80] *See* Securities Exchange Act Release No. 90227 (October 20, 2020), 85 FR 67794 (October 26, 2020) (Notice of Filing File No. SR–FINRA–2020–035).

[81] *See* FINRA Rules 12902(a)(1) and 13902(a)(1).

HEARING SESSION FEES—PROPOSED IMPLEMENTATION

Amount of claim (exclusive of interest and expenses)	2024 (current)		2025–2029	
	Hearing session w/ one arbitrator	Hearing session w/ three arbitrators	Hearing session w/ one arbitrator	Hearing session w/ three arbitrators
Up to $2,500	$50	N/A	$50	N/A
$2,500.01 to $5,000	125	N/A	125	N/A
$5,000.01 to $10,000	250	N/A	250	N/A
$10,000.01 to $25,000	450	N/A	450	N/A
$25,000.01 to $50,000	450	$600	450	$600
$50,000.01 to $100,000	450	750	450	750
$100,000.01 to $500,000	450	1,125	675	1,690
$500,000.01 to $1,000,000	450	1,325	675	1,990
$1,000,000.01 to $5,000,000	450	1,435	675	2,160
Over $5,000,000	450	1,575	675	2,370
Non-Monetary/Not Specified	450	1,150	675	1,725

To minimize the impact of the proposed rule change on customers or claimants with small claims, the proposed fee increase would only apply to claims of more than $100,000 and claims for non-monetary or unspecified damages. The tiered structure of this fee would not change under the proposed rule change.

FINRA notes the hearing session fee may not be assessed under certain circumstances. For example, if the parties timely settle the arbitration, the parties will not be assessed hearing session fees.[82] During settlement negotiations, parties have the opportunity to determine how to share any hearing session fees, if hearings are held.[83] For cases that result in an award, the panel has discretion to assess hearing session fees as part of the award,[84] which allows them to consider numerous factors to determine each party's appropriate share and assign the costs accordingly. The proposed rule change would not change a party's ability to settle or arbitrators' discretion to assess the hearing session fees.

Filing Fees

Filing Fees Paid by Customers, Associated Persons or Other Non-Members

Filing fees are due when a claim is filed. FINRA Rule 12900(a) sets forth the filing fee schedule for customers, associated persons and other non-members who file a claim, counterclaim, cross claim or third party claim in a customer dispute. FINRA Rule 13900(a) sets forth the filing fee schedule for associated persons who file a claim, counterclaim, cross claim or third party claim in an industry dispute. The filing fee is based on the claim amount or type of damages requested.

FINRA proposes to raise filing fees in 2025 as follows:

FILING FEE (CUSTOMERS, ASSOCIATED PERSONS, AND OTHER NON-MEMBERS)—PROPOSED IMPLEMENTATION

Amount of claim (exclusive of interest and expenses)	2024 (current)	2025	2026	2027	2028	2029
$.01 to $1,000	$50	$50	$50	$50	$50	$50
$1,000.01 to $2,500	75	75	75	75	75	75
$2,500.01 to $5,000	175	175	175	175	175	175
$5,000.01 to $10,000	325	325	325	325	325	325
$10,000.01 to $25,000	425	425	425	425	425	425
$25,000.01 to $50,000	600	600	600	600	600	600
$50,000.01 to $100,000	975	975	975	975	975	975
$100,000.01 to $500,000	1,425	1,790	1,790	1,790	1,790	1,790
$500,000.01 to $1,000,000	1,740	2,175	2,175	2,175	2,175	2,175
$1,000,000.01 to $5,000,000	2,025	2,540	2,540	2,540	2,540	2,540
Over $5,000,000	2,300	2,875	2,875	2,875	2,875	2,875
Non-Monetary/Not Specified	1,600	2,000	2,000	2,000	2,000	2,000

To minimize the impact of the proposed rule change on customers or claimants with small claims, and consistent with the current claim amount tier structure, the proposed fee increase would only apply to claims of more than $100,000 and claims for non-monetary or unspecified damages. The tiered structure of this fee would not change under the proposed rule change.

Filing Fees Paid by Members

FINRA Rules 12900(b) and 13900(b) set forth the filing fee schedule for members filing a claim, counterclaim, cross claim, or third party claim in customer and industry cases, respectively. FINRA proposes to increase the member filing fee in 2025 as follows:

[82] *See* FINRA Rules 12701 and 13701.

[83] *See* FINRA Rules 12701(b) and 13701(b).

[84] *See* FINRA Rules 12902(a)(1) and 13902(a)(1).

FILING FEE (MEMBERS)—PROPOSED IMPLEMENTATION

Amount of claim (exclusive of interest and expenses)	2024 (current)	2025	2026	2027	2028	2029
$.01 to $1,000	$225	$225	$225	$225	$225	$225
$1,000.01 to $2,500	350	350	350	350	350	350
$2,500.01 to $5,000	525	525	525	525	525	525
$5,000.01 to $10,000	750	750	750	750	750	750
$10,000.01 to $25,000	1,050	1,050	1,050	1,050	1,050	1,050
$25,000.01 to $50,000	1,450	1,450	1,450	1,450	1,450	1,450
$50,000.01 to $100,000	1,750	1,750	1,750	1,750	1,750	1,750
$100,000.01 to $500,000	2,125	2,660	2,660	2,660	2,660	2,660
$500,000.01 to $1,000,000	2,650	3,320	3,320	3,320	3,320	3,320
$1,000,000.01 to $5,000,000	3,550	4,440	4,440	4,440	4,440	4,440
Over $5,000,000	4,200	5,250	5,250	5,250	5,250	5,250
Non-Monetary/Not Specified	1,800	2,250	2,250	2,250	2,250	2,250

Partial Refund of Filing Fee

If a claim is settled or withdrawn more than 10 days before the date of the hearing on the merits, a party paying a filing fee will receive a partial refund of the filing fee in the amount specified under FINRA Rule 12900(c) for customer cases and FINRA Rule 13900(c) for industry cases. FINRA proposes to increase the partial filing fee refund in 2025 as follows:

PARTIAL FILING FEE REFUND—PROPOSED IMPLEMENTATION

Amount of claim (exclusive of interest and expenses)	2024 (current)	2025	2026	2027	2028	2029
$.01 to $1,000	$25	$25	$25	$25	$25	$25
$1,000.01 to $2,500	50	50	50	50	50	50
$2,500.01 to $5,000	125	125	125	125	125	125
$5,000.01 to $10,000	250	250	250	250	250	250
$10,000.01 to $25,000	300	300	300	300	300	300
$25,000.01 to $50,000	450	450	450	450	450	450
$50,000.01 to $100,000	750	750	750	750	750	750
$100,000.01 to $500,000	1,125	1,410	1,410	1,410	1,410	1,410
$500,000.01 to $1,000,000	1,300	1,625	1,625	1,625	1,625	1,625
$1,000,000.01 to $5,000,000	1,400	1,750	1,750	1,750	1,750	1,750
Over $5,000,000	1,500	1,875	1,875	1,875	1,875	1,875
Non-Monetary/Not specified	1,200	1,500	1,500	1,500	1,500	1,500

Member Surcharge

FINRA assesses a surcharge against each member that (a) files a claim, counterclaim, cross claim or third party claim under the Codes; (b) is named as a respondent in a claim, counterclaim, cross claim, or third party claim filed and served under the Codes; or (c) employed, at the time the dispute arose, an associated person who is named as a respondent in a claim, counterclaim, cross claim, or third party claim filed and served under the Codes.

FINRA Rules 12901 and 13901 set forth the schedule of the member surcharge, which is assessed based on the amount of the claim, exclusive of interest and expenses. The member is assessed one surcharge per arbitration case.[85] Member surcharges are intended to allocate the costs of administering the arbitration case to the firms that are involved in those cases. Thus, each member is assessed a member surcharge, based on the aggregate claim amount, when it is brought into the case, whether through a claim, counterclaim, cross claim or third party claim. The member surcharge is the responsibility of the member party and cannot be allocated to any other party (''non-allocable'').

FINRA proposes to increase the member surcharge in 2025 as follows:

MEMBER SURCHARGE—PROPOSED IMPLEMENTATION

Amount of claim (exclusive of interest and expenses)	2024 (current)	2025	2026	2027	2028	2029
$.01 to $5,000	$150	$165	$165	$165	$165	$165
$5,000.01–$10,000	325	360	360	360	360	360
$10,000.01–$25,000	450	495	495	495	495	495
$25,000.01–$50,000	750	975	975	975	975	975
$50,000.01–$100,000	1,100	1,430	1,430	1,430	1,430	1,430
$100,000.01–$250,000	1,700	2,210	2,210	2,210	2,210	2,210
$250,000.01–$500,000	2,025	2,640	2,640	2,640	2,640	2,640
$500,000.01–$1,000,000	2,625	3,420	3,420	3,420	3,420	3,420
$1,000,000.01–$5,000,000	3,200	4,800	4,800	4,800	4,800	4,800
$5,000,000.01–$10,000,000	3,850	5,775	5,775	5,775	5,775	5,775

[85] *See* FINRA Rules 12901(a)(6) and 13901(f).

MEMBER SURCHARGE—PROPOSED IMPLEMENTATION—Continued

Amount of claim (exclusive of interest and expenses)	2024 (current)	2025	2026	2027	2028	2029
Over $10,000,000	4,325	6,490	6,490	6,490	6,490	6,490
Non-Monetary/Not Specified	2,000	2,600	2,600	2,600	2,600	2,600

The member surcharge would remain non-allocable under the proposed rule change and, therefore, would not result in any additional costs to other parties to the arbitration, including customers.

Member Process Fee

Under the Codes, each member that is a party to an arbitration or employed an associated person who is a party to an arbitration in which more than $25,000, exclusive of interest and expenses, is in dispute must pay a non-refundable process fee.[86]

FINRA Rules 12903 and 13903 set forth the process fee schedule. FINRA assesses the member the applicable process fee when the parties are sent the arbitrator lists or notification of the hearing. Like the member surcharge, the process fee is non-allocable to other parties to the arbitration.[87]

FINRA proposes to increase the process fee in 2025 as follows:

MEMBER PROCESS FEE—PROPOSED IMPLEMENTATION

Amount of claim (exclusive of interest and expenses)	2024 (current)	2025	2026	2027	2028	2029
$.01–$25,000	$0	$0	$0	$0	$0	$0
$25,000.01–$50,000	1,750	2,275	2,275	2,275	2,275	2,275
$50,000.01–$100,000	2,250	2,925	2,925	2,925	2,925	2,925
$100,000.01–$250,000	3,250	4,225	4,225	4,225	4,225	4,225
$250,000.01–$500,000	3,875	5,040	5,040	5,040	5,040	5,040
$500,000.01–$1,000,000	5,225	6,800	6,800	6,800	6,800	6,800
$1,000,000.01–$5,000,000	6,375	9,570	9,570	9,570	9,570	9,570
$5,000,000.01–$10,000,000	7,050	10,575	10,575	10,575	10,575	10,575
Over $10,000,000	7,300	10,950	10,950	10,950	10,950	10,950
Non-Monetary/Not Specified	3,850	5,005	5,005	5,005	5,005	5,005

The member process fee would remain non-allocable under the proposed rule change and, therefore, would not result in any additional costs to other parties to the arbitration, including customers.

Regulation T and Exchange Act Rule 15c3–3(n) Requests for Extension of Time Fee

Section 8 of Schedule A to the FINRA By-Laws governs the service charge for each extension of time request pursuant to Sections 220.4(c) and 220.8(d) of Regulation T[88] of the Board of Governors of the Federal Reserve System (''Regulation T'') and Exchange Act Rule 15c3–3(n).[89] FINRA has not increased this fee since 2006.[90] FINRA proposes to raise the fee in 2025 as follows:

REGULATION T AND EXCHANGE ACT RULE 15c3–3(n) REQUESTS FOR EXTENSION OF TIME—PROPOSED IMPLEMENTATION

2024 (current)	2025	2026	2027	2028	2029
$4 per request	$8 per request	$8 per request	$8 per request	$8 per request	$8 per request.

Based on current annual extension filing volumes, the current fee does not cover the estimated personnel and technology costs necessary to process extension requests. The proposal to increase the fee would recover some of those costs. When the proposed service charge for Regulation T and Exchange Act Rule 15c3–3(n) requests for extension of time increases are fully implemented, they are designed to generate an additional $640,000 in annual revenue by 2029.

Further, to streamline Section 8, FINRA proposes to eliminate current paragraph (a), which is not needed in light of the specific fee amount language set forth in paragraph (b) of that Section. The proposed rule change would also make minor technical corrections. As such, the proposed rule change would amend Section 8 to read: ''The service charge for processing each initial extension of time request and for all subsequent extension of time requests (1) involving the same transaction under Regulation T or (2) involving an extension of time previously granted pursuant to SEA Rule 15c3–3(n) shall be $8.00 per request.''

Proposed Conforming Changes To Select Funding Portal Member Fees

Section 15 of Schedule A to the FINRA By-Laws sets forth the fees that

[86] *See* FINRA Rules 12903 and 13903. If a claim amount is $25,000 or less, the member would not be assessed any process fees.

[87] *See* FINRA Rules 12903(d) and 13903(d). *See also* FINRA Rules 12701(b) and 13701(b).

[88] 12 CFR 220.4(c) and 220.8(d), respectively.

[89] 17 CFR 240.15c3–3.

[90] *See* Securities Exchange Act Release No. 53982 (June 14, 2006), 71 FR 35720 (June 21, 2006) (Notice of Filing and Immediate Effectiveness of File No. SR–NASD–2006–063). *See also Notice to Members* 06–30 (June 2006).

govern funding portals that are FINRA members. These fees became effective in 2016. At the time they were proposed, the funding portal fees related to eligibility proceedings and fingerprint processing, among others, were ''identical to those charged to broker-dealer members.'' [91] Though amendments to the fees charged to broker-dealer members related to eligibility proceedings and fingerprint processing have since occurred, those same fees for funding portal members have not been amended, and thus, are no longer aligned.

This proposed rule change would amend Section 15(f)(1) and Section 15(g) to conform the fees for members that are funding portals with the same fees that are charged to broker-dealer members. Specifically, in 2025, the proposed rule change would raise the funding portal member fee for filing an application to initiate eligibility proceedings from $1,500 to $5,000 to conform with the same fee that currently applies to broker-dealer members. Also in 2025, the proposed rule change would raise the funding portal member fee for fingerprints submitted electronically from $15 to $20 to conform with the same fee that currently applies to broker-dealer members.[92]

FINRA has filed the proposed rule change for immediate effectiveness. Implementation of the proposed rule change will be phased in gradually over a five-year period beginning on January 1, 2025, with full implementation of all proposed fee changes by 2029.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(5) of the Act,[93] which requires, among other things, that FINRA rules provide for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system that FINRA operates or controls. FINRA further believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act, which requires, among other things, that FINRA rules are not designed to permit unfair discrimination between customers, issuers, brokers or dealers.[94]

Reasonableness of the Proposed Fees

As discussed above, FINRA's longstanding approach to funding employs a variety of fees designed to meet FINRA's overall costs. As a not-for-profit SRO with a diverse membership, FINRA designs its mix of fees to seek recovery of its overall regulatory costs in a manner that is fair, reasonable, and equitably allocated among FINRA's members and users of FINRA's services. As FINRA has explained in the past, it is not feasible to associate a direct affiliated revenue stream for each of its programs (for example, FINRA collects no revenues in connection with its examinations of members), and thus numerous operations and services must be funded by other revenue sources, which include both core regulatory fees and other use-based fees. FINRA continues to believe that its overall Commission-approved cost-based pricing structure is reasonable, achieves general equity across its membership, and correlates fees with those firm components that drive FINRA's regulatory costs to the extent feasible.

The reasonableness of this proposal is reinforced by three key cost discipline mechanisms: oversight, transparency, and rebates.

First, FINRA's funding and operations are subject to several layers of oversight, including by the FINRA Board of Governors [95] and the Commission. As discussed in FINRA's 2024 annual budget summary, FINRA's efforts to manage its expenses responsibly while appropriately funding its mission includes Board oversight of its annual budget, compensation, and capital initiatives. This oversight is spearheaded by key Board committees (such as its Finance, Operations and Technology Committee), and includes requirements for Board or relevant Committee approval with respect to various financial matters, such as the annual budget, the allocation and use of fine monies, the incurring of any expenses above certain pre-established thresholds, the amount of any annual merit or incentive compensation, and the compensation of certain key employees. The Board also relies on expert external consultants where appropriate. Notably, this Board oversight complements various staff level controls over routine costs, including expense policies that are enforced with systemic checks and escalating management approval requirements for expense requests, with the effectiveness of these policies further subject to review by FINRA's Internal Audit Department.

FINRA is also extensively supervised by the Commission throughout the year. The SEC's Division of Examinations maintains dedicated staff as part of its FINRA and Securities Industry Oversight (''FSIO'') program who are devoted exclusively to overseeing FINRA and the MSRB—the two not-for-profit regulatory SROs—including with respect to FINRA's overall financial management and the adequacy of the resources devoted to its regulatory programs. In addition, rules or fees adopted by FINRA are subject to review by the Commission's Division of Trading and Markets. The Commission's oversight of FINRA, in turn, is itself subject to Congressional oversight and evaluation by the United States Government Accountability Office (''GAO'') every three years. By statute, the GAO evaluates ten specific aspects of the Commission's oversight of FINRA, including FINRA governance, executive compensation, and the use of funding to support FINRA's mission, including the methods and sufficiency of funding, how FINRA invests funds pending use, and the impact of these aspects on FINRA's regulatory enforcement. The GAO reports the results of its evaluation to Congress.[96]

Second, FINRA's commitment to reasonable funding in support of its mission is further reinforced by the transparency it has committed to provide on an ongoing basis—pursuant to its Guiding Principles—regarding its financial performance. Each year, FINRA publishes an extensive Annual Financial Report regarding its operations, prepared in accordance with GAAP. In addition, FINRA publishes annual reports on its budget and its use of fine monies. FINRA's Board also reviews and affirms its Financial Guiding Principles bi-annually and re-publishes these as well. FINRA also files with the IRS the Form 990 mandated for all not-for-profit organizations. Collectively, these reports provide extensive and comprehensive information regarding FINRA's policies and operations with respect to its budgets, revenues, costs, financial reserves, use of fine monies, capital and strategic initiatives, and compensation of senior executives, among other information. FINRA maintains a dedicated web page that consolidates its

[91] *See* Securities Exchange Act Release No. 76238 (October 22, 2015), 80 FR 66342 (October 28, 2015) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2015–041).

[92] *See supra* note 54.

[93] 15 U.S.C. 78*o*–3(b)(5).

[94] 15 U.S.C. 78*o*–3(b)(6).

[95] The FINRA Board of Governors is composed of a mix of public and industry representatives and uses its diverse expertise to oversee management in the administration of FINRA's affairs and the promotion of FINRA's welfare, objectives, and its public service mission to protect investors and uphold the integrity of markets.

[96] *See* GAO Report to Congressional Committees (November 2023), available at *https://www.gao.gov/assets/d24106578.pdf.*

annual reports in a readily accessible place.[97]

Third, as a not-for-profit organization, FINRA is committed to aligning its revenues with its mission-driven costs. If revenues exceed costs on a sustained basis, and FINRA's reserves are sustained appropriately, FINRA will assess the merit of providing rebates. This approach helps ensure that the revenues from these proposed fee changes will not exceed FINRA's reasonable regulatory costs and reserve needs on an ongoing basis. As discussed above, FINRA will continue to be guided by its historical approach to rebates if its revenue in future years exceeds its costs and reserves needs by a material amount.

Together, these mechanisms help ensure the ongoing reasonableness of FINRA's costs and the level of fees assessed to support those costs. The effectiveness of these mechanisms is demonstrated by FINRA's experience over the last decade, during which, FINRA was able to undertake expanding regulatory responsibilities while limiting cumulative cost growth to a rate that was lower than inflation and cost growth experienced by members.

The Proposed Fees Are Equitable and Not Unfairly Discriminatory

As discussed throughout this filing, this proposed rule change is designed to increase the fees FINRA relies on to fund its regulatory mission in a manner that preserves an equitable and not unfairly discriminatory fee allocation among FINRA members and users of FINRA services. Notably, through this proposed rule change, FINRA is seeking to preserve the carefully calibrated mix of core regulatory fees and select use-based fees to fund its regulatory mission that the Commission previously approved as equitably allocated among its large and diverse membership. In addition, based on feedback from members of FINRA's advisory committees and other industry consultations that emphasized the importance of advance notice and clarity of any fee increases for budget planning, implementation of the proposed rule change would take place over several years, with some fees going into effect in 2025, others implemented in 2026 or later, and some phased in over several years between 2025 and 2029.

The fees included in this proposed rule change were selected to address the impending funding deficit by raising fees in a way that maintains proportionality across members with minimal distributional impacts across firm sizes and business models. FINRA projects an aggregate dispersion level for the rate of increase realized across members to be 2.3% once the proposal is fully implemented.[98] In other words, in choosing among options according to the principles described above, FINRA also sought to have minimal impact on the distribution of fee rate changes across members by firm size and business model, as measured by the standard deviation of the rate of the fee increases. Given this limited distributional impact, FINRA believes the proposed rule change will preserve the same equitable and not unfairly discriminatory fee allocation that has long served as the foundation for FINRA's funding model and has been approved by the Commission.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Economic Impact Assessment

FINRA has undertaken an economic impact assessment, as set forth below, to analyze the regulatory need for the proposed rule change, its potential economic impacts, including anticipated costs, benefits, and distributional and competitive effects, relative to the current baseline, and the alternatives FINRA considered in assessing how best to meet FINRA's regulatory objectives.

Regulatory Need

Based on an analysis of its funding sources, anticipated costs, and expanding responsibilities, FINRA has determined that it will require additional revenues to continue to effectively meet its regulatory obligations. FINRA anticipates that the absence of stable funding at the levels proposed here may have material negative impacts on its regulatory program, weakening investor protections. Specifically, FINRA may be unable to maintain its current capabilities at their current standards or respond to a significant market event requiring unanticipated funding. In the absence of a fee increase, eventually FINRA may not be able to hire and retain staff with the appropriate expertise to conduct its regulatory activities (including examinations, market surveillance and investigations, enforcement, regulatory policy and rulemaking, qualification examinations and credentialing, and providing transparency for markets, members and registered persons), or make the necessary investments in the technology needed to support these activities.

Economic Baseline

The baseline for this proposed rule change includes FINRA's historical costs and revenues, the current schedule of fees assessed by FINRA, and the direct and indirect allocation of those fees across members, associated persons, third parties, and investors. The baseline also encompasses the scope of activities conducted by FINRA to meet its mission, and FINRA's current ability to address changing market activities and conditions through investment in staff, infrastructure, and technology.

As a not-for-profit organization, FINRA targets break-even cash flows that allow it to appropriately fund its regulatory mission, and maintains a reasonable financial reserve necessary to meet unanticipated circumstances. Between 2013 and 2023, FINRA's cost increase CAGR was 3.5%, or 41% over the entire period.[99] Over the same period, members' reported cost increase CAGR was 8.7%, or a total increase of 129%.[100]

At the same time, capital markets have grown in size, complexity, and retail investor participation, in part, through an increase in the number of self-directed accounts and rapid technological changes. Partly in response to these changes, FINRA's regulatory responsibilities have, and continue to, grow as described above. There have been substantial increases in equity and options trading volume (respectively, over 70% and 160% increases since 2013) and in corporate and agency bond trading volume (over 230% increase since 2013). There has also been growth in the complexity of the securities markets (the number of registered national securities exchanges significantly increased since 2013, from 14 to 24 [101]) and trading of new and evolving products, such as security-based swaps and securities with crypto asset components, has increased. These changes have led to a more complex

[97] *See* FINRA Financial Reports and Policies, available at *https://www.finra.org/about/annual-reports.*

[98] *See generally* Exhibit 3, Charts 7 through 10.

[99] Based on figures drawn from FINRA's public Annual Financial Reports, which include FINRA subsidiaries.

[100] Based on FOCUS reports.

[101] *See https://www.sec.gov/fast-answers/divisionsmarketregmrexchangesshtml.* Additional registered national securities exchanges may contribute to more complex order lifecycles and trade reporting scenarios.

trading environment. This, in turn, has required enhancements to oversight by FINRA staff. In addition, as discussed above, FINRA has made substantial investments in its surveillance and examinations programs in response to new and amended SEC rules.

Over the past several years, FINRA has observed changes in the number of registered persons and members. Between 2013 and 2023, the number of registered persons was essentially unchanged (627,468 and 628,392, respectively).[102] In contrast, over the same period, the number of members decreased from 4,146 to 3,298, a decrease of approximately 20%.[103]

FINRA believes that the number of registered persons remained fairly constant because persons from exiting members migrated to other members, requiring FINRA regulatory resources to shift accordingly. FINRA staff's quarterly reviews of departing firms find that on average about 75% of their associated persons remain registered after their firm exits the securities business, either by remaining with an affiliate firm or moving to a new firm. In the last quarter of 2023, the retention rate was closer to 90%. The difference in the decline in the number of members versus registered persons is also related to the fact that most exiting firms are small,[104] such that their departure has relatively less impact on the total number of registered persons.

Despite its increased responsibilities and changes in FINRA's own oversight by the SEC, FINRA achieved relatively low expense growth through a variety of cost-saving mechanisms.[105] Staffing generates the majority of FINRA's expenses and was relatively flat until recent years, commensurate with increases in FINRA's responsibilities. As discussed above, since 2013, FINRA's total compensation costs rose by 31% on a cumulative basis as compared with a 50% increase for the average U.S. financial services employee.[106] In aggregate, since 2013, FINRA's expenses have grown less rapidly than those of members, with the ratio of member expenses to FINRA expenses gradually increasing over time. Chart 1, attached in Exhibit 3, presents these findings.[107]

Over the period between 2013 and 2023, FINRA's total regulatory and use-based fee CAGR was 3.9%. These revenues remained effectively flat from 2013 through 2019 due to a limited number of fee increases. A previously implemented fee increase was phased in between 2022 to 2024 and has resulted in increased levels of operating revenue. However, FINRA projects that increases in revenue will either remain flat or slightly decrease after 2024.

Chart 2 provides a view of actual revenues and expenses for 2013 to 2023 and anticipated revenue and expenses for 2024 to 2029 if no changes to the fee structure are made.[108] Chart 2 also includes historical and projected ''excess reserves.'' FINRA maintains a reserve fund as part of its funding framework, and excess reserves are reserves in excess of the minimum determined by the FINRA Board of Governors as appropriate, which is one year of expenditures.[109] FINRA has strategically relied on its reserves to help fund operating deficits in the past and will continue to strategically draw on its reserves where consistent with the Guiding Principles. Chart 2 illustrates, however, that without a fee increase, FINRA is projected to exhaust excess reserves and deplete its reserve balance below minimum target levels in the coming years.

Although FINRA's revenues would remain near current levels without any changes in the fee structure, FINRA reasonably anticipates that its future expenses will continue to grow at a pace of 5.9% on average per year based on the compounding impact of annual wage inflation, technology costs, and future capital initiatives.[110] In this scenario, revenues would increasingly fall behind anticipated costs. While FINRA's reserves may continue to cover the shortfall in the near-term, the reserves will reach their minimum prudent level of one year of operating costs within three to four years based on current projections if no corrective action is taken.

As described above, FINRA funds its regulatory and other related activities through a combination of regulatory fees and use-based fees. GIA, TAF, PA and Branch Office Fees, taken together, represent approximately 69% of 2023 revenues, while use-based fees represent approximately 31% of 2023 revenues. The specific fees that would be increased under this proposal represent approximately 89% of 2023 revenues.[111]

All core regulatory and use-based fees mentioned above are assessed directly to members. FINRA understands that many members shift at least some of the fees to other parties. For instance, it is regular practice among clearing and trading firms to ''pass-through'' the TAF to the underlying firm executing the trade. Further, FINRA understands that the executing firms commonly pass the TAF directly on to their customers submitting orders. Typically, TAF fees are reflected on the confirmation statement received by customers.[112]

Similarly, FINRA understands that many firms regularly pass-through to registered persons assessments such as the PA, registration fees, and qualification examination fees. FINRA understands that there may be

[102] *See* Table 1.2.2 of the FINRA Industry Snapshot, available at *https://www.finra.org/media-center/reports-studies/2024-industry-snapshot.* As FINRA notes when it publishes industry snapshots, FINRA regularly updates historical data series due to data revisions by reporting firms.

[103] *See* Table 2.2.3 of the FINRA Industry Snapshot.

[104] FINRA By-laws define the size of a member firm by the number of associated registered representative as the following: small—150 or fewer registered representatives; mid-size—151 to 500 registered representatives; and large—more than 500 registered representatives. A subgroup of the small firms are known as micro firms, firms with 10 or fewer registered representatives.

[105] As discussed above, cost savings have been accomplished in recent years through expense reduction initiatives, including conducting a comprehensive efficiency review of FINRA's core business lines; establishing a framework for improving measurement of FINRA's key objectives and results; voluntary retirement/incentive programs in 2020 and 2024; and strategic reductions in FINRA's corporate real estate footprint.

[106] *See supra* note 22.

[107] As with Chart 1, all of the charts discussed below are attached in Exhibit 3, available on FINRA's website at *http://www.finra.org.*

[108] The revenues and expenses presented in Chart 2 in terms of Cash Flow Sources and Cash Flow Uses—both historical and projected—do not include subsidiaries other than FINRA Regulation and FINRA Dispute Resolution, which was merged into FINRA Regulation at the end of 2015. Cash Flow Sources includes Operating Revenues, Investment Returns and Fines. Cash Flow Uses includes Operating Expenses and Capital Initiatives.

[109] *See supra* note 12.

[110] As discussed above, FINRA has made reasonably conservative assumptions using a variety of information points, including historical data and anticipated trends. *See supra* note 15. This estimate is based on the following assumptions for FINRA and excludes the independent budgeting of all of FINRA's active subsidiaries other than FINRA Regulation—specifically, FINRA CAT, LLC and the FINRA Investor Education Foundation: (1) wage inflation at an annual rate between 4% and 6%, consistent with the financial industry over the last five years; (2) technology expense growth: capital investments seeking long-term efficiency gains for both FINRA and the industry, rising cloud hosting costs driven by volume increases, maintaining technology labor competitiveness, and ongoing disaster recovery and cybersecurity requirements; and (3) rise in regulatory efforts and associated costs for FINRA's regulatory programs.

[111] Following the implementation of the proposed rule change, GIA, TAF, PA and Branch Office Fees, together, would represent approximately 72% of revenues, while use-based fees would represent approximately 28%.

[112] FINRA conducted a study of a sample of members, which included approximately 25 retail investor focused broker-dealers and approximately 15 institutional investor focused broker-dealers, to better understand practices of TAF pass through. The research found that the majority of the retail focused firms did pass through the TAF to their customers. FINRA does not know the full extent of this practice across all members.

differences in this practice across firms depending on each firms' business model. Competitive markets for the provision of brokerage and related financial intermediation services, along with difficulty in allocating certain fees to specific transactions, can limit the extent to which these fees can be passed-through.

Core regulatory fees are calibrated so that larger, more active and more geographically dispersed members are assessed higher fees, reflecting regulatory resource allocation. Likewise, the use-based fees that are part of core regulatory fees are designed to capture some of the costs associated with core regulatory activities in addition to the direct and indirect costs of the associated services. For example, FINRA believes it is appropriate that registration and qualification examination fees help defray the costs of regulating registered persons because members employing more persons require more regulatory effort on FINRA's part. This approach is consistent with a structure where the fees paid increase with the size of the firm's revenues (GIA) and the amount of trading activity it conducts (TAF). In addition, core regulatory fees tend to be correlated with member size and structure. As such, core regulatory fees are designed cohesively and comprehensively such that they should be evaluated in aggregate and not on a fee-by-fee or service-by-service basis.

The fee structure is also designed, purposefully, to account for diversity in firm size. Compliance and regulatory oversight naturally represent a larger relative cost to small firms. Because FINRA wants to prevent regulatory costs from either creating a barrier to entry for small firms, or over-burdening existing small firms, the current fee structure includes a level of cross-subsidization by larger firms.

FINRA believes that this practice supports two objectives. First, it is important that retail investors have access to diverse types of financial services intermediaries, including members of varying size. For example, some investors may prefer to engage registered persons associated with smaller firms. Second, the extent to which firms benefit from well-regulated markets is relative to firm size. Under well-regulated markets, investors are more willing to trust financial intermediaries because they are confident that they are treated fairly in their access to securities markets and products. Greater participation in the financial markets by investors allows firms to grow larger and become more diversified, leading to cost savings and reduced risk through economies of scale and scope. The concentration in both retail and institutional investor activity at larger firms suggests that larger firms reap substantial benefits from strong regulation and should therefore provide a substantial portion of the fees that support this regulation. At the same time, the impact of widespread misconduct at a larger firm may impair investor confidence more broadly than similar misconduct at a smaller firm. This lends further support to the practice of assessing higher fees on larger firms.

Chart 3 presents the distribution in 2024 of FINRA's regulatory and use-based fee revenue and the proportion of FINRA's examination time, along with the proportion of firms and registered persons, by firm-size category as defined in the FINRA By-Laws.[113] Small firms, including micro firms, account for 89% of the firms in the industry, 10% of total registered persons, 57% of FINRA's total firm examination time, and 12% of FINRA's revenues. Large firms, conversely, represent less than 5% of firms, over 80% of registered persons, 32% of FINRA's firm examination effort, and approximately 67% of FINRA's revenues. The remaining portions of firm examination time and revenues are attributable to mid-size firms.

Chart 4 presents the same measures as in Chart 3 by the business model category. The categories of capital markets and retail firms account for 80% of the firms in the industry, 72% of total registered persons, 55% of FINRA's total examination time, and 33% of FINRA's regulatory and use-based fee revenues.[114] The category of diversified firms, including most of the largest firms, accounts for approximately 5% of firms in the industry, almost 25% of total registered persons, over 27% of FINRA's total examination time, and 44% of FINRA's revenues. The remaining portions are attributable to the category of trading firms and the category of clearing firms.

Economic Impact

FINRA's fee proposal is intended to ensure that FINRA can continue to meet its mission of promoting investor protection and market integrity in a manner that facilitates vibrant capital markets. This proposed rule change preserves FINRA's ability to be a robust and effective SRO, protecting investors from manipulation, exploitation, and other harms. Adequate funding allows FINRA to develop regulatory approaches that are effective and efficient, and to revise its rules through, among other ways, its robust retrospective review process. Through appropriate funding, FINRA will be better situated to adapt to changing markets, market behaviors, and expanding responsibilities. A stable and reliable funding model also permits members to better anticipate and plan for FINRA's fees. These benefits accrue to current and prospective investors, firms, issuers, and others participating in financial intermediation.

FINRA notes that academic literature has provided evidence of the linkage between strong regulation in securities markets and improved outcomes, including more trading, lower transaction costs, and greater investor participation in the markets.[115] Bruggemann, et al. [2018] study the impact of differences in state regulation on OTC stocks. They find that firms issuing in the OTC market subject to stricter regulation are more liquid and are subject to lower ''crash risk.'' Cazier, et al. [2023] examine the effect of the SEC's initiative to prevent fraud in OTC markets by suspending inactive shell companies that could be targeted by market manipulators. The authors find that these suspensions are associated with fraud deterrence among other OTC firms operating within the same regulatory jurisdiction as the suspended firm. Silvers [2016] studies the impact of SEC enforcement actions against foreign cross-listed issuers. He shows evidence that other cross-listed issuers (not cited by the SEC) experienced positive returns, suggesting that increased regulatory attention increases valuation. Silvers [2020] and Lang et al.

[113] The revenue in Charts 3–10 excludes Corporate Financing fees, which are generally passed through to issuers, and a portion of DRS fees that are paid directly by customers. *See supra* note 31. The revenue in these charts also excludes MAP fees, which are incurred irregularly. *See also supra* note 8 and accompanying text.

[114] *See supra* note 113. Here, business model represents the primary type of services provided by the member firm.

[115] *See, e.g.,* U. Bruggemann, A. Kaul, C. Leuz & I. Werner, The Twilight Zone: OTC Regulatory Regimes and Market Quality, 31(3) The Review of Financial Studies, 898–942 (2018); R. Cazier, J. Huang & F. Zhou, Regulatory Spillover Effects in OTC Markets, Review of Accounting Studies, 1–33 (2023); Roger Silvers, The Valuation Impact of SEC Enforcement Actions on Nontarget Foreign Firms, 54 (1) Journal of Accounting Research, 187–234 (2016); Roger Silvers, Cross-Border Cooperation between Securities Regulators, 69 (2–3) Journal of Accounting and Economics, 101301 (2020); M. Lang, M. Maffett, J.D. Omartian & R. Silvers, Regulatory Cooperation and Foreign Portfolio Investment, 138 (1) Journal of Financial Economics 138–158 (2020); H. Christensen, M. Maffett & L. Vollon, Securities Regulation, Household Equity Ownership, and Trust in the Stock Market, 24 (3) Review of Accounting Studies, 824–859 (2019); and D. Aghanya, V. Agarwal & S. Poshakwale. Market in Financial Instruments Directive (MiFID), Stock Price Informativeness and Liquidity, 113 Journal of Banking & Finance, 105730 (2020).

[2020] further show that cross-border cooperation between securities regulators reduces the cost of liquidity provision and increases cross-border investment in the capital markets of participating countries. Finally, Christensen et al. [2019] and Aghanya et al. [2020] study the impact of the introduction of the European Union's Market Abuse Directive and MiFID. These studies conclude that these initiatives, designed to enhance investor protections, have led to higher household ownership of equities, higher liquidity, and higher stock price informativeness.

The proposed rule change would implement fee changes that would maintain the current distribution of total fees allocated across members by size and business model. Based on FINRA's projections of fee increases from 2024 to 2029, approximately 67% of the fee increases would be borne by large firms, 22% by mid-size firms, 9% by small firms, 1% by micro firms and the remaining 1% by non-members.[116]

Chart 5 describes the proportion of regulatory and use-based fees anticipated to be collected under the proposed rule change across firm size categories during the period from 2024 through 2029.[117] In each year, 66%–68% of the fee is expected to be borne by large firms, 16%–17% by mid-size firms, 11%–12% by small firms, approximately 1% by micro firms, and 3–4% by non-members. Therefore, the overall allocation of fees by firm size is expected to remain relatively unchanged with the implementation of the increase in fees.

Chart 6 describes the proportion of regulatory and use-based fees anticipated to be collected across firm business models during the period from 2024 through 2029.[118] In each year, approximately 70% of the fees are expected to be borne by diversified and retail firms, with the remaining fees distributed relatively evenly across trading, capital markets, and clearing firms. As with FINRA's analysis of the proposed fee increases by firm size, the chart demonstrates that the overall allocation by firm business models is expected to remain unchanged with the implementation of the increase in fees.

Taken together, these charts indicate that the proposed fee increases are designed to allocate the growth in fees in an equitable manner, all else held equal, by maintaining a similar allocation of fees across firm sizes and business models, both overall and year-by-year.

As discussed, while potentially material, FINRA fees represent a small dollar amount relative to industry activity. Since 2013, as a percentage of member revenue, FINRA's total fees have ranged between 0.2% and 0.4%, with an average of 0.30%. Under the assumption that members' revenues resume growth at a level commensurate with recent history,[119] FINRA's fees would be 0.31% percent by 2029.[120] This share of member revenue is close to the historical average of 0.30%.

The amount of the fee increase borne by members depends on the extent to which they shift the burden of these fees to their associated persons and customers. As discussed above, FINRA understands that of the fees addressed by this proposal, the fee most likely to be passed through to customers is TAF, which is directly tied to customer trading activities. Despite the pass-through, FINRA believes the proposed TAF increase would not significantly affect customer trading behavior as TAF represents a small proportion of the average value of customer transactions. In 2023, TAF per share traded was 0.031 basis points (0.00031%) of the average price of the traded shares. When the new rates are fully implemented in 2029, TAF per share traded would be approximately 0.058 basis points of the average price of traded shares.[121]

To better understand the impact of the proposed fee increases across members within each firm size category, FINRA analyzed the expected distribution of fee increases for all existing firms under the proposed fee structure, based on the expected rate of dispersion. Dispersion is a way to compare the anticipated growth rate in fees across a range of firms. Lower dispersion is associated with a higher degree of consistency in terms of the impact of the proposed fee increases and can be interpreted as more firms in a given group experiencing similar rates of growth. By seeking to limit dispersion, the proposal is effectively limiting the potential for inequitable treatment across members. This approach also reduces the potential for the proposed fee increase to create unintended impacts on the provision of financial services by members and the business models adopted by them.

FINRA's analysis examines the level of dispersion based on the CAGR of the expected fee increase. CAGR is measured in this analysis relative to FINRA's projection of total fees in 2024.[122] CAGR provides a standard metric to compare the relative impact of the fee increases within and across subgroups. Because the number of registered persons, trading and other business activities, and resulting aggregate fee dollar amounts vary significantly across firms and firm sizes, benchmarking to CAGR permits FINRA to closely compare the magnitude of the distribution across firms.

As discussed, implementation of the proposed rule change would take place over several years, with a minority of fees going into effect in 2025, most fees implemented in 2026 or later, and several fees phased in over several years between 2025 and 2029. Due to the variability in when fees are implemented, and whether they are implemented at one time or phased in, FINRA believes that considering dispersion by firm size category over the five-year period is more useful than on an annual basis.

Charts 7 through 10 provide a view on the distribution of fee increases within each firm size category. These charts also report the median increase in FINRA fees that are the subject of this proposal over the full period from 2025 through 2029 by firm size. Within the charts, each of the four central bars represents one standard deviation from the median, so that the two most central dark blue bars together would theoretically represent approximately 67% of all firms evaluated (plus or minus one standard deviation) and approximately 95% of firms evaluated should be represented under the four most central dark blue and mid-blue bars (plus or minus two standard deviations) presented in the charts.

While it is not feasible to eliminate the possibility that some members will experience a rate of fee growth that is outside of the two standard deviation range, FINRA sought to limit the number of firms falling into this category when structuring this proposal. These charts demonstrate that the proposal significantly limits the number of firms that fall beyond two standard deviations from the median increase. In particular, the proposal limits those

[116] The firm size categories are defined above, *see supra* note 104.

[117] *See supra* note 113.

[118] *See supra* note 113.

[119] This 2029 industry revenue projection is based on historical FOCUS revenue growth of 8.5% (2013–2023).

[120] *See supra* note 33 and accompanying text.

[121] The average share price estimate is based on the number of shares and dollar trading volume from CBOE. *See https://www.cboe.com/data_and_access_solutions* for details.

[122] We exclude firms that are not assessed GIA in the base year from CAGR distribution analysis. Since GIA in the base year drives the denominator of the CAGR formula, firms that are not assessed GIA would have inflated CAGRs by construction. Therefore, we exclude these firms to ensure that the tails of our distribution reflect a more accurate measure of fee growth.

firms that would be expected to experience a materially higher fee increase than the median (as defined by two standard deviations). When considering all the fees in this proposal, FINRA estimates that fewer than 2.5% of members would experience a fee increase greater than two standard deviations from the median. When only core regulatory fees are considered (*i.e.,* excluding select use-based fees that only impact the users of those programs or services) fewer than 1% of firms would experience a fee increase greater than two standard deviations from the median.[123]

Based on this analysis, FINRA concludes the following:

- For micro firms, the median firm would anticipate an annual increase of 3.4%, translating to a dollar increase of $625. Approximately three-quarters of these firms would experience an annual increase between 1.4% and 5.4% between 2025 and 2029. Holding revenues constant at 2024 levels, total regulatory and use-based fees would increase from 0.26% to 0.31% of FOCUS reported revenues on average. This group includes 1,538 firms and represents 46.5% of all FINRA members.
- For other small firms, the median firm would anticipate an annual increase of 3.9%, translating to a dollar increase of approximately $4,135. Approximately 80% of these firms would experience an annual increase in fees between 1.3% and 6.4% between 2025 and 2029. Holding revenues constant at 2024 levels, total regulatory and use-based fees would increase from 0.23% to 0.29% of FOCUS reported revenues on average. This group includes 1,414 firms and represents 42.8% of all FINRA members.
- For mid-size firms, the median firm would anticipate a 5% annual increase, translating to a dollar increase of approximately $82,500. Approximately three-quarters of these firms would experience an annual increase between 2.9% and 7.1% between 2025 and 2029. Holding firm revenues constant at 2024 levels, total regulatory and use-based fees would increase from 0.26% to 0.36% of FOCUS reported revenues on average. This group includes 212 firms and represents 6.4% of all FINRA members.
- For large firms, the median firm would anticipate a 5.4% annual increase, translating to a dollar increase of approximately $415,000. Approximately three-quarters of these firms would experience an annual increase between 4.0% and 6.9% between 2025 and 2029. Holding revenues constant at 2024 levels, total regulatory and use-based fees would increase from 0.18% to 0.23% of FOCUS reported revenues on average. This group includes 141 firms and represents 4.3% of all FINRA members.

FINRA notes that 1.7% of micro firms would experience a fee increase greater than two standard deviations above the median. Because the median increase is relatively low ($625), small dollar increases in fees can result in a large change in CAGR and its distribution.

FINRA also notes that the 2.5% of small firms that would experience a fee increase greater than two standard deviations are mostly firms that would incur new or increased use-based fees for FINRA services that are not core regulatory activities. If only core regulatory fees are considered, only 1.1% of small firms would experience a fee increase greater than two standard deviations from the median increase.

The 2.4% of mid-size firms that would experience a fee increase greater than two standard deviations above the median are mostly firms that incur a significant increase in TAF. If TAF is excluded, only 1.4% of mid-size firms would experience a fee increase greater than two standard deviations from the median increase. As mentioned above, FINRA understands that the TAF is typically passed-through to customers.

As part of its analysis, FINRA also considered the broad potential impacts on competition under this proposal. The analysis considers the impact across all FINRA members, across members based on size or business model, and between members and other financial services providers.

FINRA does not anticipate that the proposal will materially impact competition among members. The proposal is designed to maintain the current funding model and the relative allocation of fees across its core regulatory fees and select use-based fees. In other words, each of the affected fees would increase commensurate with fees charged under the current framework; no individual fee would be raised such that it may create inordinate hardships for some firms and benefit others. Implementation of the proposed rule change would not require significant system or process changes by firms.

Similarly, FINRA does not anticipate that the proposed rule change will materially impact competition across members of different sizes or business models. The analysis of distributions within firm size indicates that firms may anticipate some differences in fee increases based on the services they provide and the way they provide those services. Nevertheless, as designed, the proposal maintains the relative allocation of fees across firm size and business model, meaning the proposed rule change is designed to preserve a consistent rate of growth in fee increases across firm size and business model. As noted above, this approach is designed to limit the likelihood that any specific fee change may create hardships for some firms and benefit others. Further, this proposed rule change maintains the current approach for cross-subsidization of the cost of regulatory oversight of members of different sizes.

FINRA can identify two potential impacts of this proposal on the competition between its members and other providers of financial services. Although these increases are calibrated to limit the impact on individual members, at the margin, some members may find these increases material to their business. Further, where members may have the ability to provide similar services, or a subset of services, under an alternative business model that does not require FINRA membership, increased FINRA costs may increase the likelihood that these firms withdraw from FINRA in favor of the alternative business model. Based on the information available to it today, FINRA does not have an accurate measure of the number of members that may choose to withdraw registration as a FINRA member as a result of this proposed rule change.[124]

The proposed rule change may have an additional impact on competition through funding FINRA's regulatory activities. As discussed above, strong and effective surveillance and regulation of securities markets has been shown to increase investor confidence in the fairness of the market. This has been measured by an increase in retail participation in the securities markets, greater liquidity, and higher securities valuations. Given the presence of substitutes to broker-dealers for retail clients—*e.g.,* investment advisory services, issuers selling directly to the public, or certain market-linked insurance products—it may be reasonable to expect that effective regulation by FINRA would continue to

[123] As discussed above, the select use-based fees include Corporate Financing Private Placement Review; Corporate Financing Public Offering Review; Advertising Regulation Review; DRS Arbitration; and Regulation T and Exchange Act Rule 15c3–3(n) Requests for Extension of Time. *See supra* note 24.

[124] FINRA notes that because of the time lapse between proposal, adoption and implementation of fee increases, combined with changing business environments over time, it is difficult to reliably estimate the number of firms that might have exited historically because of previous fee increases.

be a positive externality to those competitors. That is, increased confidence by retail investors due to FINRA's activities may increase business opportunities and lower transaction costs in the securities industry as a whole. This would benefit non-FINRA member competitors, especially in instances where investors do not recognize these competitors are not regulated by FINRA.

Alternatives Considered

In developing this proposal, FINRA considered several options. First, FINRA considered making all the fee changes effective in 2025. FINRA did not pursue this alternative because it believed that, where possible, members should be provided an extended time period to plan for the proposed fee increase. In light of uncertainty and volatility in the markets, FINRA believes that implementing the proposed fee increase at one time would impose a greater burden on members than phasing in the implementation of the fee increases, as proposed.

FINRA also considered making all of the fee changes effective in 2026, but decided against that approach for many of the same reasons noted above. However, FINRA believes that deferring implementation of all fees in this proposed rule change is unnecessary and would hinder FINRA's ability to support its regulatory mission. As discussed, the uncertainty in the markets, which creates challenges for members and investors, also impacts FINRA. For example, market volatility increases the risk that FINRA's reserve portfolio will fall below the appropriate minimum.[125] This limits FINRA's flexibility in relying on its reserves to cover funding gaps and indicates the need for stable funding as soon as practicable.

Further, FINRA notes that consistent investor protection is of vital importance, particularly in times of uncertainty, where FINRA has seen an increase in customer complaints and alerts from its surveillance programs.[126] Financial limitations that constrain FINRA's ability to carry out its mission would have material negative implications for investors and the financial markets. Taking these concerns into account, FINRA believes that the most prudent course of action is to start increasing some fees in 2025, but to stagger the implementation over multiple years.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[127] and paragraph (f)(2) of Rule 19b–4 thereunder.[128] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–FINRA–2024–019 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–FINRA–2024–019. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of FINRA. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection.

All submissions should refer to file number SR–FINRA–2024–019 and should be submitted on or before December 18, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[129]

Sherry R. Haywood,

Assistant Secretary.

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[125] *See supra* note 12.

[126] In the first quarter of 2020, FINRA saw an increase in alerts generated through its market surveillance of over 250% compared to the same quarter in 2019.

[127] 15 U.S.C. 78s(b)(3)(A).

[128] 17 CFR 240.19b–4(f)(2).

[129] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101690; File No. SR–NASDAQ–2024–067]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Fees for Connectivity and Co-Location Services

November 21, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 8, 2024, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's fees for connectivity and co-location services, as described further below.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/nasdaq/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the Exchange's fees relating to connectivity and co-location services.[3] Specifically, the Exchange proposes a one-time adjustment to raise its fees for connectivity and co-location services in General 8, fees assessed for remote multi-cast ITCH (''MITCH'') Wave Ports in Equity 7, Section 115, and certain fees related to Nasdaq Testing Facilities in Equity 7, Section 130 by 10%, with certain exceptions.

General 8, Section 1 includes the Exchange's fees that relate to connectivity, including fees for cabinets, external telco/inter-cabinet connectivity fees, fees for connectivity to the Exchange, fees for connectivity to third party services, fees for market data connectivity, fees for cabinet power install, and fees for additional charges and services. General 8, Section 2 includes the Exchange's fees for direct connectivity services, including fees for direct circuit connection to the Exchange, fees for direct circuit connection to third party services, and fees for point of presence connectivity. With the exceptions of the Exchange's GPS Antenna fees and the Cabinet Proximity Option Fee for cabinets with power density >10kW,[4] the Exchange proposes to increase its fees throughout General 8 by 10%.

In addition to increasing fees in General 8, the Exchange also proposes to increase certain fees in Equity 7. First, the Exchange proposes to increase the installation and recurring monthly fees assessed for remote MITCH Wave Ports[5] in Equity 7, Section 115(g)(1) by 10%. In addition, the Exchange proposes to increase certain fees in Section 130(d), which relate to the Nasdaq Testing Facility. Equity 7, Section 130(d)(1)(C) provides that subscribers to the Nasdaq Testing Facility (''NTF'') located in Carteret, New Jersey shall pay a fee of $1,000 per hand-off, per month for connection to the NTF. The hand-off fee includes either a 1Gb or 10Gb switch port and a cross connect to the NTF. In addition, Equity 7, Section 130(d)(1)(C) provides that subscribers shall also pay a one-time installation fee of $1,000 per hand-off. The Exchange proposes to increase these aforementioned fees by 10% to require that subscribers to the NTF shall pay a fee of $1,100 per hand-off, per month for connection to the NTF and a one-time installation fee of $1,100 per hand-off.

The proposed increases in fees would enable the Exchange to maintain and improve its market technology and services to remain competitive with its peers. Over the years, customer demand for more sophisticated, higher-throughput, lower-latency, and higher-power connectivity solutions has increased. The Exchange continues to invest in maintaining, improving, and enhancing its connectivity and co-location products, services, and facilities—for the benefit and often at the behest of its customers. Such enhancements include refreshing hardware and expanding Nasdaq's existing co-location facility to offer customers additional space and power. Nevertheless, and with the exception of fees that were established as part of a new service in 2017 (and have remained unchanged since their adoption), the Exchange has not increased any of the fees included in the proposal since prior to 2017, and many of the fees date back to between 2010 and 2014. For each of the connectivity products and services that pre-date 2017, inflation (as measured using the ''Data PPI'' metric described below) has been between roughly 15–17%, and in no instance has such inflation been less than 10%. Nevertheless, the Exchange proposes to increase its fees only with respect to the 10% inflation that has occurred since 2017.

As discussed below, the Exchange proposes to adjust its fees by an industry- and product-specific inflationary measure. It is reasonable and consistent with the Act for the Exchange to recoup its investments, at least in part, by adjusting its fees. Continuing to operate at fees frozen at 2010–2017 levels impacts the Exchange's ability to enhance its offerings and the interests of market participants and investors.

The fee increases the Exchange proposes are based on an industry-specific Producer Price Index (''PPI''), which is a tailored measure of inflation.[6] As a general matter, the Producer Price Index is a family of indexes that measures the average change over time in selling prices received by domestic producers of goods and services. PPI measures price change from the perspective of the seller. This contrasts with other metrics, such as the Consumer Price Index (''CPI''), that measure price change from the purchaser's perspective.[7] About 10,000 PPIs for individual products and groups of products are tracked and released each month.[8] PPIs are available for the output of nearly all industries in the goods-producing sectors of the U.S. economy—mining, manufacturing,

[3] The Exchange initially filed the proposed pricing change on March 1, 2024 (SR–NASDAQ–2024–008). On April 29, 2024, the Exchange withdrew that filing and submitted SR–NASDAQ–2024–020. The Exchange withdrew SR–NASDAQ–2024–020 on June 27, 2024 and replaced it with SR–NASDAQ–2024–032. The Exchange withdrew SR–NASDAQ–2024–032 and replaced it with SR–NASDAQ–2024–053 on September 10, 2024. On October 11, 2024, the Exchange replaced SR–NASDAQ–2024–053 with SR–NASDAQ–2024–060. The instant filing replaces SR–NASDAQ–2024–060.

[4] The Exchange proposes to exclude the GPS Antenna fees from the proposed fee increase because, unlike the other fees in General 8, the Exchange recently increased its GPS Antenna fees. *See* Securities Exchange Act Release No. 34–99126 (December 8, 2023), 88 FR 86712 (December 14, 2023) (SR–NASDAQ–2023–052). The Exchange also proposes to exclude the Cabinet Proximity Option Fee for cabinets with power density >10kW from the proposed fee increase because the Exchange recently established such fee. *See* Securities Exchange Act Release No. 34–99796 (March 20, 2024), 89 FR 21088 (March 26, 2024) (SR–NASDAQ–2024–013). Similarly, the Exchange proposes to exclude from the proposed fee increase those fees that the Exchange recently established for services in its new NY11–4 expansion facility. *See* Securities Exchange Act Release No. 34–101267 (October 7, 2024), 89 FR 82666 (October 11, 2024) (SR–NASDAQ–2024–056).

[5] Remote MITCH Wave Ports are for clients co-located at other third-party data centers, through which NASDAQ TotalView ITCH market data is distributed after delivery to those data centers via wireless network.

[6] *See https://fred.stlouisfed.org/series/PCU51825182#0.*

[7] *See https://www.bls.gov/ppi/overview.htm.*

[8] *See Id.*

agriculture, fishing, and forestry—as well as natural gas, electricity, and construction, among others. The PPI program covers approximately 69 percent of the service sector's output, as measured by revenue reported in the 2017 Economic Census.

For purposes of this proposal, the relevant industry-specific PPI is the Data Processing and Related Services PPI (''Data PPI''), which is an industry net-output PPI that measures the average change in selling prices received by companies that provide data processing services.

The Data PPI was introduced in January 2002 by the Bureau of Labor Statistics (''BLS'') as part of an ongoing effort to expand Producer Price Index coverage of the services sector of the U.S. economy and is identified as NAICS—518210 in the North American Industry Classification System.[9] According to the BLS ''[t]he primary output of NAICS 518210 is the provision of electronic data processing services. In the broadest sense, computer services companies help their customers efficiently use technology. The processing services market consists of vendors who use their own computer systems—often utilizing proprietary software—to process customers' transactions and data. Companies that offer processing services collect, organize, and store a customer's transactions and other data for record-keeping purposes. Price movements for the NAICS 518210 index are based on changes in the revenue received by companies that provide data processing services. Each month, companies provide net transaction prices for a specified service. The transaction is an actual contract selected by probability, where the price-determining characteristics are held constant while the service is repriced. The prices used in index calculation are the actual prices billed for the selected service contract.'' [10]

The Exchange believes the Data PPI is an appropriate measure to be considered in the context of the proposed rule change to modify the fee for its connectivity products because the Exchange uses its ''own computer systems'' and ''proprietary software,'' *i.e.,* its own data center and proprietary matching engine software, respectively, to collect, organize, store and report customers' transactions in U.S. equity securities on the Exchange's proprietary trading platform. In other words, the Exchange is in the business of data processing and related services.

For purposes of this proposed rule change, the Exchange examined the Data PPI value for the period from January 2017 to August 2024. The Data PPI had a starting value of 105.6 in January 2017 and an ending value of 116.022 in August 2024, a 10.422% increase. This indicates that companies who are also in the data storage and processing business have generally increased prices for a specified service covered under NAICS 518210 by an average of 10.422% during this period. Based on that percentage change, the Exchange proposes to make a one-time fee increase of only 10%, which reflects an increase covering roughly the entire period since the last price adjustments to these fees were made.

The Exchange further believes the Data PPI is an appropriate measure for purposes of the proposed rule change on the basis that it is a stable metric with limited volatility, unlike other consumer-side inflation metrics. In fact, the Data PPI has not experienced a greater than 2.16% increase for any one calendar year period since Data PPI was introduced into the PPI in January 2002. The average calendar year change from January 2002 to December 2023 was .62%, with a cumulative increase of 15.67% over this 21-year period. The Exchange believes the Data PPI is considerably less volatile than other inflation metrics such as CPI, which has had individual calendar-year increases of more than 6.5%, and a cumulative increase of over 73% over the same period.[11]

The Exchange believes the Data PPI, and significant investments into, and enhanced performance of, the Exchange support the reasonableness of the proposed fee increases.[12]

These proposed fee increases will be immediately effective upon filing. However, going forward and until December 1, 2024, the Exchange will waive all fees set forth herein to the extent that such fees exceed the levels that would have been charged for the same products and services purchased during that time period, had such fees been calculated at the rates set forth in SR–NASDAQ–2024–053 (*i.e.,* pricing reflective of a 5.5% increase from prior fee levels). This waiver is reasonable, equitable, and not unfairly discriminatory because it will afford all customers in excess of the 30-day prior notice period for fee changes set forth in the Exchange's service terms.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[13] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[14] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

This belief is based on two factors. First, the current fees do not properly reflect the quality of the services and products, as fees for the services and products in question have been static in nominal terms, and therefore falling in real terms due to inflation. Second, the Exchange believes that investments made in enhancing the capacity and speed of Exchange systems increase the performance of the services and products.

The Proposed Rule Change Is Reasonable

As noted above, the Exchange has not increased any of the fees included in the proposal since 2017 or earlier. However, in the years following the last fee increases, the Exchange has made significant investments in upgrades to its connectivity products, services, and facilities, enhancing the quality of its services. In other words, Exchange customers have greatly benefitted, while the Exchange's ability to recoup its investments has been hampered. Between 2017 and 2024, the inflation rate is 3.64% per year, on average, producing a cumulative inflation rate of 28.43%.[15] Using the more targeted inflation number of Data PPI, the cumulative inflation rate was 10.422%. The exchange believes the Data PPI is a reasonable metric to base this fee increase on because it is targeted to producer-side increases in the data processing industry.

Notwithstanding inflation, as noted above, the Exchange has not increased

[9] *NAICS appears in table 5 of the PPI Detailed Report and is available at https://data.bls.gov/timeseries/PCU518210518210.*

[10] *See https://www.bls.gov/ppi/factsheets/producer-price-index-for-the-data-processing-and-related-servicesindustry-naics-518210.htm.*

[11] *See https://www.usinflationcalculator.com/inflation/consumer-price-index-and-annual-percent-changesfrom-1913-to-2008/.*

[12] *See supra* discussion of connectivity product and facility improvements. Additionally, other exchanges have filed for increases in certain fees, based in part on comparisons to inflation. *See, e.g.,* Securities Exchange Act Release Nos. 34–100004 (April 22, 2024), 89 FR 32465 (April 26, 2024) (SR–CboeBYX–2024–012); and 34–100398 (June 21, 2024), 89 FR 53676 (June 27, 2024) (SR–BOX–2024–16); Securities Exchange Act Release No. 34–100994 (September 10, 2024), 89 FR 75612 (September 16, 2024) (SR–NYSEARCA–2024–79).

[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(4) and (5).

[15] *See https://www.officialdata.org/us/inflation/2017?amount=1.*

its fees at all for over seven years for the subject services. The proposed fee changes represent a modest increase from the current fees. The Exchange believes the proposed fee increase is reasonable in light of the Exchange's continued expenditure in maintaining a robust technology ecosystem. Furthermore, the Exchange continues to invest in maintaining and enhancing its connectivity products—for the benefit and often at the behest of its customers and global investors. Such enhancements include refreshing all aspects of the technology ecosystem including software, hardware, and network while introducing new and innovative products and expanded and modernized facilities.[16] The goal of the enhancements discussed above, among other things, is to provide faster, higher-capacity, and more modern connectivity products and services. Accordingly, the Exchange continues to expend resources to innovate and modernize technology so that it may benefit its members in offering its connectivity products and services.

The Proposed Fees Are Equitably Allocated and Not Unfairly Discriminatory

The Exchange believes that the proposed fee increases are equitably allocated and not unfairly discriminatory because they would apply to all market participants that choose to purchase connectivity products and services from the Exchange. Any participant that chooses to purchase the Exchange's connectivity products and services would be subject to the same Fee Schedule, regardless of what type of business they operate or the use they plan to make use of the products and services. Additionally, the fee increase would be applied uniformly to market participants without regard to Exchange membership status or the extent of any other business with the Exchange or affiliated entities. The Exchange also believes that the proposal represents an equitable allocation of reasonable dues, fees and other charges because Exchange fees have fallen in real terms during the relevant period. Finally, the Exchange believes that the proposed fee changes are not unfairly discriminatory because the fees would be assessed uniformly across all market participants, in the same manner they are today, that voluntarily purchase the Exchange's connectivity products and services, which would remain available for purchase by all market participants.

These proposed fee increases will be immediately effective upon filing. However, going forward and until December 1, 2024, the Exchange will waive all fees set forth herein to the extent that such fees exceed the levels that would have been charged for the same products and services purchased during that time period, had such fees been calculated at the rates set forth in SR–NASDAQ–2024–053 (*i.e.,* pricing reflective of a 5.5% increase from prior fee levels). This waiver is reasonable, equitable, and not unfairly discriminatory because it will afford all customers in excess of the 30-day prior notice period for fee changes set forth in the Exchange's service terms.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed fees will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Intramarket Competition

The Exchange believes that the proposed fees do not put any market participants at a relative disadvantage compared to other market participants. As noted above, the fee schedule would continue to apply to all purchasers of the Exchange's connectivity products and services in the same manner as it does today albeit at inflation-adjusted rates for certain fees, and customers may choose whether to purchase these products and services at all. The Exchange also believes that the level of the proposed fees neither favor nor penalize one or more categories of market participants in a manner that would impose an undue burden on competition. Likewise, the proposed fee waiver described above will apply to all purchasers of the Exchange's connectivity products and services in the same manner and therefore will not burden competition among them.

Intermarket Competition

The Exchange believes that the proposed fees do not impose a burden on competition or on other SROs that is not necessary or appropriate. In determining the proposed fees, the Exchange utilized an objective and stable metric with limited volatility. Utilizing Data PPI over a specified period of time is a reasonable means of recouping the Exchange's investment in maintaining and enhancing its connectivity products, services, and facilities. The Exchange believes utilizing Data PPI, a tailored measure of inflation, to increase certain fees for connectivity products and services to recoup the Exchange's investment in maintaining and enhancing such products, services, and its facilities would not impose a burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[17]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–NASDAQ–2024–067 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NASDAQ–2024–067. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the

[16] *See, e.g.,* Securities Exchange Act Release No. 34–101078 (September 18, 2024), 89 FR 77937 (September 2024, 2024) (SR–NASDAQ–2024–054 (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Expand [the Exchange's] Co-Location Services).

[17] 15 U.S.C. 78s(b)(3)(A)(ii).

submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NASDAQ–2024–067 and should be submitted on or before December 18, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–27759 Filed 11–26–24; 8:45 am]

BILLING CODE 8011–01–P

[18] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101675; File No. SR–FICC–2024–802]

Self-Regulatory Organizations; Fixed Income Clearing Corporation; Notice of No Objection To Advance Notice, as Modified by Partial Amendment No. 1, To Modify the GSD Rules (i) Regarding the Separate Calculation, Collection and Holding of Margin for Proprietary Transactions and That for Indirect Participant Transactions, and (ii) To Address the Conditions of Note H to Rule 15c3–3a

November 21, 2024.

On March 14, 2024, Fixed Income Clearing Corporation (''FICC'') filed with the Securities and Exchange Commission (''Commission'') advance notice SR–FICC–2024–802 pursuant to Section 806(e)(1) of Title VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act entitled the Payment, Clearing, and Settlement Supervision Act of 2010 (''Clearing Supervision Act'') [1] and Rule 19b–4(n)(1)(i) under the Securities Exchange Act of 1934 (''Exchange Act'').[2] In the advance notice, FICC proposes to modify its Government Securities Division (''GSD'') Rulebook (''GSD Rules'') to calculate, collect, and hold margin for transactions that a direct GSD participant enters into for its own benefit (''proprietary transactions'') separately from margin a direct participant submits to FICC on behalf of indirect participants, and to address conditions of Note H to Rule 15c3–3a under the Exchange Act (''Advance Notice'').[3] The Advance Notice was published for public comment in the **Federal Register** on March 28, 2024.[4] Upon publication of notice of filing of the advance notice, the Commission extended the review period of the advance notice for an additional 60 days because the Commission determined that the advance notice raised novel and complex issues.[5]

On April 24, 2024, the Commission requested additional information from FICC pursuant to Section 806(e)(1)(D) of the Clearing Supervision Act, which tolled the Commission's period of review of the advance notice until 120 days from the date the information requested by the Commission was received by the Commission.[6] On June 25, 2024, the Commission received FICC's response to the Commission's request for additional information.[7] On September 24, 2024, the Commission requested additional information from FICC pursuant to Section 806(e)(1)(D) of the Clearing Supervision Act, which tolled the Commission's period of review of the advance notice until 120 days from the date the information requested by the Commission was received by the Commission.[8] On October 21, 2024, the Commission received FICC's response to the Commission's September 24, 2024 request for additional information.[9] On October 25, 2024, FICC filed Partial Amendment No. 1 to the Advance Notice.[10] The Advance Notice, as modified by Partial Amendment No. 1, is referred to herein as the ''Advance Notice.''

The Commission has received comments regarding the substance of the Advance Notice.[11] The Commission

[1] 12 U.S.C. 5465(e)(1).

[2] 17 CFR 240.19b–4(n)(1)(i).

[3] *See* Securities Exchange Act Release No. 99149 (Dec. 13, 2023), 89 FR 2714 (Jan. 16, 2024) (S7–23–22) (''Adopting Release,'' and the rules adopted therein as ''Treasury Clearing Rules''). *See also* 17 CFR 240.15c3–3a.

[4] Securities Exchange Act Release No. 99845 (Mar. 22, 2024), 89 FR 21586 (Mar. 28, 2024) (File No. SR–FICC–2024–802) (''Notice of Filing''). On March 14, 2024, FICC filed the advance notice as a proposed rule change with the Commission pursuant to Section 19(b)(1) of the Exchange Act, 15 U.S.C. 78s(b)(1), and Rule 19b–4 thereunder, 17 CFR 240.19b–4. Securities Exchange Act Release No. 99844 (March 22, 2024), 89 FR 21603 (Mar. 28, 2024) (File No. SR–FICC–2024–007) (''Proposed Rule Change''). On April 24, 2024, the Commission designated a longer period within which to approve, disapprove, or institute proceedings to determine whether to approve or disapprove the proposed rule change, pursuant to section 19(b)(2) of the Exchange Act, 15 U.S.C. 78s(b)(2)(ii). Securities Exchange Act Release No. 100022 (Apr. 24, 2024), 89 FR 34289 (Apr. 30, 2024) (File No. SR–FICC–2024–007). On June 21, 2024, the Commission published in the **Federal Register** an Order Instituting Proceedings to determine whether to approve or disapprove the proposed rule change. Securities Exchange Act Release No. 100401 (Jun. 21, 2024), 89 FR 53690 (Jun. 27, 2024) (File No. SR–FICC–2024–007). On September 18, 2024, the Commission designated a longer period for Commission action on the proceedings to determine whether to disapprove the proposed rule change, until November 10, 2024. Securities Exchange Act Release No. 101082 (Sep. 18, 2024), 89 FR 77949 (Sep. 24, 2024) (File No. SR–FICC–2024–007). On October 25, 2024, FICC filed Partial Amendment No. 1 to the Proposed Rule Change. Securities Exchange Act Release No. 101454 (Oct. 28, 2024), 89 FR 87441 (Nov. 1, 2024) (File No. SR–FICC–2024–007).

[5] Pursuant to Section 806(e)(1)(H) of the Clearing Supervision Act, the Commission may extend the review period of an advance notice for an additional 60 days, if the changes proposed in the advance notice raise novel or complex issues, subject to the Commission providing the financial market utility (''FMU'') with prompt written notice of the extension.12 U.S.C. 5465(e)(1)(H); *see supra* note 4, at 21602 (explaining the Commission's rationale for determining that the proposed changes in the advance notice raise novel and complex issues).

[6] *See* 12 U.S.C. 5465(e)(1)(D). A memo regarding the Request for Additional Information and the tolled period of review is *available at https://www.sec.gov/comments/sr-ficc-2024-802/srficc2024802-462751-1210414.pdf.*

[7] *See* 12 U.S.C. 5465(e)(1)(E)(ii) and (G)(ii). A memo regarding receipt of FICC's response to the Request for Additional Information is *available at https://www.sec.gov/comments/sr-ficc-2024-802/srficc2024802-494123-1433426.pdf.*

[8] *See* 12 U.S.C. 5465(e)(1)(D). A memo regarding the Request for Additional Information and the tolled period of review is *available at https://www.sec.gov/comments/sr-ficc-2024-802/srficc2024802-524215-1504462.pdf.*

[9] *See* 12 U.S.C. 5465(e)(1)(E)(ii) and (G)(ii). A memo regarding receipt of FICC's response to the Request for Additional Information is *available at https://www.sec.gov/comments/sr-ficc-2024-802/srficc2024802-539295-1544222.pdf.*

[10] Securities Exchange Act Release No. 101455 (Oct. 28, 2024), 89 FR 87449 (Nov. 1, 2024) (File No. SR–FICC–2024–802) (''Notice of Partial Amendment'').

[11] Comments on the Advance Notice are *available at https://www.sec.gov/comments/sr-ficc-2024-802/srficc2024802.htm.* Comments on the Proposed Rule Change are *available at https://www.sec.gov/comments/sr-ficc-2024-007/srficc2024007.htm.* Because the proposals contained in the Proposed Rule Change and the Advance Notice are the same, the Commission considers all comments received on the proposal, regardless of whether the comments are submitted with respect to the Advance Notice or the Proposed Rule Change. The

Continued

also received a letter from FICC responding to the comments.[12] This publication serves as notice of no objection to the Advance Notice.

I. Description of the Advance Notice

A. Background and Terminology

FICC, through its GSD, is a central counterparty and provider of clearance and settlement services for the U.S. government securities markets. As a central counterparty in the U.S. government securities markets, FICC novates transactions between two counterparties, effectively becoming the buyer to every seller and the seller to every buyer, and guarantees the settlement of the novated transactions. This means that FICC is exposed to a number of risks arising from such transactions, including counterparty credit risk. FICC seeks to maintain sufficient resources (*i.e.,* margin) to cover its credit exposures to its participants fully with a high degree of confidence and mitigate potential losses from a default of a direct GSD participant, which is generally referred to as a Netting Member under the GSD Rules[13] (and in this Notice of No Objection).

On December 13, 2023, the Commission adopted amendments to the standards applicable to covered clearing agencies that clear transactions in U.S. Treasury securities (''Treasury CCAs''), such as FICC.[14] These amendments require Treasury CCAs to establish, implement, maintain, and enforce written policies and procedures reasonably designed to, among other things, calculate, collect, and hold margin for direct participants' proprietary positions separately and independently from margin calculated, collected, and held for indirect participants that rely on the services provided by the direct participant to access the Treasury CCA's payment, clearing, or settlement facilities.[15] The Commission also amended its broker-dealer customer protection rule (''Rule 15c3–3'')[16] and the customer and proprietary accounts of broker-dealer (''PAB'') reserve formulas thereunder (''Rule 15c3–3a'')[17] to permit margin required and on deposit with Treasury CCAs to be included under certain conditions as a debit in the reserve formulas.[18]

The GSD Rules describe how FICC provides clearance and settlement services to both direct participants and indirect participants, the latter of which rely on the services provided by direct participants to access FICC's clearance and settlement facilities. Currently, the GSD Rules allow indirect participants to access GSD's clearing services through a Netting Member (that is, a direct participant) via two models: the correspondent clearing/prime broker services[19] and the Sponsored Service.[20] The primary difference between the two models is that an indirect participant who becomes a Sponsored Member via the Sponsored Service model must establish an indirect, limited purpose FICC membership, whereas the correspondent clearing/prime broker services do not require an indirect member to establish any relationship with FICC.[21]

The correspondent clearing/prime broker services allow a Netting Member to submit eligible transactions to FICC on behalf of an indirect participant (referred to as the ''Executing Firm''), record these transactions in the same account as the proprietary transactions that the Netting Member (referred to as a ''Submitting Member'') enters into for its own benefit, and net the indirect participants' transactions against the Netting Member's proprietary transactions for purposes of calculating the Netting Member's margin requirements. Unlike the Sponsored Service, FICC has no relationship with the Executing Firm, and all obligations (*i.e.,* margin and settlement) under the GSD Rules remain with the Submitting Member.[22]

Under a proposed rule change being approved concurrently, FICC is renaming the prime broker/correspondent clearing model to be known as the Agent Clearing Service and providing further specificity around the operation of that service.[23] In that service, the Netting Member which serves as the direct participant to FICC would be referred to as the Agent Clearing Member, and the indirect participant would be referred to as an Executing Firm Customer. An Executing Firm Customer would have no direct relationship to FICC. This separate change would require that a Netting Member using the Agent Clearing Service submit transactions for Executing Firm Customers through an Agent Clearing Member Omnibus Account, to be recorded separately from its other clearing activity, including its proprietary activity. It would also add a definition for transactions eligible to be submitted by an Agent Clearing Member on behalf of its Executing Firm Customers (''Agent Clearing Transactions'').

In addition, in the Sponsored Service, both currently and in a concurrently approved proposed rule change,[24] Netting Members that are approved to be Sponsoring Members are able to sponsor certain indirect participants, referred to as Sponsored Members, into GSD membership and submit transactions on behalf of those Sponsored Members. A Sponsored Member is the legal counterparty to FICC for any submitted transactions.[25] However, the Sponsoring Member unconditionally guarantees to FICC the Sponsored Member's performance under a Sponsoring Member Guaranty, which guarantees to FICC the payment and performance of a Sponsored Member's obligations to FICC.[26] Therefore, reliance upon the Sponsoring Member Guaranty necessarily involves FICC's reliance upon the financial resources of the Sponsoring Member.

Unlike the correspondent clearing/prime broker services, transactions by the Sponsoring Member's Sponsored Members (''Sponsored Member Trades'') are not netted, for margining purposes, against transactions of the Sponsoring Member or another Sponsored Member. Instead, FICC records Sponsored Member Trades in a Sponsored Member Omnibus Account, and calculates margin requirements for each Sponsored Member individually on a gross basis (*i.e.,* without netting their transactions against transactions of the Sponsoring

comment letters to the Proposed Rule Change and Advance Notice also contained comments on the substance of another FICC proposed rule change, FICC–2024–005. The Commission will only be addressing comments relevant to this proposal and will address the comments on the other proposed rule change in a separate order.

[12] *See* Letter from Laura Klimpel, Managing Director, Head of Fixed Income and Financing Solutions, Depository Trust & Clearing Corporation, (Aug. 1, 2024) (''FICC Letter'').

[13] The GSD Rules are *available at https://www.dtcc.com/~/media/Files/Downloads/legal/rules/ficc_gov_rules.pdf.* Terms not otherwise defined herein are defined in the GSD Rules.

[14] *See supra* note 3.

[15] 17 CFR 240.17ad–22(e)(6)(i).

[16] 17 CFR 240.15c3–3.

[17] 17 CFR 240.15c3–3a.

[18] *See supra* note 3.

[19] *See* GSD Rule 8, *supra* note 13.

[20] *See generally* GSD Rule 3A, *supra* note 13.

[21] *See* Securities Exchange Act Release No. 99817 (Mar. 21, 2024), 89 FR 21362, at 21364 (Mar. 27, 2024) (File No. SR–FICC–2024–005).

[22] *Id.* at 21365; *see also* GSD Rule 8, *supra* note 13.

[23] *See* Order, FICC–2024–005, *available at https://www.sec.gov/rules-regulations/self-regulatory-organization-rulemaking/ficc.*

[24] *See id.*

[25] *See* GSD Rule 3A, section 7 (describing novation of Sponsored Member Trades) and 2 (identifying membership types), *supra* note 13.

[26] *See* GSD Rules 3A (describing the operation of the Sponsoring Member Guaranty) and 1 (defining the Sponsoring Member Guaranty), *supra* note 13.

Member or another Sponsored Member).[27]

B. Proposed Changes

In the Advance Notice, FICC seeks to address the Commission's new margin and account separation requirements and the conditions for including margin in the broker-dealer reserve formulas discussed in part I.A above.[28] As described in greater detail below, the Advance Notice would (1) provide for the separate and independent calculation, collection, and holding of margin for proprietary transactions of a Netting Member from margin submitted to FICC by a Netting Member to support the transactions of an indirect participant (*i.e.,* either an Executing Firm Customer or a Sponsored Member); (2) establish segregated accounts for direct and indirect participants, including establishing a minimum $1 million cash margin requirement for each Segregated Indirect Participant; (3) consolidate the methodology for calculating the margin requirements, including definitions of relevant terms and components for calculating margin requirements from various sections of the current GSD Rules into a single margin component schedule (''Margin Component Schedule''), specify how the various components relate to different types of margin, and make certain changes to the margin methodology, including revising the Margin Liquidity Adjustment (''MLA Charge'') [29] definition, providing a method for allocating net unsettled positions to individual indirect participants for calculating margin requirements, and revising and clarifying the calculation of the Excess Capital Premium (''ECP'') component [30] of the Clearing Fund; and (4) modify the terms relating to transactions submitted by Inter-Dealer Broker Netting Members [31] to FICC for clearance and settlement (''Brokered Transactions'').

1. Separate Calculation, Collection, and Holding of Margin

The Advance Notice would provide for the separate and independent calculation, collection, and holding of (i) margin deposited by a Netting Member to support its proprietary transactions, and (ii) margin deposited by a Netting Member to support the transactions of an indirect participant, that is, either an Executing Firm Customer or a Sponsored Member. To facilitate the separate and independent calculation, collection, and holding proprietary and indirect participant margin, FICC would establish proprietary accounts to record the proprietary transactions that the Netting Member enters into for its own benefit and separate indirect participant accounts to record transactions that the Netting Member submits on behalf of an indirect participant, which could be either a Sponsored Member or an Executing Firm Customer.

For proprietary transactions, the accounts would include Dealer Accounts, which would be available for all Netting Members, and Cash Broker Accounts and Repo Broker Accounts, which would only be available for Inter-Dealer Broker Netting Members.[32] Cash Broker Accounts would be available for recording an Inter-Dealer Broker Netting Member's Brokered Transactions (other than Brokered Repo Transactions), and Repo Broker Accounts would be for purposes of recording an Inter-Dealer Broker Netting Member's Brokered Repo Transactions.

For indirect participant transactions, FICC would establish Indirect Participants Accounts to record transactions that a Netting Member submits to FICC on behalf of Sponsored Members and Executing Firm Customers. These Indirect Participants Accounts would include Sponsoring Member Omnibus Accounts for recording Sponsored Member Trades and Agent Clearing Member Omnibus Accounts for recording Agent Clearing Transactions submitted on behalf of Executing Firm Customers. In addition, the proposal would permit a Sponsoring Member or Agent Clearing Member to designate any of its Indirect Participants Accounts as a segregated customer account (a ''Segregated Indirect Participants Account''). Such designation, as further described in part I.B.2 below, would give Netting Members a mechanism to direct FICC to calculate and segregate margin deposited in connection with the relevant Segregated Indirect Participants Account in accordance with the conditions described in Note H to Rule 15c3–3a.[33]

The proposal would require each Netting Member to deposit two forms of margin: the Required Fund Deposit and the Segregated Customer Margin Requirement. The Required Fund Deposit, which would be deposited to the Clearing Fund, would be the sum of each Netting Member's proprietary accounts (*e.g.,* Dealer Accounts and Broker Accounts) and indirect participant accounts (*e.g.,* Agent Clearing Omnibus Accounts and Sponsoring Member Omnibus Accounts) not designated as Segregated Indirect Participants Accounts. The Segregated Customer Margin Requirement, which would be excluded from the Clearing Fund, would be the sum of the Netting Member's Sponsoring Member Omnibus Accounts designated as Segregated Indirect Participants Accounts and Agent Clearing Member Omnibus Accounts designated as Segregated Indirect Participants Accounts.

FICC's proposal would also provide that a Netting Member's Margin Portfolio, which is utilized to determine a Netting Member's margin requirement, cannot include both proprietary and indirect participant accounts. As a result, the transactions a Netting

[27] *See* GSD Rule 3A, Section 10(c), *supra* note 13.

[28] *See supra* note 3.

[29] The MLA Charge is a margin component designed to address the market impact costs of liquidating a defaulted Netting Member's portfolio that may increase when that portfolio includes large net unsettled positions in a particular group of securities with a similar risk profile or in a particular asset type, thereby causing those costs to be higher than the amount collected for the Netting Member's volatility charge, which is designed to capture the market price risk associated with liquidating each Netting Member's portfolio at a 99th percentile level of confidence. *See* GSD Rule 1 (defining Margin Liquidity Adjustment Charge), *supra* note 13; *see also* Securities Exchange Act Release No. 89560 (Aug. 14, 2020), 85 FR 51503 (Aug. 20, 2020) (File No. SR–FICC–2020–09) (approving the MLA charge as a new component of the margin methodology); Securities Exchange Act Release No. 98558 (Sep. 27, 2023), 88 FR 68179 (Oct. 3, 2023) (File No. SR–FICC–2023–012) (approving revisions to ECP charge).

[30] The ECP is a margin component that allows FICC to collect additional margin if a member's exposure to FICC, based on its clearing activity, is out of proportion to its capital levels. It is designed to mitigate the heightened default risk a member could pose to FICC if it operates with lower capital levels relative to its margin requirements. *See* Margin Component Schedule (defining Excess Capital Premium), *supra* note 13; *see also* Securities Exchange Act Release No. 54457 (Sep. 15, 2006), 71 FR 55239 (Sep. 21, 2006) (File Nos. SR–FICC–2006–03 and SR–NSCC–2006–03) (approving the ECP charge as a new component of the margin methodology); Securities Exchange Act Release No. 96786 (Feb. 7, 2023), 88 FR 8013 (Feb. 7, 2023) (File No. SR–NSCC–2022–005) (approving revisions to ECP charge).

[31] An Inter-Dealer Broker is defined as a Person which is in the business of buying and selling securities as agent on behalf of dealers and is registered under Section 15 or Section 15C of the Exchange Act. GSD Rule 1 (defining Inter-Dealer Broker), *supra* note 13. An Inter-Dealer Broker Netting Member must meet that definition and certain applicable membership requirements. *See id.* and Rule 2A (setting forth membership requirements).

[32] Under the proposed changes, ''Cash Broker Account'' would be a proprietary account maintained by FICC for an Inter-Dealer Broker Netting Member to record Brokered Transactions, other than Brokered Repo Transactions, submitted to the Corporation by the Inter-Dealer Broker Netting Member. ''Repo Broker Account'' would be a proprietary account maintained by the FICC for an Inter-Dealer Broker Netting Member in its capacity as a Repo Broker to record Brokered Repo Transactions submitted to the Corporation by the Inter-Dealer Broker Netting Member.

[33] 17 CFR 240.15c3–3a.

Member submits to FICC on behalf of an indirect participant either as a Sponsoring Member or an Agent Clearing Member would no longer be netted against a Netting Member's proprietary transactions for calculating a Netting Member's margin requirements.[34] Since proprietary transactions and transactions submitted for indirect participants would not be recorded in the same type of account, these changes would result in margin for a Netting Member's proprietary transactions being calculated separately and independently from margin calculated for the transactions that the Netting Member submits on behalf of indirect participants.

To help ensure that margin for proprietary transactions is calculated, collected, and held separately and independently of margin for indirect participant transactions, FICC would require each Netting Member, at the time it submits a transaction to FICC for clearance and settlement, to designate the account in which the particular transaction should be recorded using a separate Deposit ID, which is an existing operational mechanism used by Netting Members to identify the type of account for which a margin deposit is being made. The use of these separate Deposit IDs would result in margin for each type of account being separately transferred to FICC and recorded on FICC's books as separate margin amounts for each account type. The proposal would also require FICC to report a Netting Member's Required Fund Deposit and Segregated Customer Margin Requirement twice daily and specify the amount of margin attributable to each Required Fund Deposit Portion or Segregated Indirect Participants Account so that the Netting Member can transfer the different margin amounts separately.

In addition, the proposal would eliminate the concept of a Permitted Margin Affiliate, which allows a Netting Member to include accounts of an affiliate that is also a Netting Member in the same Margin Portfolio as its accounts and net their transactions for margin calculation purposes. FICC states that no Netting Member currently has a Permitted Margin Affiliate, so keeping this option in the rules in conjunction with the proposed changes to establish separate and independent calculation, collection, and holding of margin would introduce unnecessary complexity in FICC's rules.[35]

2. Segregation of Customer Margin

FICC is proposing several changes to allow for the segregation of customer margin in a manner that satisfies the conditions for recording a debit in the customer reserve formula under Note H to Exchange Act Rule 15c3–3a.[36] First, to satisfy Section (b)(2)(i) of Note H to Rule 15c3–3a,[37] FICC would calculate the margin requirements applicable to any segregated account on a gross basis (*i.e.,* FICC would treat each indirect participant as if it were a separate Netting Member for margin calculations and would not net the transactions of one indirect participant against the transactions of another indirect participant). Second, to satisfy Section (b)(2)(iii) of Note H to Rule 15c3–3a,[38] FICC would establish Segregated Customer Margin Custody Accounts for eligible customers on its books and records. These accounts would segregate the margin deposited for transactions in that account from any margin for a Netting Member's proprietary positions, both on FICC's own books and records and at FICC's custodians. FICC would only be able to use such segregated margin to secure or satisfy the obligations of the customer for whom such margin is held, and it would not be considered part of the mutualized Clearing Fund. FICC would not be able to apply such margin to the proprietary obligations of the Netting Member that deposited it with FICC, to the obligations of any other Netting Member or indirect participant, or to any lien or claim against FICC.[39] FICC would provide written notice to any Netting Member that is a broker-dealer that any Segregated Customer Margin Custody Account is being held for the exclusive benefit of the customers and is being kept separate from any other accounts maintained by the broker-dealer or any other Netting Member at FICC, as required by Section (b)(2)(iii)(C) of Note H.[40]

Further, as amended, the proposal would clarify that any interest earned on Segregated Customer Margin consisting of cash must be paid to the Netting Member on behalf of, and as agent for, its Segregated Indirect Participant.[41]

Moreover, to comply with the custody requirements of (b)(2)(iv) of Note H,[42] FICC would require segregated margin accounts to be held at either a bank within the meaning of the Exchange Act that is insured by the Federal Deposit Insurance Corporation and is a qualified custodian under the 1940 Act, or the Federal Reserve Bank of New York.[43] FICC would require these accounts to be segregated from any other account of FICC and used exclusively to hold Segregated Customer Margin, in accordance with Section (b)(2)(iv)(A) of Note H. Moreover, each of these accounts would be subject to (i) a written notice of the bank or Federal Reserve Bank that the account is being held by the bank or Federal Reserve Bank pursuant to Rule 15c3–3 and is being kept separate from and not commingled with any other accounts maintained by FICC or any other person at the bank or Federal Reserve Bank and (ii) a written contract between FICC and the bank or Federal Reserve Bank which would provide that the Segregated Customer Margin in the account is subject to no right, charge, security interest, lien, or claim in favor of the bank or Federal Reserve Bank or any person claiming through the bank or Federal Reserve Bank, in accordance with Sections (b)(2)(iv)(B) and (C) of Note H.[44] FICC would also only allow Segregated Customer Margin consisting of cash to be invested in U.S. Treasury securities with a maturity of one year or less, in accordance with Section (b)(2)(ii) of Note H.[45]

Finally, to satisfy Section (b)(2)(v) of Note H,[46] FICC would provide specific procedures to allow Netting Members to request the return of excess segregated

[34] The Advance Notice would also specify the types of accounts in which Netting Members may record transactions to identify the purpose and use of these accounts. FICC's ''Accounts'' are not custodial accounts in which FICC holds assets, but rather a mechanism for FICC to record and group transactions. These records are utilized by FICC in its calculation of a Netting Member's margining, settlement, and other obligations. Proprietary Accounts would include ''Dealer Accounts,'' which would be available for all Netting Members, and ''Cash Broker Accounts'' and ''Repo Broker Accounts,'' which would only be available for Inter-Dealer Broker Netting Members. Non-Proprietary Accounts would include, in the case of a Sponsoring Member, Sponsoring Member Omnibus Accounts for purposes of recording Sponsored Member Trades, and, in the case of an Agent Clearing Member, Agent Clearing Member Omnibus Accounts for purposes of recording Agent Clearing Transactions of its Executing Firm Customers.

[35] *See* Notice of Filing, *supra* note 4, at 89 FR 21592.

[36] *See id.,* at 21592 (citing 17 CFR 240.15c3–3a).

[37] *Id.* at 21592–93.

[38] *Id.* at 21593–94.

[39] *See* FICC Letter at 35 (describing this as ''an express prohibition on FICC using Segregated Customer Margin held in respect of one Segregated Indirect Participant for the obligations of any other person'' and stating that, as a result, the default of one Segregated Indirect Participant should not generally cause another segregated Indirect participant to lose its margin).

[40] *Id.* at 21594.

[41] *See* Notice of Partial Amendment, *supra* note 10, at 87450.

[42] *See* Notice of Filing, *supra* note 4, at 21595–96.

[43] *See* Notice of Partial Amendment, *supra* note 10, at 87450.

[44] *See* Notice of Filing, *supra* note 4, at 21594–95.

[45] *Id.* at 21595.

[46] *Id.* at 21595–96.

margin. FICC notes that these changes would allow broker-dealer Netting Members to collect margin from customers and deposit it with FICC and to provide all customers, including those that access FICC through non-broker-dealers, the ability to segregate margin they deposit.[47] FICC would have the ability to retain some or all of the excess segregated customer margin if the Netting Member had an outstanding payment or margin obligation to FICC for transactions of any Segregated Indirect Participant. FICC could not retain the excess segregated customer margin for a Segregated Indirect Participant when FICC has determined, in its sole discretion, that such outstanding payment or margin obligation is unrelated to the transactions of that Segregated Indirect Participant.[48] FICC states that these aspects of the Advance Notice would allow for the segregation of certain customer margin in a manner that satisfies the conditions for a broker-dealer to record a debit in the customer reserve formula under Note H to Rule 15c3–3a.[49]

a. $1 Million Minimum Cash Margin Requirement

FICC is also proposing a minimum $1 million cash margin requirement for each Segregated Indirect Participant Account, similar to the $1 million minimum cash margin requirement currently applicable to each Netting Member.[50] FICC conducts daily backtesting to evaluate whether each Netting Member's margin is sufficient to cover FICC's credit exposures to that member based on a simulated liquidation of the member's portfolio on that day. FICC's daily backtesting of the sufficiency of Clearing Fund deposits has shown a heightened risk of backtesting deficiencies (*i.e.,* the projected liquidation losses to FICC due to a Netting Member's default would be greater than the member's margin) for members with lower deposits.[51] Because FICC is required to calculate the margin requirements for Segregated Indirect Participants on a gross basis, as if each Segregated Indirect Participant were a separate Margin Portfolio, and Segregated Customer Margin would not be available to address losses from other direct or indirect participants, FICC believes it is also appropriate to apply the same minimum cash requirement to each Segregated Indirect Participant that it applies to each Margin Portfolio.[52] Moreover, FICC believes that the $1 million cash requirement is the appropriate minimum amount to optimize the balance between financial impact of the requirement to participants and FICC's ability to continue to meet its regulatory obligation to maintain a backtesting performance coverage ratio above its 99 percent coverage target.[53] FICC states that the $1 million minimum is supported by its prior analyses of the appropriate minimum margin requirement for Netting Members.[54] FICC further describes this minimum requirement as critical to ensuring that the account segregation does not expose FICC and its participants to undue loss. FICC explains that the Segregated Customer Margin posted by an individual Segregated Indirect Participant needs to be enough, on its own, to address losses arising from the Segregated Indirect Participant's positions, and that, otherwise, such losses may be mutualized.[55]

However, FICC, in its sole discretion, would have the ability to adjust the amount of the minimum $1 million margin requirement if FICC determines that a different minimum charge would be appropriate and consistent with achieving its backtesting coverage target.[56] FICC would notify Netting Members of any such adjustment to the minimum margin requirement through an Important Notice.[57] In discussing this proposed ability, FICC states that it will review the $1 million floor for Segregated Customer Margin as part of ongoing internal surveillance and risk management monitoring procedures.[58] FICC further states that it would be prudent to have the ability to adjust the $1 million floor proactively to the extent that FICC identifies as part of these reviews that activity levels, margin performance observed through backtesting, and other measures indicate that FICC would be able to continue to manage the risks presented to it and meet its regulatory risk management obligations (including, for example, its 99% backtesting coverage target) with a lower minimum Segregated Customer Margin Requirement (that is, an amount below $1 million).[59]

3. Margin Component Schedule

To improve the clarity and transparency of its margin components and Clearing Fund calculation methodology,[60] FICC would move the margin calculation methodology, including the relevant defined terms, into a new Margin Component Schedule. Currently, the terms and information concerning the margin calculation methodology, as well as the relevant definitions, appear in several different locations.[61] FICC states that its methodology and the included components would continue to be substantively the same as the methodology under the current Rules.[62]

The new Margin Component Schedule would set out the methodology for calculating margin amounts. That Margin Component Schedule would provide for FICC to perform substantially the same calculation it currently performs when determining a Netting Member's Required Fund Deposit, except that (i) the calculation would be performed on a Segregated Indirect Participant-by-Segregated Indirect Participant basis as though each Segregated Indirect Participant represented a separate Margin Portfolio and (ii) FICC would not impose an ECP on Segregated Indirect Participant Accounts. Specifically, for Required Fund Deposit calculations, the margin amount shall equal the VaR Charge, plus or minus the Blackout Period Exposure Adjustment (as applicable), plus the Portfolio Differential Charge, with the following potential additional charges, as applicable: the Backtesting Charge, the Holiday Charge, the MLA Charge, the ECP, and the Intraday Supplemental Fund Deposit.[63] For Segregated Customer Margin Requirement calculations, the margin amount shall equal the VaR Charge, plus or minus the Blackout Period Exposure Adjustment (as applicable), plus the Portfolio Differential Charge, with the following potential additional charges, as

[47] *Id.* at 21590.

[48] *See* Notice of Partial Amendment, *supra* note 10, at 87450.

[49] *See* Notice of Filing, *supra* note 4, at 21592.

[50] Like the current requirement for Netting Member Required Fund Deposits, the proposal would require that a minimum of 40 percent of the Segregated Customer Margin Requirement be satisfied with cash and/or Eligible Clearing Fund Treasury Securities.

[51] *See* Notice of Filing, *supra* note 4, at 21595.

[52] *Id.*

[53] *Id.;* FICC Letter at 28–29.

[54] *See* FICC Letter at 28–29.

[55] *Id.* at 29.

[56] *See* Notice of Partial Amendment, *supra* note 10, at 87451.

[57] *Id.*

[58] *See* FICC Letter at 30.

[59] *Id.* at 31.

[60] *See* Notice of Filing, *supra* note 4, at 21596.

[61] FICC would move the calculation methodology from Rule 4, Sections 1b, and 2a, Rule 3, Section 14, and Rule 3A, Section 10 to the new Margin Component Schedule. FICC would move the definitions from Rule 1 to Section 5 of the Margin Component Schedule.

[62] *See* Notice of Filing, *supra* note 4, at 21596.

[63] This method does not represent a change from the current method of calculating Required Fund Deposits, but merely moves the description from current Rule 4 to the new Margin Component Schedule.

applicable: the Backtesting Charge, the Holiday Charge, the MLA Charge, and the Intraday Supplemental Fund Deposit.

For both types of calculations, the Margin Component Schedule addresses the applicable minimum cash margin requirements ($1 million for each Netting Member and Segregated Indirect Participant) [64] and FICC's authority to require increased deposits as appropriate, including the use of a special charge. FICC would not add Segregated Customer Margin to Section 4 of the Margin Component Schedule, which describes FICC's ability to impose increased Required Fund Deposits under certain circumstances.[65] However, when determining whether to increase the Required Fund Deposit of a Netting Member under the circumstances described in Section 4, FICC would consider the risk presented by a Netting Member from the activity it submits to FICC, including activity of indirect participants.[66]

a. MLA Charge

FICC would amend the definition of the MLA Charge to account for the use of Segregated Indirect Participant Accounts. Specifically, the definition would provide that, if a Segregated Indirect Participant clears through multiple Accounts [67] (including Accounts of different Netting Members), then the MLA Charge for transactions in a Segregated Indirect Participants Account would be the greater of (i) an amount calculated for only the transactions maintained in that Account (*i.e.,* excluding the other Accounts where the Segregated Indirect Participant's transactions are recorded) and (ii) an amount calculated on a consolidated portfolio basis (*i.e.,* taking into account the transactions in each of the Accounts). This would be the same methodology currently used for Sponsored Members clearing through multiple Accounts.[68]

b. Allocation of Net Unsettled Positions

The Advance Notice would also provide a method for allocating net unsettled positions to individual indirect participants for calculating margin requirements. Specifically, as amended, FICC would modify the definition of Current Net Settlement Positions in Rule 1 to provide that, for calculating margin requirements and not for purposes of calculating the Net Settlement Position under GSD Rule 11, positions that are not clearly allocable to an individual Sponsored Member or Segregated Indirect Participant (other than Sponsored GC Trades), because one or more transactions recorded for indirect participants did not settle on the original Scheduled Settlement Date, would be allocated *pro rata* to Sponsored Members or Segregated Indirect Participants that had positions in the same direction and CUSIP as the un-allocable Current Net Unsettled Positions at the end of the preceding business day. FICC states that this situation could arise if a transaction recorded in a Sponsoring Member Omnibus Account or Segregated Indirect Participants Account fails to settle and that such failure to settle would not occur with Sponsored GC Trades.[69] FICC believes this methodology facilitates a reasonable and fair allocation for purposes of calculating gross margin requirements.[70]

c. Calculation of Excess Capital Premium

In addition, the Advance Notice would amend the terms related to the ECP component of the Clearing Fund, which is used to collect additional margin if a Netting Member's exposure to FICC through its clearing activity is out of proportion to its capital. Currently, the ECP applicable to a Netting Member equals the Netting Member's ''Excess Capital Ratio'' (*i.e.,* its VaR Charge divided by its Netting Member Capital) multiplied by its ''Excess Capital Differential'' (*i.e.,* the amount by which a Netting Member's VaR Charge exceeds its Netting Member Capital). However, FICC currently reserves the right to collect less than this amount or to return some or all of this amount.[71]

The changes would seek to make the calculation of the ECP component clearer and more predictable by (i) capping the amount of the ECP at two times the amount by which a Netting Member's VaR Charge exceeds its Netting Capital,[72] (ii) specifying the Netting Member Capital amounts used to calculate the ECP (that is, the Net Capital amount from each Netting Member's most recent Form X–17–A–5 (Financial and Operational Combined Uniform Single Report (''FOCUS Report'')) or the Equity Capital amount on its most recent Consolidated Report of Condition and Income (''Call Report'')), (iii) providing that FICC may calculate the premium based on updated available information, and (iv) permitting FICC, in its discretion, to waive the amount of the ECP and setting forth a specific procedure for doing so. Regarding the waiver procedure, only a Managing Director in FICC's Group Chief Risk Office would be able to grant a waiver of an ECP in certain situations. These situations would be limited to exigent circumstances or other unexpected events. When deciding whether to grant a waiver, FICC would consider the degree to which a Netting Member's capital position and trading activity compare or correlate to the exigent circumstances and whether FICC can effectively manage the risk exposure from the Netting Member without collecting the ECP.[73] Any waiver would be documented in a written report made available to the Netting Member. FICC states that these changes are substantially similar to changes recently adopted by the National Securities Clearing Corporation (''NSCC'') and they would enhance the ability of Netting Members to identify what their ECP will be and to ensure such amount is accurately calibrated.[74]

In addition, the Advance Notice would revise the definitions of Excess Capital Ratio and Excess Capital Differential to exclude the VaR Charge for Segregated Indirect Participants. FICC is proposing this change because each indirect participant would be responsible for satisfying its own

[64] *See supra* Section I.B.2.a for a description of the proposed $1 million minimum cash margin requirement for each Segregated Indirect Participant Account.

[65] *See* Notice of Filing, *supra* note 4, at 21593.

[66] *Id.*

[67] FICC proposed to amend the definition of Account to be an account maintained by FICC for a Member to record transactions submitted by the member. FICC states that this change would clarify that Accounts are recordkeeping mechanisms for FICC to determine which transactions should be netted against each other, but are not custodial accounts through which FICC holds assets for a Netting Member. *See* Notice of Filing, *supra* note 4, at 21592.

[68] *See* GSD Rule 1 (defining MLA Charge, including for Sponsored Members sponsored by multiple Sponsoring Members), *supra* note 13; Securities Exchange Act Release No. 98558 (Sep. 27, 2024), 89 FR 68179 (Oct. 3, 2023) (File No. SR–FICC–2023–012).

[69] *See* Notice of Filing, *supra* note 4, at 21596–97; Notice of Partial Amendment, *supra* note 10, at 87451.

[70] *See* Notice of Filing, *supra* note 4, at 21596–97.

[71] *See* GSD Rule 1 (defining Excess Capital Ratio and Excess Capital Differential) and Rule 3, Section 14 (describing the Excess Capital Premium), *supra* note 13.

[72] In addition, FICC would amend the definition of Netting Member Capital to refer to a Netting Member's Net Capital, Net Assets, or Equity Capital to link the calculation to the appropriate regulatory framework for each Netting Member and add the term Equity Capital to clarify that a Netting Member's most recent Call Report, or financial statements or equivalent reporting if a Netting Member is not required to file a Call Report, will be used for the calculation of the Excess Capital Premium.

[73] *See* Notice of Filing, *supra* note 4, at 21597.

[74] *Id. See* Securities Exchange Act Release No. 96786 (Feb. 1, 2023), 88 FR 8013 (Feb. 7, 2023) (SR–NSCC–2022–005).

respective VaR Charge, not the Netting Member, and the Excess Margin Charge is designed to address the risk that a Netting Member with low capital relative to value-at-risk is not able to perform its obligations.[75] FICC states that including the VaR Charge that is calculated for an indirect participant and is satisfied by the capital of that indirect participant in the calculation of the Netting Member's ECP could result in assessing an ECP for that Netting Member that is greater than the amount required to mitigate the risk this margin component is designed to address.[76] FICC also states that this change is designed to ensure that the ECP does not result in differential treatment of Netting Members that act as intermediaries for Segregated Indirect Participants.

4. Modification of Terms for Brokered Transactions

The Advance Notice would modify the terms relating to Brokered Transactions. FICC's rules currently cap the amount of loss allocation that may be applied to Inter-Dealer Broker Netting Members and Non-IDB Repo Brokers submitting Brokered Transactions. FICC would revise the definition of Brokered Transactions to include only the side of the transactions submitted to FICC for novation by an Inter-Dealer Broker Netting Member and entered into on the Inter-Dealer Broker Netting Member's own trading platform.[77] As a result, the favorable loss allocation treatment for Brokered Transactions would apply only to the transactions that present limited risk since an Inter-Dealer Broker is standing between two counterparties in those transactions and is therefore completely flat (that is, subject to offsetting exposures).[78] Since FICC believes the favorable loss allocation treatment is appropriate only for Inter-Dealer Broker Netting Members submitting Brokered Transactions, it would delete the term ''Non-IDB Repo Broker'' from its rules.[79] FICC states that these changes would improve FICC's risk management and promote access by ensuring that its differential treatment of different parties and transactions has a sound risk management justification.[80]

In addition, the proposed changes would provide that transactions entered into on inter-dealer brokers and similar platforms may be cleared using the Sponsored Service or the Agent Clearing Service.[81]

II. Discussion and Commission Findings

Although the Clearing Supervision Act does not specify a standard of review for an advance notice, the stated purpose of the Clearing Supervision Act is instructive: to mitigate systemic risk in the financial system and promote financial stability by, among other things, promoting uniform risk management standards for systemically important financial market utilities (SIFMUs) and strengthening the liquidity of SIFMUs.[82]

Section 805(a)(2) of the Clearing Supervision Act authorizes the Commission to prescribe regulations containing risk management standards for the payment, clearing, and settlement activities of designated clearing entities engaged in designated activities for which the Commission is the supervisory agency.[83] Section 805(b) of the Clearing Supervision Act provides the following objectives and principles for the Commission's risk management standards prescribed under Section 805(a):[84]

- to promote robust risk management;
- to promote safety and soundness;
- to reduce systemic risks; and
- to support the stability of the broader financial system.

Section 805(c) provides, in addition, that the Commission's risk management standards may address risk management and default policies and procedures, among other areas.[85]

The Commission has adopted risk management standards under Section 805(a)(2) of the Clearing Supervision Act and Section 17A of the Exchange Act (the ''Clearing Agency Rules'').[86] The Clearing Agency Rules require, among other things, each covered clearing agency to establish, implement, maintain, and enforce written policies and procedures that are reasonably designed to meet certain minimum requirements for its operations and risk management practices on an ongoing basis.[87] As such, it is appropriate for the Commission to review advance notices against the Clearing Agency Rules and the objectives and principles of these risk management standards as described in Section 805(b) of the Clearing Supervision Act. As discussed below, the proposals in the Advance Notice are consistent with the objectives and principles described in Section 805(b) of the Clearing Supervision Act[88] and in the Clearing Agency Rules, in particular Rules 17ad–22(e)(4)(i), (e)(6)(i), (e)(6)(iii), (e)(18)(ii), (e)(18)(iii), (e)(18)(iv)(C), (e)(19), and (e)(23)(ii) thereunder.[89]

A. Consistency With Section 805(b) of the Clearing Supervision Act

The proposals in the Advance Notice are consistent with the stated objectives and principles of Section 805(b) of the Clearing Supervision Act.[90] Specifically, the changes proposed in the Advance Notice are consistent with promoting robust risk management, promoting safety and soundness, reducing systemic risks, and supporting the broader financial system.[91]

1. Separate Calculation and Collection of Margin for Proprietary and Customer Accounts

The proposed changes to require the separate and independent calculation

[75] *Id.*

[76] *Id.*

[77] *See* Notice of Partial Amendment, *supra* note 10, at 87451.

[78] *See* Notice of Filing, *supra* note 4, at 21598.

[79] *Id.*

[80] *See* Notice of Filing, *supra* note 4, at 89 FR 21588.

[81] Notice of Partial Amendment, *supra* note 10, at 87451; *see also* FICC Letter at 22–23.

[82] *See* 12 U.S.C. 5461(b).

[83] 12 U.S.C. 5464(a)(2).

[84] 12 U.S.C. 5464(b).

[85] 12 U.S.C. 5464(c).

[86] 17 CFR 240.17ad–22. *See* Securities Exchange Act Release No. 68080 (Oct. 22, 2012), 77 FR 66220 (Nov. 2, 2012) (S7–08–11). *See also* Securities Exchange Act Release No. 78961 (Sep. 28, 2016), 81 FR 70786 (Oct. 13, 2016) (S7–03–14). FICC is a ''covered clearing agency'' as defined in Rule 17ad–22(a)(5).

[87] *Id.*

[88] 12 U.S.C. 5464(b).

[89] 17 CFR 240.17ad–22(e)(4)(i), (e)(6)(i), (e)(6)(iii), (e)(18)(ii), (e)(18)(iii), (e)(18)(iv)(C), (e)(19), and (e)(23)(ii).

[90] 12 U.S.C. 5464(b).

[91] Several of the issues raised by the commenters are directed at issues specific to the proposed rule change and will be addressed in that context. These comments generally relate to the proposal's impact on competition and its consistency with the Exchange Act. *See* Letter from Jiří Król, Deputy CEO, Global Head of Government Affairs, Alternative Investment Management Association, at 6–7 (Apr. 23, 2024) (''AIMA Letter''); Letter from Joanna Mallers, Secretary, Futures Industry of America, Principal Traders Group (Oct. 11, 2024) (''FIA PTG Letter II'') at 2–3; Letter from Sarah A. Bessin, Deputy General Counsel and Nhan Nguyen, Associate General Counsel, Investment Company Institute, at 12 (Jun. 20, 2024) (''ICI Letter''); Letter from Katherine Darras, General Counsel, International Swaps and Derivatives Association, at 4 (Apr. 17, 2024) (''ISDA Letter I''); Letter from Jennifer W. Han, Executive Vice President, Chief Counsel and Head of Global Regulatory Affairs, Managed Funds Association, at 7 (Apr. 17, 2024) (''MFA Letter I''); Letter from Jennifer W. Han, Executive Vice President, Chief Counsel and Head of Global Regulatory Affairs, Managed Funds Association (Nov. 12, 2024) (''MFA Letter II'') at 7; Letter from William C. Thum, Managing Director and Assistant General Counsel, Securities Industry and Financial Markets Association, Asset Management Group, at 9 (May 24, 2024) (''SIFMA AMG Letter'') (commenting on the proposal's impact on competition). The Commission's evaluation of the Advance Notice is conducted under the Clearing Supervision Act and, as discussed above, generally considers whether the proposal would promote robust risk management, promote safety and soundness, reduce systemic risks, and support the broader financial system.

and collection of margin for Netting Members' proprietary transactions and indirect participants' transactions, as described in Section I.B.1., should allow FICC to better identify and measure the unique risk profiles of each Netting Member and indirect participant. This proposed change would ensure that an indirect participant's positions are no longer netted against a Netting Member's positions, that margin is collected with respect to the indirect participant's positions specific to those transactions, and that interest on an indirect participant's cash margin would be paid to the Netting Member for the benefit of, and as agent for, the indirect participant. As discussed in more detail in Section II.C.1 below, this should enhance FICC's ability to calculate and collect the appropriate margin from each direct and indirect participant, which is consistent with promoting robust risk management.

The separate and independent calculation and collection of margin for proprietary and indirect participants' transactions should allow FICC to better identify and measure the unique risk profiles of each Netting Member and indirect participant, enhancing FICC's ability to calculate and collect sufficient margin from each Netting Member and indirect participant to cover potential losses from a Netting Member or indirect participant default, thereby reducing the likelihood that any losses arising out of a default would exceed FICC's prefunded resources, as discussed in more detail in Section II.C.1 below, and threaten the safety and soundness of FICC's ongoing clearance and settlement services. Accordingly, the proposals are consistent with promoting safety and soundness at FICC.

The separation of proprietary and customer margin discussed in Section I.B.1 above is consistent with reducing systemic risks and supporting the stability of the broader financial system. The separation of proprietary and customer accounts should also help avoid the risk of mutualizing loss among non-defaulting members as part of the close-out process and/or a disorderly default in the event of a direct participant default, in that FICC would be responsible for the central liquidation of the defaulting participant's trades and would be able to have a more holistic view of the market. These effects should, in turn, reduce the potential resultant effects on non-defaulting Netting Members, their customers, and the broader market, which is consistent with reducing systemic risks and supporting the stability of the broader financial system.

2. $1 Million Minimum Cash Margin Requirement

For the reasons discussed below in more detail in Section II.B.2, the proposed $1 million minimum cash margin requirement for Segregated Indirect Participants, which could be adjusted by FICC if it determines that a different minimum amount would be appropriate and consistent with achieving its backtesting coverage target, should help ensure that each indirect participant provides sufficient margin to cover its potential obligations to FICC, thereby helping to allow FICC to meet its settlement obligations in the event of a default and to protect FICC, non-defaulting Netting Members, indirect participants, and the market from losses from an indirect participant default. Accordingly, the proposed $1 million minimum cash margin requirement is consistent with reducing systemic risks and supporting the stability of the broader financial system, as well as promoting safety and soundness.

In addition, as indicated by FICC's backtesting results, and discussed further in Section II.B.2 below, the $1 million minimum margin requirement should enhance FICC's ability to collect the appropriate margin from each indirect participant, which is consistent with robust risk management. FICC's flexibility to adjust the minimum margin amount if it determines that a different amount would be appropriate and consistent with achieving its backtesting coverage target is also consistent with robust risk management, because meeting backtesting coverage targets is essential to ensuring that the margin collected would be sufficient for FICC to cover its credit exposures to its Netting Members and indirect participants fully with a high degree of confidence, as required for a covered clearing agency such as FICC.[92] As defined in the Covered Clearing Agency Standards, backtesting is an ex-post comparison of actual outcomes with expected outcomes derived from the use of margin models,[93] and it is a key analytical mechanism for a CCP to consider the effectiveness of its margin model. FICC's ability to adjust the minimum margin amount would apply only where it would be appropriate and consistent with achieving its backtesting coverage target. This ability would, therefore, be limited to circumstances where its backtesting coverage target requirements are not being met or the amount of margin being collected exceeds the amount needed to cover the indirect participant's exposure to FICC.

Based on FICC's representations, the Commission understands that FICC generally intends to use this ability to adjust the minimum margin requirement below $1 million if a lower minimum would suffice to reduce backtesting deficiencies comparably to the $1 million.[94] As part of its ongoing supervision of FICC, the Commission will continue to monitor the performance of the $1 million minimum margin requirement, including as its performance compares to backtesting, and will engage with FICC regarding any changes to that requirement and the supporting analysis for such changes, to help ensure that FICC is appropriately exercising that discretion consistent with the requirements imposed upon it by the rule (*i.e.,* that it determines that any such adjustments would be appropriate and consistent with achieving its backtesting coverage target).[95] For example, not meeting backtesting coverage requirements would be an indication that the minimum margin amount is insufficient to cover FICC's credit exposure to its Netting Members and indirect participants, whereas, on the contrary, higher backtesting performance could indicate that the margin collected exceeds the exposure to FICC.

3. Margin Component Schedule

The proposed changes in section I.B.3 regarding the calculation of margin for segregated and non-segregated accounts should help ensure that FICC collects margin sufficient to cover its exposures with respect to both direct and indirect participants. Requiring that the margin requirement for a Segregated Indirect Participant Account be calculated in generally the same manner as a Netting Member's requirement, which the Commission generally has reviewed and approved as part of FICC's rules,[96]

[92] 17 CFR 240.17ad–22(e)(6).

[93] 17 CFR 240.17ad–22(a).

[94] *See* FICC Letter at 3, 30–31.

[95] In addition, the requirements applicable to FICC as a self-regulatory organization under Section 19(b) of the Exchange Act and as a designated financial market utility under Title VIII of the Payment, Clearing, and Supervision Act (12 U.S.C. 5465(e)) would continue to apply. Thus, for example, if FICC were to amend the $1 million minimum margin requirement to an amount that would materially alter the level or nature of risk presented, FICC would be obligated to submit an advance notice of such change with the Commission.

[96] *See, e.g.,* Self-Regulatory Organizations; Fixed Income Clearing Corporation; Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To Implement Changes to the Required Fund Deposit Calculation in the Government Securities Division Rulebook, Exchange Act Release No. 83362 (June 1, 2018), 83 FR 26514 (June 7, 2018) (approving changes to how

should help ensure that FICC collects margin sufficient to cover its exposures with respect to both direct and indirect participants, as discussed further in Sections II.B.3 and II.C.2 below, which is consistent with promoting robust risk management. In addition, by doing so, these proposed changes should help ensure that, in the event of such a default, FICC's operation of its critical clearance and settlement services would not be disrupted because of insufficient financial resources, which is consistent with safety and soundness at FICC. For the same reasons, these proposed changes should also help ensure that FICC is able to continue to meet its obligation in the event of a default, without accessing non-defaulting Netting Members' or indirect participants' margin deposits, which is consistent with reducing systemic risks and supporting the stability of the broader financial system.

4. Allocation of Net Unsettled Positions

The proposed changes described in Section I.B.3.b. to adopt a method for allocating net unsettled positions to individual indirect participants for calculating margin requirements should reduce the potential exposure to FICC arising from indirect participant transactions that fail to settle by ensuring that FICC has a mechanism to collect margin for such transactions. Further, these proposed changes should make clear that such obligations are allocated only to participants that are outside the Sponsored GC service, since such fails to deliver do not occur in that service. By accounting for risks arising from net unsettled positions, the proposed changes are consistent with promoting robust risk management.

5. Calculation of Excess Capital Premium

The proposed changes to the calculation of the ECP described in Section I.B.3.c. above are consistent with promoting robust risk management, because the changes should help ensure that FICC continues to collect margin sufficient to address the heightened default risk presented by a Netting Member operating with lower capital levels relative to its margin requirements. Based on its review of the Advance Notice, including the detailed impact analysis submitted as a confidential exhibit, FICC's margin coverage would not be impacted by this change and FICC would continue to collect sufficient margin to manage its potential exposure to its Netting Members.

In addition, the proposed changes to the calculation of the ECP should result in a simplified and more straightforward method for calculating the ECP, based on understandable metrics with which FICC's Netting Members are familiar. Using a clearly defined source for determining Netting Member Capital in the calculation of the ECP would result in a more consistent calculation across different types of Netting Members. Moreover, capping the Excess Capital Ratio at 2.0 would provide transparency to Netting Members so they can understand how the ECP will be calculated, and it also would align FICC's cap with the recently approved changes to the ECP calculation at NSCC.[97] By improving the consistency and predictability of the ECP, the proposed enhancements would also improve FICC's ability to collect margin amounts that reflect the risks posed by its Netting Members such that, in the event of Netting Member default, FICC's operations would not be disrupted, and non-defaulting Netting Members and indirect participants would not be exposed to losses they cannot anticipate or control. In this way, this portion of the Advance Notice is consistent with promoting safety and soundness, as well as reducing systemic risks and supporting the stability of the broader financial system.

6. Modification of Terms for Brokered Transactions

The proposed changes described in Section I.B.4. to revise the definition of Brokered Transactions to include only the side of the transactions submitted to FICC for novation by an Inter-Dealer Broker Netting Member and entered into on the Inter-Dealer Broker Netting Member's own trading platform should enhance FICC's risk management by providing favorable loss allocation treatment only to transactions that present limited risk to FICC. As a result, these changes should help ensure that FICC has sufficient prefunded financial resources to continue meeting its obligations in the event of a default, which is consistent with promoting safety and soundness at FICC, as well as reducing systemic risk and supporting the stability of the broader financial system.

A. Consistency With Rule 17ad–22(e)(4)(i)

Rule 17ad–22(e)(4)(i) requires that FICC establish, implement, maintain and enforce written policies and procedures reasonably designed to effectively identify, measure, monitor, and manage its credit exposures to participants and those arising from its payment, clearing, and settlement processes, including by maintaining sufficient financial resources to cover its credit exposure to each participant fully with a high degree of confidence.[98]

1. Separate Calculation and Collection of Margin for Proprietary and Customer Accounts

The proposed changes to require the separate and independent calculation and collection of margin for Netting Members' proprietary transactions and indirect participants' transactions, as described in Section I.B.1., are consistent with Rule 17ad–22(e)(4)(i).[99] The separate calculation and collection of margin from Netting Members and indirect participants should allow FICC to better identify and measure the unique risk profile of each participant, enhancing FICC's ability to calculate and collect the appropriate margin from each direct and indirect participant. As a result, the proposed changes should help ensure that FICC has sufficient margin to cover potential losses from a Netting Member or indirect participant default, thereby reducing the probability that FICC, non-defaulting Netting Members, or non-defaulting indirect participants would incur losses resulting from a default.

2. $1 Million Minimum Cash Margin Requirement

The proposed minimum $1 million cash margin requirement for each Segregated Indirect Participant Account, as described in Section I.B.2.a, is consistent with Rule 17ad–22(e)(4)(i). Several commenters state that FICC lacks a sufficient basis or justification for the required $1 million minimum margin amount.[100] Specifically, one commenter stated that using the amount applicable to Netting Members is not an appropriate basis for establishing a minimum for indirect participants, and also stated that the requirement lacks any support or analysis as to the level of margin attributable to a typical fund's positions in cleared Treasury repo, which is data FICC should have readily

FICC calculates the Value at Risk component of its margin methodology, addition of the new ''Blackout Period Exposure adjustment'' component to the margin methodology, eliminating certain existing components, and revising additional components).

[97] *See* Securities Exchange Act Release No. 96786 (Feb. 1, 2023), 88 FR 8013 (Feb. 7, 2023) (SR–NSCC–2022–005); *see also id.* (discussing the view that capping the ratio at 2.0 strikes an appropriate balance between addressing the heightened default risk without imposing overly burdensome Excess Capital Premium charges).

[98] 17 CFR 240.17ad–22(e)(4)(i).

[99] *See id.*

[100] *See* ISDA Letter I at 4; ICI Letter at 12; AIMA Letter at 6–7; MFA Letter II at 6.

available.[101] An additional commenter stated the requirement seems arbitrary, and not practical or necessary, especially in the current done-with model, to force every segregated customer to be subject to the same minimum requirement as a Netting Member.[102]

In addition, commenters state that FICC should adopt a lower minimum requirement ($100,000 to $250,000), a dynamic minimum based on average exposure subject to a $250,000 cap, or a minimum set by the relevant Netting Member.[103] Commenters also state that FICC should determine a minimum deposit based on the individual client and the risk that such client presents to FICC and other market participants.[104]

In response, FICC states that the $1 million floor for Segregated Indirect Participants is the same floor FICC already has in place for its Netting Members.[105] FICC states that its impact study, conducted in 2022 when adopting the rule applicable to Netting Members, demonstrated that a $1 million floor would protect FICC and its participants from incurring a loss in the event of a Netting Member failure because the study indicated that a $1 million floor would provide an adequate buffer for additional repo activity due to increases in repo interest rates and would have mitigated 65 out of 396 backtesting deficiencies (16%) during the period from July 1, 2021 to June 30, 2022.[106] FICC further states that it analyzed alternative minimum margin amounts, such as $500,000, and, based on the results of its analysis, the $1 million floor provided the appropriate balance of improving backtesting performance and margin coverage while minimizing the impact on Netting Members.[107]

FICC also states that the backtesting data from the period after the $1 million minimum floor was implemented indicated a ''material reduction of backtesting deficiencies at FICC.'' [108] From December 5, 2022 to June 30, 2024, FICC states that the $1 million floor eliminated 24 backtesting deficiencies, a 12% reduction.[109] Further, during a period of 12-month period of moderate market volatility from July 1, 2023 to June 30, 2024, FICC states that the $1 million floor eliminated 15 backtesting deficiencies, a 22% reduction.[110]

FICC further states that the $1 million floor is appropriate because the Segregated Customer Margin posted by each individual Segregated Indirect Participant needs to be sufficient on its own to address losses arising from the Segregated Indirect Participant's positions.[111] This is because Segregated Customer Margin is not subject to loss mutualization under the proposal, so FICC can only use Segregated Customer Margin posted by an individual Segregated Indirect Participant to satisfy that customer's obligations. As a result, each Segregated Indirect Participant's portfolio would present a risk to FICC that is equivalent to the risk of a proprietary portfolio of an individual Netting Member.[112] If the Segregated Customer Margin is insufficient, losses would need to be mutualized, with harm to FICC, its non-defaulting Netting Members, and, potentially, the market as a whole.[113]

In addition, FICC stated that the risk cited by the Commission of inconsistent activity giving rise to dramatic changes in risk exposure, discussed by the Commission in the FICC–2022–006 Order,[114] is arguably more pronounced for indirect participants than for Netting Members.[115] First, indirect participants may clear through multiple Netting Members and shift their activity through different Netting Members, which can present risks to FICC since FICC cannot use the Segregated Customer Margin posted by the Segregated Indirect Participant through one Netting Member to address the Segregated Indirect Participant's transactions cleared by another Netting Member.[116] As a result, FICC states that, even if the Segregated Indirect Participant's overall activity remains steady, FICC could see dramatic shifts in its risk simply because the Segregated Indirect Participant shifts the Netting Members it uses as its intermediary at FICC.[117] Second, FICC states that it does not have the same general understanding of indirect participants' business that it has for its Netting Members, since it does not collect the same information on individual customers' business or finances that it does for its Netting Members.[118] As a result, FICC states that it is less likely to know when there may be significant swings in indirect participant risk exposures as it would for its Netting Members and, since indirect participants are likely to have a far more diverse array of business models and interest rate considerations than FICC's Netting Members, they could engage in inconsistent activity that could increase risk exposure to FICC.[119] According to FICC, the possibility of inconsistent activity among indirect participants is potentially greater.[120]

The Commission disagrees with commenters who stated that using the same minimum as Netting Members is not appropriate for Segregated Indirect Participants. As stated in Section I.A. above, FICC and non-defaulting Netting Members and indirect participants may be subject to losses should the Segregated Customer Margin of an indirect participant be insufficient to satisfy losses caused by the liquidation of that indirect participant's portfolio. This potential exposure both to FICC and non-defaulting Netting Members and indirect participants makes it essential that FICC determine margin amounts for Segregated Indirect Participant Accounts that are reasonably designed to ensure that FICC has sufficient margin to cover the losses of a defaulting Segregated Indirect Participant.

The analyses conducted by FICC both in connection with the 2022 change to the required minimum margin amount for Netting Members and after the implementation of that requirement, which the Commission has reviewed and analyzed, support the use of the $1 million margin requirement for Segregated Indirect Participant Accounts. The Commission agrees that these studies demonstrate that a $1 million margin floor has a material impact on reducing the number of backtesting deficiencies experienced by FICC's Netting Members, which would likely help FICC better manage its credit exposure to its Netting Members and indirect participants and credit

[101] ICI Letter at 12.

[102] AIMA Letter at 6. *See also* MFA Letter II at 7.

[103] AIMA Letter at 7; MFA Letter I at 7; SIFMA AMG Letter at 9.

[104] ISDA I at 4; *see also* MFA Letter II at 7 (stating that the requirement should be determined based on a participant's particular risk profile, including its planned and historical clearing activity).

[105] *See* FICC Letter at 28; Securities Exchange Act Release No. 96136 (Oct. 24, 2022), 87 FR 65268 (Oct. 28, 2022) (SR–FICC–2022–006) (''FICC–2022–006 Order''). The impact study contains an analysis of backtesting results on a member-by-member basis over a twelve-month period ending June 30, 2022, and it includes, for both the then-current rule and the proposed $1 million minimum rule, the number of backtesting deficiencies and the level of coverage obtained. It contains the same analysis for a $500,000 minimum as well, including the same data points on a member-by-member basis.

[106] *See* FICC Letter at 28.

[107] *Id.*

[108] *See* FICC Letter at 29.

[109] *Id.*

[110] *Id.*

[111] *Id.*

[112] *Id.*

[113] *Id.*

[114] FICC–2022–006 Order, *supra* note 105, at 65270.

[115] *See* FICC Letter at 30.

[116] *Id.*

[117] *Id.*

[118] *Id.*

[119] *Id.*

[120] *Id.*

exposures arising from its payment, clearing, and settlement processes.

Consideration of the appropriate Netting Member minimum is directly relevant to what is appropriate for Segregated Indirect Participant Accounts because FICC would treat such accounts the same as Netting Member accounts in the event of a default of that individual customer.[121] Even though a Segregated Indirect Participant would be the customer of a Sponsoring Member or an Agent Clearing Member, each Segregated Indirect Participant Account would need to provide sufficient margin to independently cover its losses in the event of a default. FICC will determine the appropriate margin for each Segregated Indirect Participant Account as if it were a separate Netting Member. As discussed above, indirect participants may increase risk by clearing through different Netting Members, which would provide FICC with less insight into their overall portfolio. Accordingly, it is appropriate for the minimum amount to be the same for both Netting Members and indirect participants.

In response to commenters who proposed an alternative amount or approach, the Commission also has reviewed and analyzed the analysis of alternative minimum amounts that FICC conducted, which show that there would still be potential for higher amounts of backtesting deficiencies using a $500,000 alternative minimum, making the alternatives proposed by commenters ($100,000, $250,000 or a dynamic minimum with a $250,000 cap) not reasonably designed to allow FICC to collect sufficient margin to cover its exposures. As discussed above, FICC's backtesting data from December 5, 2022 to June 30, 2024 indicates that increasing the minimum margin amount from $100,000 to $1 million eliminated 24 Netting Member backtesting deficiencies, a 12% reduction.[122] Further, during a 12-month period of moderate market volatility from July 1, 2023 to June 30, 2024, the $1 million floor eliminated 15 backtesting deficiencies, a 22% reduction.[123]

Because FICC is not able to predict how many indirect participants may elect to submit activity to FICC through a Segregated Indirect Participants Account or the size or volume of that activity, margin requirements for each Segregated Indirect Participant would be calculated in the same manner as for Netting Members.[124] FICC's impact studies of Netting Members provide a reasonable approximation of the risks FICC may face if the minimum margin amount is set below $1 million. Therefore, the proposed $1 million floor is appropriate to increase the probability that the margin amount collected by FICC is sufficient to cover FICC's credit exposure to Segregated Indirect Participants and protect non-defaulting parties from experiencing losses. However, as described above in Section I.B.2.a., if FICC determines that a different minimum charge would be appropriate and consistent with achieving its backtesting coverage target, FICC would have the ability to adjust the minimum charge of $1 million margin requirement. This added flexibility should allow FICC to continue to collect the appropriate amount of margin to cover its credit exposure to each participant fully with a high degree of confidence, as demonstrated by FICC's meeting its backtesting coverage targets, while minimizing the burden on indirect participants.

Moreover, the Commission disagrees that allowing the Netting Member to determine a minimum would be appropriate. It is unclear what basis a Netting Member would use to determine such a minimum in a way that would ensure that the amount is sufficient to meet FICC's regulatory obligations and minimize backtesting deficiencies because a Netting Member would not be able to replicate FICC's backtesting or calculate FICC's regulatory obligations.

The Commission disagrees that determining a minimum deposit on a case-by-case basis would be feasible for every Segregated Indirect Participant. FICC has stated that it does not know how many Segregated Indirect Participants will participate in FICC. At this time, there are over 2500 Sponsored Members at FICC,[125] and it is likely that additional indirect participants will want to access clearing going forward in light of the Treasury Clearing rules. Determining a minimum for even half the current Sponsored Members on a case-by-case basis would be extremely burdensome for FICC and would require the submission of detailed financial information by each Sponsored Member to inform FICC of its planned business activities, and it is unclear how or on what basis such a minimum would be adjusted over time. Establishment of a minimum requirement is appropriate to ensure that FICC can meet its obligations under Rule 17ad–22(e)(4)(i), and reliance upon the minimum for Netting Members is appropriate because, as discussed above, FICC has to treat each Segregated Indirect Participant as a stand-alone account for risk management purposes to segregate its margin appropriately.

For these reasons, the $1 million minimum margin requirement should help ensure that FICC has sufficient margin to cover potential losses from a Segregated Indirect Participant default, thereby reducing the probability that FICC, non-defaulting Netting Members, and non-defaulting indirect participants would incur losses resulting from a default. Moreover, as described above in Section I.B.2.a., FICC would have the ability to adjust the amount of the minimum $1 million margin requirement if FICC determines that a different minimum charge would be appropriate and consistent with achieving its backtesting coverage target. The Commission agrees with FICC that it should continue to assess the performance of this minimum requirement with respect to FICC's backtesting coverage requirements, as it provided in the Amendment to this filing, to ensure that FICC is not collecting more margin than is necessary to meet its regulatory obligations to cover its exposure to its participants.[126] Although the Commission recognizes that FICC could use this ability to increase the $1 million minimum to some greater amount, it would only be able to do so if determines that a different minimum charge would be appropriate and consistent with achieving its backtesting coverage target.

3. Margin Component Schedule

The proposed changes in section I.B.3 regarding the calculation of margin for segregated and non-segregated accounts should ensure that FICC collects margin sufficient to cover its exposures with respect to both direct and indirect participants. Requiring that the margin

[121] This also makes the 2022 impact study relevant to this determination because FICC would calculate margin requirements for each Segregated Indirect Participant in the same manner as margin requirements for each Netting Member. The Commission reviewed and analyzed that impact study when approving the current minimum applicable to Netting Members, and the same analysis should apply here as well.

[122] *See* FICC Letter at 29.

[123] *Id.*

[124] *See* Notice of Filing, *supra* note 4, at 89 FR 21595.

[125] *See* GSD Member Directories, *available at https://www.dtcc.com/client-center/ficc-gov-directories.*

[126] One commenter states that FICC should not delay recalibration of the minimum margin requirement to a later date. MFA Letter II at 6–7. However, as the Commission discussed above, the minimum margin requirement is appropriate, based on the data available at this time. The Commission will continue to monitor implementation of this requirement going forward once more data regarding the use of segregated accounts is available.

requirement for a Segregated Indirect Participant Account be calculated in generally the same manner as a Netting Member's requirement, which the Commission has reviewed and approved as part of FICC's rules, should help ensure that FICC collects margin sufficient to cover its exposures with respect to both direct and indirect participants. By doing so, this portion of the Advance Notice should better ensure that, in the event of a Netting Member's or indirect participant's default, FICC has sufficient margin to cover potential losses from the default, thereby reducing the probability that FICC, non-defaulting Netting Members, and non-defaulting indirect participants would incur losses resulting from a default. Collecting the same margin components for a Segregated Indirect Participant Account as those used for a Netting Member Account is appropriate because FICC has to risk-manage each Segregated Indirect Participant Account individually, and application of the existing margin methodology would help ensure that FICC collects sufficient margin to cover its exposures to participants for all Accounts. FICC has, however, taken into account how the ECP should apply differently when determining a Segregated Customer Margin Requirement, which is appropriate for the reasons discussed in Section II.C.3 below, and the changes related to the ECP Charge would ensure that Segregated Indirect Participants are not required to post additional margin to account for the capital position of its Netting Member.

Accordingly, for the reasons discussed above, the Advance Notice is reasonably designed to enable FICC to effectively identify, measure, monitor, and manage its credit exposure to Netting Members and indirect participants, consistent with Rule 17ad–22(e)(4)(i).[127]

B. Consistency With Rule 17ad–22(e)(6)(i)

Rule 17ad–22(e)(6)(i) requires FICC to establish, implement, maintain and enforce written policies and procedures reasonably designed to cover its credit exposures to its participants by establishing a risk-based margin system that, at a minimum, considers, and produces margin levels commensurate with, the risks and particular attributes of each relevant product, portfolio, and market, and, if the covered clearing agency provides central counterparty services for U.S. Treasury securities, calculates, collects, and holds margin amounts from a direct participant for its proprietary positions in Treasury securities separately and independently from margin calculated and collected from that direct participant in connection with U.S. Treasury securities transactions by an indirect participant that relies on the services provided by the direct participant to access the covered clearing agency's payment, clearing, or settlement facilities.[128]

1. Separation of Proprietary and Customer Margin

The proposed changes to separate proprietary and customer margin are consistent with Rule 17ad–22(e)(6)(i). First, to help ensure that proprietary transactions and transactions submitted to FICC on behalf of indirect participants are margined separately, FICC would require that each margin portfolio contain only transactions from the same account type and that Netting Members use separate Deposit IDs for different transaction types. Second, FICC would calculate each Segregated Indirect Participant's margin requirement separately on a gross basis as though each Segregated Indirect Participant were a separate Netting Member. Finally, FICC would create a separate ''Segregated Customer Margin Custody Account'' for each Netting Member that contains deposits of Segregated Customer Margin for indirect participants, with interest earned on cash margin paid to each Segregated Indirect Participant's Netting Member for the benefit of, and as an agent for, the Segregated Indirect Participant. Collectively, these proposed changes should ensure that a Netting Member's proprietary transactions are not netted with indirect participant transactions for margin calculations and that margin for indirect participant transactions is collected and held separately and independently from margin for a Netting Member's proprietary transactions. Moreover, by calculating each Segregated Indirect Participant's margin requirement separately from Netting Members and other Segregated Indirect Participants, the proposed changes should allow FICC to better isolate the risk profiles of individual indirect participants from Netting Members, which should help FICC better understand and monitor each individual participant's risk exposures.[129]

One commenter expressed concern that the proposal would not fully eliminate fellow customer risk because it would allow for the *pro rata* allocation of Current Net Settlement positions among Segregated Indirect Participant positions held in the same Segregated Indirect Participants Account.[130] In response, FICC explained that, due to the requirement in the Treasury Clearing Rules that margin for customer positions be calculated separately from margin for a Netting Member's proprietary positions, FICC would not be able to allocate the margin obligations from Current Net Settlement Positions to a Netting Member's portfolio.[131] As a result, such margin must be allocated to customer positions and FICC states that, when it is not aware of the allocation of Current Net Settlement Positions among customers, it is most equitable to allocate such positions *pro rata* to customers who were long or short the relevant securities.[132] The Commission agrees that allocating the positions to the Netting Member's account would be inconsistent with Rule 17ad–22(e)(6)(i) because it would impermissibly net proprietary transactions against indirect participant transactions. The Commission further agrees that the positions must be allocated to ensure that FICC is able to appropriately risk-manage those positions (that is, to collect appropriate margin). The Commission further agrees with FICC's approach of limiting such *pro rata* allocations only to customers engaging in non-Sponsored GC Trades because settlement failures do not occur with respect to Sponsored GC Trades. Therefore, in the event that the positions are not allocated, a *pro rata* allocation among customers is appropriate.

Accordingly, the proposed changes in the Advance Notice would be consistent with Rule 17ad–22(e)(6)(i) because they should help ensure that FICC calculates, collects, and holds margin for a Netting Member's proprietary positions

[127] *See id.*

[128] 17 CFR 240.17ad–22(e)(6)(i).

[129] Commenters requested clarification that FICC's funds-only settlement amounts are settlement payments rather than margin. *See* ISDA Letter at 6; Letter from Katherine Darras, General Counsel, International Swaps and Derivatives Association (July 18, 2024) (''ISDA Letter II'') at 6; SIFMA Letter at 4; Letter from Walt L. Lukken, President and Chief Executive Officer, Futures Industry of America (Apr. 18, 2024) (''FIA Letter'') at 11. The Advance Notice does not make any amendments to the funds-only settlement process at FICC. *See* GSD Rule 13. This aspect of FICC's rules is, therefore, not relevant to this Advance Notice. However, FICC clarified that it views such payments as constituting settlements that discharge outstanding payment obligations, rather than as margin or collateral. FICC Letter at 43. The Commission agrees with this clarification, based upon its knowledge of FICC's margin and payment flows and the applicable GSD Rules.

[130] *See* SIFMA AMG Letter at 10.

[131] *See* FICC Letter at 36.

[132] *Id.*

separately from the margin for positions the member clears for customers.[133]

5. Margin Component Schedule

The proposed changes to establish a Margin Component Schedule, which would consolidate the terms and information relating to margin calculation throughout the Rules into a single schedule, are consistent with Rule 17ad–22(e)(6)(i). Under the proposed Margin Component Schedule, FICC would perform substantially the same calculation it currently performs when determining a Netting Member's Required Fund Deposit and include the methodology for calculating a Netting Member's Segregated Customer Margin Requirement. By including a methodology to calculate each Segregated Indirect Participant's margin requirement separately from Netting Members and other Segregated Indirect Participants, the proposed changes should help ensure that FICC calculates, collects, and holds margin for a Netting Member's proprietary positions separately from the margin for positions the member clears for customers. Moreover, calculating margin requirements for each Segregated Indirect Participant should allow FICC to better isolate the risk profiles of individual indirect participants from Netting Members, which should help FICC better understand and monitor each individual participant's risk exposures and thereby collect margin commensurate with the risks of each Netting Member and indirect participant portfolio.

A commenter states that FICC should confirm that segregation of margin for indirect participants does not magnify risk for Netting Members. Specifically, the commenter states that it is not clear whether the Required Fund Deposit to be posted by Netting Members incorporates any exposure associated with Segregated Indirect Participant Accounts and expresses concern as to whether FICC's rules allow FICC to collect additional margin to cover any enhanced risk that may arise relating to the Netting Member's obligations to FICC for its clients who are indirect participants generally or who choose segregation specifically.[134] However, FICC's proposed rules establish that the calculation of a Netting Member's Required Fund Deposit excludes the exposure of its Segregated Indirect Participants.[135] FICC's rules do permit FICC to collect increased Required Fund Deposits from Netting Members if ''necessary to protect [FICC] and its Members from Legal Risk,'' which, FICC states, would include the consideration of the Netting Members' indirect participants.[136]

This commenter also states the fact that the ability to prefund margin for a customer is only temporary puts pressure on the Netting Member's own Required Fund Deposits, which ''it seems would still cover the obligations of all its clients'' and also on the Netting Member and the broader FICC membership, in the event of a failure by any Segregated Indirect Participant.[137] However, the Netting Member's Required Fund Deposits would not be calculated based on the obligations of its clients, and, in the event of the default of an indirect participant, FICC would use the Segregated Customer Margin for only that indirect participant. Therefore, the Commission disagrees that the inability to permanently prefund the customer's margin requirement puts additional pressure on the Netting Member's own Required Fund Deposits.

Another commenter states that FICC should explain why it is appropriate to calculate a segregated customer's margin requirement as if it were a Netting Member, even though the margin calculation for FICC Netting Members covers both initial margin and guaranty fund contributions (and customers are not expected to be contributing to the guaranty fund).[138] However, FICC does not maintain a separate guaranty fund into which a Netting Member contributes for its customers. The Segregated Customer Margin Requirement must be sufficient to cover the exposures to FICC arising from that particular customer's activity because, under the segregation system proposed by the Advance Notice which would allow broker-dealers participating in FICC to comply with the conditions of Note H to Rule 15c3–3, FICC would not be able to use the margin collected from a Segregated Indirect Participant for any reason unrelated to the Segregated Indirect Participant. Therefore, calculating each Segregated Customer Margin Requirement in this manner is appropriate to ensure that FICC has appropriate resources to cover each customer's exposures. Therefore, this aspect of the Advance Notice is consistent with Rule 17ad–22(e)(6)(i) under the Exchange Act.

6. Excess Capital Premium

The proposed changes to the calculation of the ECP charge are consistent with Rule 17ad–22(e)(6)(i). FICC's margin deposits are made up of risk-based components (as margin) that are calculated and assessed daily to limit FICC's exposures to Netting Members. FICC's proposed changes to use clearly defined sources in the calculation of the ECP charge would collectively make the calculation clearer and more predictable to Netting Members, while continuing to apply an appropriate risk-based charge designed to mitigate the risks presented to FICC. Similarly, the proposal to cap the Excess Capital Ratio at 2.0 would allow FICC to appropriately address the risks it faces without imposing an overly burdensome ECP and would reduce the circumstances in which FICC may waive the charge, resulting in a more transparent margining methodology. Finally, the proposed rule change would clarify the exigent circumstances under which FICC may determine that it is appropriate to waive the ECP charge. Overall, these proposed changes would improve the effectiveness of the calculation of the ECP and, therefore, allow FICC to more effectively address the increased default risks presented by Netting Members that operate with lower capital levels relative to their margin requirements.

In addition, FICC proposes to exclude VaR Charges for Segregated Indirect Participants Accounts when determining a Netting Member's Excess Capital Differential, in order to take into account the fact that each indirect participant would be responsible for satisfying its own respective VaR Charge. Not including these Segregated Indirect Participants Accounts when determining the Excess Capital Differential, and, therefore, the ECP Charge, is consistent with the purpose of the Excess Premium Charge. This charge is designed to address the risk that a Netting Member with low capital relative to its value-at-risk to FICC is not able to perform its obligations. Because the Netting Member's capital is not used to meet the indirect participant's obligation to FICC, excluding the indirect participant VaR Charges from the determination of the ECP should result in FICC collecting margin commensurate with the risks and particular attributes of each relevant portfolio.

Taken together, the proposed changes enhance the ability of the ECP to produce margin levels commensurate

[133] 17 CFR 240.17ad–22(e)(6)(i).

[134] ISDA Letter I at 7; ISDA Letter II at 6.

[135] *Compare* proposed Margin Component Schedule section 2 (regarding Required Fund Deposits) *with* section 3 (regarding Segregated Customer Margin).

[136] *See* proposed Margin Component Schedule section 4; *see also* Notice of Filing, *supra* note 4, at 21593.

[137] *See* ISDA Letter I at 7.

[138] *See* Letter from Joanna Mallers, Secretary, Futures Industry of America, Principal Traders Group (Apr. 17, 2024) (''FIA PTG Letter I'') at 8.

with the risks FICC faces related to its Netting Members' operating capital levels. Therefore, this aspect of the Advance Notice is consistent with Rule 17ad–22(e)(6)(i) under the Exchange Act.

C. Consistency With Rule 17ad–22(e)(6)(iii)

Rule 17ad–22(e)(6)(iii) requires that FICC establish, implement, maintain and enforce written policies and procedures reasonably designed to cover its credit exposures to its participants by establishing a risk-based margin system that, at a minimum, calculates margin sufficient to cover its potential future exposure to members in the interval between the last margin collection and the close out of positions following a member default.[139]

As summarized in Section I.B.3 above, FICC employs daily backtesting to determine the adequacy of each Netting Member's Required Fund Deposit, paying particular attention to members that have backtesting deficiencies below the 99% confidence target. Such backtesting deficiencies highlight exposure that could subject FICC to potential losses if a Netting Member defaults. As discussed in Section II.C.2, FICC's impact study during the period from July 1, 2021 to June 30, 2022 demonstrated that a $1 million floor would have protected FICC and its participants by reducing the possibility of incurring a loss in the event of a Netting Member failure by mitigating 16% of backtesting deficiencies.[140] Moreover, after the $1 million floor was implemented for Netting Members, FICC states that it eliminated 22% of backtesting deficiencies during a 12-month period of moderate market volatility from July 1, 2023 to June 30, 2024.[141]

Therefore, adding the proposed $1 million minimum requirement for Segregated Customer Margin, and the ability to adjust the minimum million margin requirement to achieve FICC's backtesting coverage target, should better ensure that FICC maintains sufficient margin to cover its potential future exposure to its indirect participants in the interval between the last margin collection and the close out of positions following an indirect participant default. This should, thereby, reduce the likelihood FICC or non-defaulting Netting Members or indirect participants would incur losses as a result. Accordingly, FICC's proposed $1 million minimum requirement for Segregated Customer Margin would be consistent with Rule 17ad–22(e)(6)(iii).[142]

D. Consistency With Rule 17ad–22(e)(18)(ii)

Rule 17ad–22(e)(18)(ii) requires that FICC establish, implement, maintain and enforce written policies and procedures reasonably designed to establish objective, risk-based, and publicly disclosed criteria for participation, which require participants to have sufficient financial resources and robust operational capacity to meet obligations arising from participation in the clearing agency.[143] The proposed changes to consolidate FICC's margin methodology in a single location, identify the particular Required Fund Deposit Portions and Segregated Customer Margin Requirements, and clarify the calculation of the Excess Capital Premium and circumstances in which FICC would waive the application of such premium should enhance FICC's public disclosure of the risk-based margin obligations that Netting Members and their indirect participants would have as a result of their participation in FICC's clearance and settlement services. This improved public disclosure should allow Netting Members and their indirect participants to better understand how their activity would impact margin calculations, which are designed to ensure that participants have sufficient financial resources and robust operational capacity to meet obligations to FICC. Accordingly, the proposed changes would be consistent with Rule 17ad–22(e)(18)(ii).[144]

E. Consistency With Rule 17ad–22(e)(18)(iii)

Rule 17ad–22(e)(18)(iii) requires that FICC establish, implement, maintain and enforce written policies and procedures reasonably designed to establish objective, risk-based, and publicly disclosed criteria for participation, which monitor compliance with its participant requirements on an ongoing basis.[145] The proposed changes would require Netting Members to designate the specific account type when submitting transactions and to identify any Sponsored Member or Executing Firm Customer for whom the transaction is submitted. These changes should enhance FICC's ability to monitor which transactions are being entered into by which entities and assess the specific risks associated with those entities. This enhanced monitoring of participant activity should allow FICC to better monitor participants' compliance with FICC's Rules. Accordingly, the proposed changes would be consistent with Rule 17ad–22(e)(18)(iii) because they should enhance FICC's ability to monitor compliance with its participant requirements on an ongoing basis.[146]

F. Consistency With Rule 17ad–22(e)(18)(iv)(C)

Rule 17ad–22(e)(18)(iv)(C) requires that FICC establish, implement, maintain and enforce written policies and procedures reasonably designed to ensure that it has appropriate means to facilitate access to clearance and settlement services of all eligible secondary market transactions in U.S. Treasury securities, including those of indirect participants.[147]

As discussed above in Section II.B.3, by improving the transparency of FICC's account offerings and margin calculation methodology, the proposed changes should enhance market participants' understanding of how margin is calculated and their options for posting margin, thereby facilitating access to FICC's clearance and settlement services. In addition, the proposed changes should offer greater optionality to Netting Members and indirect participants, which should allow Netting Members and indirect participants to adopt a margining arrangement that aligns with their business objectives and regulatory, operational, and practical constraints. By enhancing transparency of FICC's margin framework and account options and offering greater optionality to participants concerning the type of account they transact in and how their margin is posted, the proposal should facilitate access to FICC's clearance and settlement systems.

Several commenters proposed that FICC should require Netting Members to offer account segregation to customers.[148] One such commenter

[139] 17 CFR 240.17ad–22(e)(6)(iii).

[140] *See* FICC Letter at 28.

[141] *Id.*

[142] 17 CFR 240.17ad–22(e)(6)(iii).

[143] 17 CFR 240.17ad–22(e)(4)(18)(ii).

[144] *Id.*

[145] 17 CFR 240.17ad–22(e)(18)(iii).

[146] 17 CFR 240.17ad–22(e)(18)(iii).

[147] 17 CFR 240.17ad–22(e)(18)(iv)(C).

[148] Specifically, one commenter stated that for indirect participants, having a ''right'' to direct their Netting Member to segregate their margin is highly desirable because it would allow an indirect participant to have certainty that margin that it posts receives the protection afforded by segregation. SIFMA AMG Letter at 6. Another such commenter stated that, despite what a customer may desire with respect to margin and segregation, there could be incentives for direct participants to finance the margin for their customers' transactions (and thereby earn extra fees for doing so) instead of the customer financing or posting that margin,

specified that this should include bank Netting Members, who would not face the same restrictions on the use of customer margin as broker-dealer customers subject to Rule 15c3–3 and therefore may not be as incentivized to provide segregated account services.[149]

FICC did not propose a requirement that its Netting Members offer segregated accounts to their customers. Therefore, the Commission is not addressing any changes related to such a requirement in this Advance Notice. Nothing in the Treasury Clearing Rules or Rule 15c3–3 requires a covered clearing agency, like FICC, to require its Netting Members to provide certain services. Moreover, certain Netting Members may have regulatory or other reasons not to offer segregation, and, if required to offer such services, may choose to cease providing customer clearing services, which could, in turn, increase concentration in the market and reduce liquidity.[150]

Additionally, a commenter urged FICC to allow indirect participants to post margin directly to FICC without intermediation from a Netting Member.[151] The Treasury Clearing Rules do not require FICC to provide this function, and FICC did not propose such a method for direct posting of margin.[152] Accordingly, the Commission is not addressing any changes related to such a requirement in this Advance Notice.

One commenter sought clarification whether Netting Members other than broker-dealers can elect segregation for their customers.[153] Based on the Advance Notice, the Commission understands, and FICC confirmed,[154] that any Sponsoring Member or Agent Clearing Member, regardless of whether registered as broker-dealers, would be able to designate an account as a Segregated Indirect Participants Account.

The same commenter also sought clarification whether a customer may segregate margin obtained through a margin financing arrangement.[155] Based on the Advance Notice, the Commission understands, and FICC confirmed,[156] that such segregation would be permissible under FICC's rules.

This commenter also asked why excess margin would only be returned on request and states that an indirect participant should not have to request a return of its excess margin.[157] The Treasury Clearing Rules do not require FICC to provide this function, and FICC did not propose such a function. Accordingly, the Commission is not addressing any changes related to such a requirement in this Advance Notice. Moreover, when it adopted the amendments to Rule 15c3–3, the Commission declined to adopt a requirement to ''push'' excess margin to direct participants.[158]

Another commenter suggested that FICC allow customer margin to be segregated, even when customers do not post the full amount of the margin needed to cover their positions.[159] FICC states that allowing customer margin to be segregated when customers do not post the full amount of margin would lead to disparities that would put broker-dealer Netting Members at competitive disadvantage to other Netting Members.[160] The Treasury Clearing Rules do not require FICC to provide this function, and FICC did not propose such a function. Any changes to FICC's rules to impose such a requirement would have to be filed with the Commission pursuant to Section 19(b)[161] of the Exchange Act, as well as, potentially, in an advance notice filed pursuant to Section 806(e) of the Clearing Supervision Act.[162] Therefore, the Commission is not addressing any changes related to such a requirement in this Advance Notice.

Finally, one commenter urged FICC to address the cross-border implications of the proposal and provide a framework for compliance by non-U.S. Netting Members and indirect participants.[163] Specifically, this commenter was concerned that the U.S. Treasury clearing mandate will adversely impact foreign customers that are limited in their ability, or prohibited entirely, to post margin in connection with transactions involving U.S. Treasury securities.[164] However, nothing in the Advance Notice would require a particular market participant to post margin in connection with transactions involving U.S. Treasury securities. Indirect participants remain able to access FICC's central clearing services through access models that do not require the direct posting of margin to FICC (*e.g.,* via the non-segregated versions of FICC's Sponsored and Agent Clearing Services), which should allow flexibility for market participants to determine the most effective way to access FICC indirectly regardless of potential regulatory or other constraints on the ability to post margin directly.

Accordingly, the proposed changes would be consistent with Rule 17ad–22(e)(18)(iv)(C).[165]

G. Consistency With Rule 17ad–22(e)(19)

Rule 17ad–22(e)(19) requires that FICC establish, implement, maintain and enforce written policies and procedures reasonably designed to identify, monitor, and manage the material risks to the covered clearing agency arising from arrangements in which firms that are indirect participants in FICC rely on the services provided by direct participants to access FICC's clearance and settlement facilities.[166] The proposed changes

and for the direct participant to accept the customer's margin without offering the option of segregation (and thereby avoid the additional operational and other costs associated with segregation), which would still be permissible if FICC were not to require its Netting Members to offer account segregation. MFA Letter I at 4.

[149] SIFMA AMG Letter at 6.

[150] FICC Letter at 33.

[151] *See* ICI Letter at 13.

[152] *See supra* note 3 at 2751.

[153] FIA–PTG Letter at 7–9.

[154] FICC Letter at 39.

[155] FIA–PTG Letter at 7–9.

[156] FICC Letter at 40.

[157] *See* FIA PTG Letter I at 7–9.

[158] *See* Treasury Clearing Adopting Release, *supra* note 3, at 2767 (removing, in response to commenters, the requirement that the covered clearing agency have procedures to return customer position margin to the broker-dealer that is no longer needed to meet a current margin requirement resulting from positions in U.S. Treasury securities of the broker-dealer's customers no later than the close of the next business day after the day the customer position margin is no longer needed for this purpose because such a requirement may add significant operational burdens to covered clearing agencies for U.S. Treasury securities and because the debit is limited to margin required and on deposit at the covered clearing agency and therefore does not include the excess margin).

[159] *See* MFA Letter I at 6.

[160] *See* FICC Letter at 32. Specifically, FICC stated that the Treasury Clearing Rules, in particular the amendments to Exchange Act Rule 15c3–3a, provide that a broker-dealer may record a debit in the customer and PAB reserve formulas for margin it collects from customers and on-posts to FICC, but only if the broker-dealer collects from the customer the full amount of margin required for the customer's positions. Accordingly, a broker-dealer is effectively precluded from collecting from customers only a portion of the margin that their positions require and on-posting that amount to FICC. Were FICC to allow segregation of customer margin even if the customer did not fully fund its margin obligations, such segregation would effectively allow non-broker-dealer Netting Members to offer what broker-dealers cannot, *i.e.,* permitting their customers to post a portion of the margin required by FICC and on-post that margin to FICC. This ability would place such Netting Members at a competitive advantage relative to broker-dealer Netting Members.

[161] 15 U.S.C. 78s(b)(1).

[162] *See supra* note 3 at 2751.

[163] *See* SIFMA AMG Letter at 12–13.

[164] *See id.* (citing Article 15(2) of the European Union's Money Market Fund Regulation, which it describes as prohibiting European Money Market Mutual Funds from pledging any assets received under reverse repos and certain restrictions on Undertakings for Collective Investments in Transferable Securities and similar investment vehicles related to their ability to post margin that will be held on deposit at FICC).

[165] 17 CFR 240.17ad–22(e)(18)(iv)(C).

[166] 17 CFR 240.17ad–22(e)(19).

described in Section I.B.1 would require that each margin portfolio contains only transactions from the same account type, Netting Members use separate Deposit IDs for different transaction types, each Segregated Indirect Participant's margin requirement be calculated separately on a gross basis as though each Segregated Indirect Participant were a separate Netting Member, and Segregated Customer Margin for each indirect participant be deposited into a separate interest-earning Segregated Customer Margin Custody Account. These changes should enhance FICC's ability to isolate the risk profiles of individual indirect participants from Netting Members, which should help FICC better understand and monitor each individual participant's risk exposures. In addition, the calculation and collection of Segregated Customer Margin on a gross basis, as described in Section I.B.1 and 1.B.2, and the establishment of a $1 million cash floor for Segregated Customer Margin, as described in Section I.B.2.a, should help ensure that FICC will have sufficient margin to manage the risk to FICC during an indirect participant default.

Accordingly, the proposed changes would be consistent with Rule 17ad–22(e)(19) because they should enhance FICC's ability to identify, monitor, and manage the material risks to FICC associated with indirect participants relying on Netting Members to access FICC's clearance and settlement services.[167]

H. Consistency With Rule 17ad–22(e)(23)(ii)

Rule 17ad–22(e)(23)(ii) requires that FICC establish, implement, maintain and enforce written policies and procedures providing sufficient information to enable participants to identify and evaluate the risks, fees, and other material costs they incur by participating in FICC.[168] The proposed changes described in Section I.B.3 to consolidate and clarify FICC's margin calculation methodology in the proposed Margin Component Schedule, adopt a method for allocating net unsettled positions to individual indirect participants for purposes of calculating margin requirements and to clarify the calculation of the ECP should make it easier for both Netting Members and indirect participants to identify and price the potential margining costs associated with how each chooses to submit transactions to FICC for clearance and settlement.

Accordingly, the proposed changes would be consistent with Rule 17ad–22(e)(23)(ii) because they should enhance the ability of Netting Members and indirect participants to identify and evaluate the costs to access FICC's clearance and settlement services.[169]

IV. Conclusion

It is therefore noticed, pursuant to Section 806(e)(1)(I) of the Clearing Supervision Act, that the Commission DOES NOT OBJECT to Advance Notice (SR–FICC–2024–802), as modified by Partial Amendment No. 1, and that FICC is AUTHORIZED to implement the proposed change as of the date of this notice or the date of an order by the Commission approving proposed rule change SR–FICC–2024–007, whichever is later.

By the Commission.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–27766 Filed 11–26–24; 8:45 am]

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[167] 17 CFR 240.17ad–22(e)(19).

[168] 17 CFR 240.17ad–22(e)(23)(ii).

[169] 17 CFR 240.17ad–22(e)(23)(ii).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101697; File No. SR–FINRA–2024–020]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Adopt Fees in FINRA Rule 7720 (Securities Lending and Transparency Engine (SLATE™))

November 21, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 20, 2024, the Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by FINRA. FINRA has designated the proposed rule change as ''establishing or changing a due, fee or other charge'' under Section 19(b)(3)(A)(ii) of the Act[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposal effective upon receipt of this filing by the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

FINRA is proposing to adopt new FINRA Rule 7720 (Securities Lending and Transparency Engine (SLATE™)) to establish securities loan reporting fees and securities loan data products with associated fees in connection with FINRA's separately proposed Rule 6500 Series (Securities Lending and Transparency Engine (SLATE)) establishing securities loan reporting and data dissemination requirements.[5]

The text of the proposed rule change is available on FINRA's website at *http://www.finra.org,* at the principal office of FINRA and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. FINRA has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

(i) Background

On October 13, 2023, the Commission adopted new SEA Rule 10c–1a[6] to require any ''covered person''[7] who agrees to a ''covered securities loan''[8] to

[5] *See infra* note 6.

[6] *See* 17 CFR 240.10c–1a (''SEA Rule 10c–1a''); Securities Exchange Act Release No. 98737 (October 13, 2023), 88 FR 75644 (November 3, 2023) (Reporting of Securities Loans) (''Adopting Release'').

[7] SEA Rule 10c–1a(j)(1) defines a ''covered person'' as (i) any person that agrees to a covered securities loan on behalf of a lender (''intermediary'') other than a clearing agency when providing only the functions of a central counterparty pursuant to Rule 17Ad–22(a)(2) of the Exchange Act or a central securities depository pursuant to Rule 17Ad–22(a)(3) of the Exchange Act; or (ii) any person that agrees to a covered securities loan as a lender when an intermediary is not used unless paragraph (j)(1)(iii) of this section applies; or (iii) a broker or dealer when borrowing fully paid or excess margin securities pursuant to Rule 15c3–3(b)(3) of the Exchange Act.

[8] SEA Rule 10c–1a(j)(2) defines a ''covered securities loan'' as a transaction in which any

provide specified information to a registered national securities association (''RNSA'').[9] The RNSA is then required to make publicly available information regarding reported securities loans, as described in SEA Rule 10c–1a.[10] In its Adopting Release, the Commission stated its belief that SEA Rule 10c–1a would increase transparency in the securities lending market, resulting in a reduction in the information disadvantage faced by end borrowers and beneficial owners, improve price discovery, increase competition among providers of securities lending analytics services, reduce costs associated with tracking market conditions for broker-dealers and lending programs, and improve decision-making by investors, beneficial owners, and other market participants.[11]

SEA Rule 10c–1a(f) requires an RNSA that is collecting the information required to be reported under the rule to implement rules regarding the format and manner of its collection of information described in paragraphs 10c–1a(c) through 10c–1a(e) of SEA Rule 10c–1a and make publicly available such information in accordance with rules promulgated by the RNSA pursuant to Section 19(b) of the Exchange Act and Rule 19b–4 thereunder. In accordance with this requirement, on May 1, 2024, FINRA filed with the Commission a proposed rule change to adopt the new FINRA Rule 6500 Series (Securities Lending and Transparency Engine (SLATE)) to establish reporting requirements for Covered Securities Loans[12] and to provide for the public dissemination of loan information.[13]

In its Adopting Release, the Commission recognized that an RNSA would incur costs to develop and maintain systems to comply with the covered securities loan reporting and data dissemination requirements of SEA Rule 10c–1a[14] and expressly permitted an RNSA to establish and collect reasonable fees pursuant to rules established under Section 19(b) of the Exchange Act and Rule 19b–4 thereunder.[15] The purpose of this proposed rule change is to establish a SLATE fee structure to allow FINRA to recover reasonably estimated incremental direct ongoing costs associated with complying with SEA Rule 10c–1a.[16]

Among other things, the SLATE Proposal would establish the requirements for reporting Initial Covered Securities Loans[17] and Loan Modifications[18] to SLATE and would require that such reports be submitted to FINRA timely, accurately, and completely.[19] In the SLATE Proposal, FINRA stated its intention to file separately a proposed rule change to establish covered securities loan reporting fees and to establish securities loan data products with associated fees.[20] The SLATE Proposal also provided that FINRA would make specified securities loan information available on its website free of charge for personal, non-commercial purposes only.[21] In the instant filing, FINRA proposes to establish such reporting fees and to establish SLATE data products with associated fees, as described below.

(ii) Proposed Rule Change

FINRA is proposing to establish new Rule 7720 to provide for reporting fees for: (1) SLATE system connectivity; (2) Initial Covered Securities Loan reporting; (3) Loan Modification reporting; (4) late reporting; and (5) reporting cancellations, corrections, and deletions. Rule 7720 also establishes data products with associated fees for SLATE Loan-Level Data and Daily Loan Statistics;[22] and Historic SLATE Data.[23]

SLATE Reporting Fees

Previously proposed new Rule 6530(a) would establish the requirements relating to the reporting of Initial Covered Securities Loans to SLATE. Proposed Rule 7720(b)(1) provides that, for each such Initial Covered Securities Loan report, a SLATE Participant will be subject to a reporting fee of $0.07 per submission. Previously proposed new Rule 6530(b) would establish the requirements relating to the reporting of Covered Securities Loan Modifications to SLATE. Proposed Rule 7720(b)(2) provides that, for each such Loan Modification report, a SLATE Participant will be subject to a reporting fee of $0.03 per submission.

Proposed Rule 7720 also establishes fees for the reporting of cancellations, corrections, and deletions of previously submitted Covered Securities Loans and for the late submission of Initial Covered Securities Loan and Loan Modification reports, which is consistent with the requirement that Covered Persons report timely, accurately, and completely to SLATE,[24] and facilitates the dissemination of accurate and complete information to regulators and the public.[25] Specifically,

person on behalf of itself or one or more other persons, lends a reportable security to another person, with exclusions for a position at a clearing agency that results from central counterparty services pursuant to Rule 17Ad–22(a)(2) of the Exchange Act or central securities depository services pursuant to Rule 17Ad–22(a)(3) of the Exchange Act, and the use of margin securities, as defined in Rule 15c3–3(a)(4) of the Exchange Act, by a broker or dealer. ''Reportable security'' is defined in SEA Rule 10c–1a(j)(3) as any security or class of an issuer's securities for which information is reported or required to be reported to the consolidated audit trail as required by § 242.613 of the Exchange Act and the CAT NMS Plan (''CAT''), the Financial Industry Regulatory Authority's Trade Reporting and Compliance Engine (''TRACE''), or the Municipal Securities Rulemaking Board's Real-Time Transaction Reporting System (''RTRS''), or any reporting system that replaces one of these systems.

[9] SEA Rule 10c–1a(j)(5) defines an ''RNSA'' as an association of brokers and dealers that is registered as a national securities association pursuant to 15 U.S.C. 78*o*–3 of the Exchange Act. FINRA currently is the only RNSA.

[10] *See* SEA Rule 10c–1a(g).

[11] *See* Adopting Release, 88 FR 75644, 75692.

[12] A ''Covered Securities Loan'' means a ''covered securities loan'' as defined in SEA Rule 10c1–a(j)(2).

[13] *See* Securities Exchange Act Release No. 100046 (May 1, 2024); 89 FR 38203 (May 7, 2024) (Notice of Filing of File No. SR–FINRA–2024–007) (Proposed Rule Change to Adopt the FINRA Rule 6500 Series (Securities Lending and Transparency Engine)) (''SLATE Proposal'').

[14] *See* Adopting Release, 88 FR 75644, 75717.

[15] *See* Adopting Release, 88 FR 75644, 75648.

[16] FINRA does not have regulatory authority over Covered Persons or Reporting Agents that are non-FINRA members. As FINRA does today, FINRA would refer to the SEC potential violations of the federal securities laws and rules by non-members, including failures to comply with SEA Rule 10c–1a and FINRA rules adopted pursuant to SEA Rule 10c–1a (*e.g.,* potential SLATE reporting violations or failures to pay when due any SLATE fees).

[17] ''Initial Covered Securities Loan'' means a new Covered Securities Loan not previously reported to SLATE. *See* proposed Rule 6510(d).

[18] ''Loan Modification'' means a change to any Data Element with respect to a Covered Securities Loan (irrespective of whether such Covered Securities Loan was previously reported to SLATE). *See* proposed Rule 6510(e).

[19] *See* proposed Rule 6530(c)(1); *see also* SLATE Proposal, 89 FR 38203, 38210.

[20] *See* SLATE Proposal, 89 FR 38203, 38206.

[21] *See* SLATE Proposal, 89 FR 38203, 38212 n.80. The SLATE data that FINRA will make available (pursuant to FINRA Rule 6540.02) will be displayed (viewable) free of charge on the FINRA website for personal, non-commercial purposes and will not be available in downloadable form through this means. Persons interested in receiving from FINRA downloadable files of SLATE data must subscribe to the appropriate data product made available pursuant to proposed Rule 7720.

[22] ''SLATE Loan-Level Data and Daily Loan Statistics'' means the data described in proposed Rule 6540(a) through (c).

[23] ''Historic SLATE Data'' means SLATE Loan-Level Data and Daily Loan Statistics from the beginning of SLATE data reporting through the end of the most recent calendar year.

[24] *See* proposed Rule 6530(c)(1). Proposed Rule 6530(c)(2) further provides that a member's pattern or practice of late reporting without exceptional circumstances may be considered conduct inconsistent with high standards of commercial honor and just and equitable principles of trade, in violation of FINRA Rule 2010. *See* SLATE Proposal, 89 FR 38203, 38210.

[25] ''[SEA Rule 10c–1a] is designed to provide access to timely, comprehensive securities loan information to market participants, the public, and

Continued

pursuant to proposed Rule 7720(b)(3), a SLATE Participant will be charged a cancel,[26] correct,[27] or delete[28] fee of $0.10 per canceled, corrected, or deleted Covered Securities Loan report. In addition, proposed Rule 7720(b)(4) establishes a late fee of $0.20 per Initial Covered Securities Loan report or Loan Modification report that is not timely reported to SLATE as required pursuant to the Rule 6500 Series.[29]

Proposed Rule 7720 also sets forth the fees for connecting to SLATE. Specifically, proposed Rule 7720(a) provides that a SLATE Participant may choose to report Covered Securities Loans to FINRA pursuant to the Rule 6500 Series either via: (1) the SLATE web browser; or (2) a third-party reporting intermediary (and such third party must use the SLATE web browser). The fee for connecting to the SLATE web browser is $25 per month per user ID and will be assessed for connecting to SLATE through the browser, whether a Covered Person Reporting Agent, or other third party.[30]

SLATE Loan-Level Data and Daily Loan Statistics

FINRA is proposing Rule 7720(c) to establish the SLATE Loan-Level Data and Daily Loan Statistics data product with associated fees. As defined in Rule 7720(e)(2), ''SLATE Loan-Level Data and Daily Loan Statistics'' means the data described in proposed Rule 6540 (Dissemination of Loan Information) paragraph (a), which addresses next-day dissemination;[31] paragraph (b), which addresses delayed dissemination;[32] and paragraph (c), which addresses daily loan statistics (*i.e.,* aggregate loan transaction activity[33] and loan rate distribution data[34]). Proposed Rule 7720(c) sets forth the fees applicable to subscribers that are persons and organizations other than qualifying Tax-Exempt Organizations[35] and subscribers that are qualifying Tax-Exempt Organizations. Recipients of the SLATE Loan-Level Data and Daily Loan Statistics product described herein will be required to execute appropriate agreements with FINRA to subscribe to SLATE Loan-Level Data and Daily Loan Statistics.

Under proposed Rule 7720(c)(1)(A), a fee of $3,000 per month will apply for daily receipt of the SLATE Loan-Level Data and Daily Loan Statistics, except for qualifying Tax-Exempt Organizations. The data is enabled for unlimited internal use through any number of display applications; separate fees and uses apply to qualifying Tax-Exempt Organizations (as discussed below). As further provided in proposed Rule 7720(c)(1)(A), the fee of $3,000 per month entitles subscribers to use SLATE Loan-Level Data and Daily Loan Statistics in one or more of the following ways: internal operational and processing systems, internal monitoring and surveillance systems, internal price validation, internal portfolio valuation services, internal analytical programs leading to purchase/sale or other trading decisions, and other related activities, and the repackaging of market data for delivery and dissemination outside the organization, such as indices or other derivative products. Bulk redistribution of SLATE Loan-Level Data and Daily Loan Statistics[36] is not permitted under this subscription type, which is limited to internal use. In addition, any derivative products shall not permit end users to determine underlying SLATE Loan-Level Data and Daily Loan Statistics.

Under proposed Rule 7720(c)(1)(B), a vendor display redistribution fee of $10,000 per month will apply for the display of SLATE Loan-Level Data and Daily Loan Statistics through any number of external display applications. However, bulk redistribution of SLATE Loan-Level Data and Daily Loan Statistics is not permitted. Therefore, any party wishing to receive a distribution of SLATE Loan-Level Data and Daily Loan Statistics files must subscribe directly with FINRA.

Proposed Rule 7720(c)(2) establishes a monthly fee of $1,500 applicable to qualifying Tax-Exempt Organizations for the daily receipt of SLATE Loan-Level Data and Daily Loan Statistics. FINRA is establishing a fee level for qualifying Tax-Exempt Organizations that is half of the fee that will be assessed on parties other than qualifying Tax-Exempt Organizations. The data is enabled for unlimited internal use. A Tax-Exempt Organization qualifies to receive SLATE Loan-Level Data and Daily Loan Statistics if it does not redistribute such data in bulk, or it redistributes such data in bulk or otherwise (*e.g.,* unlimited external display) at no charge solely to other

regulators, which will help provide borrowers and lenders with better tools to assess the terms of their securities loans and enhance the ability of regulators to oversee the securities lending market.'' Adopting Release, 88 FR 75644, 75648.

[26] A ''cancellation'' is used to remove a single event from the SLATE system. *See* Draft SLATE Participant Reporting Specifications, available at *https://www.finra.org/filing-reporting/slate.*

[27] A ''correction'' is used to replace fields in a prior reported event. *See* Draft SLATE Participant Reporting Specifications, available at *https://www.finra.org/filing-reporting/slate.*

[28] A ''deletion'' is used to remove an entire loan and all corresponding loan events (*i.e.,* modifications, corrections, etc.). *See* Draft SLATE Participant Reporting Specifications, available at *https://www.finra.org/filing-reporting/slate.*

[29] While FINRA will seek to address late or inaccurate SLATE reporting through its customary means, FINRA believes it is appropriate to establish fees to promote timely and accurate reporting. *See also* SLATE Proposal, 89 FR 38203, 38206 n.17.

[30] The $25 per month fee for connecting to the SLATE web browser is assessed per user (not per entity). Therefore, a single SLATE Participant will be charged $25 per month times the number of users that it determines to authorize for connecting to SLATE through the browser for SLATE reporting. This connectivity fee is not applicable to, or assessed on, SLATE data product subscribers for the purposes of receiving SLATE data.

[31] SLATE data that is subject to next day dissemination generally consists of the data set forth in Rule 6540(a): (1) the unique identifier assigned by FINRA to the loan; (2) the security identifier(s) specified in Rule 6530(a)(2)(A) or (B) that FINRA determines is appropriate to disseminate; (3)(a) for each Initial Covered Securities Loan, all other Data Elements reported to SLATE, except the amount of securities loaned and confidential data elements; (b) for each Loan Modification, the modified Data Elements reported to SLATE, except the amount of securities loaned and confidential data elements; or (c) for each Loan Modification to a Covered Securities Loan that was not previously required to be reported to SLATE, all other Data Elements reported to SLATE, except the amount of securities loaned and confidential data elements.

[32] SLATE data that is subject to delayed dissemination (20 business days after the date on which the Initial Covered Securities Loan was effected or the loan was modified) generally consists of the data set forth in Rule 6540(b): (1) the unique identifier assigned by FINRA to the Covered Securities Loan; (2) the security identifier(s) specified in Rule 6530(a)(2)(A) or (B) that FINRA determines is appropriate to disseminate; and (3) the amount of securities loaned reported to SLATE.

[33] Aggregate loan transaction activity data generally consists of the data set forth in Rule 6540(c)(1); specifically, the security identifier specified in Rule 6530(a)(2)(A) or (B) that FINRA determines is appropriate to disseminate and the aggregate volume of securities subject to an Initial Covered Securities Loan or modification to the amount of Reportable Securities loaned, reported on the prior business day.

[34] Loan rate distribution data generally consists of: (1) the security identifier specified in Rule 6530(a)(2)(A) or (B) that FINRA determines is appropriate to identify the relevant Reportable Security; (2) the highest rebate rate, lowest rebate rate, and volume weighted average of the rebate rates by U.S. currency and non-U.S. currency, as applicable, reported for Initial Covered Securities Loans collateralized by cash and for Loan Modifications collateralized by cash (where the Loan Modification involved a change to the rebate rate); and (3) the highest lending fee or rate, lowest lending fee or rate, and volume weighted average of the lending fees or rates reported for Initial Covered Securities Loans not collateralized by cash and for Loan Modifications not collateralized by cash (where the Loan Modification involved a change to the lending fee or rate).

[35] A ''Tax-Exempt Organization'' means an organization that is described in Section 501(c) of the Internal Revenue Code (26 U.S.C. 501(c)) and has received recognition of the exemption from federal income taxes from the Internal Revenue Service. *See* Proposed Rule 7720(e)(3).

[36] Bulk redistribution of SLATE data refers to the redistribution of the SLATE data files described in proposed Rule 7720. Bulk redistribution of SLATE data generally is not permitted, except for qualifying Tax-Exempt Organizations, subject to specified restrictions, as described in proposed Rule 7720(c)(2) and (d)(2).

Tax-Exempt Organizations that agree to be subject to the same restrictions.

Historic SLATE Data

FINRA also is proposing Rule 7720(d) to establish the Historic SLATE Data product with associated fees. As defined in Rule 7720(e)(1), ''Historic SLATE Data'' means ''SLATE Loan-Level Data and Daily Loan Statistics'' from the beginning of SLATE data reporting (currently scheduled to commence on January 2, 2026) through the end of the most recent calendar year. Historic SLATE Data will be made available within one month of year-end (*e.g.,* Historic SLATE Data for calendar year 2026 will be available by January 31, 2027; Historic SLATE Data for calendar year 2027 will be available by January 31, 2028, and so on). Proposed Rule 7720(d) sets forth the fees for Historic SLATE Data applicable to subscribers that are persons and organizations other than qualifying Tax-Exempt Organizations, and subscribers that are qualifying Tax-Exempt Organizations. Recipients of the Historic SLATE Data product described herein will be required to execute appropriate agreements with FINRA.

Under proposed Rule 7720(d)(1)(A), a single fee of $2,000 will apply to persons or organizations other than qualifying Tax-Exempt Organizations for development and set-up to begin receiving Historic SLATE Data. The set-up fee is a one-time fee. Proposed Rule 7720(d)(1)(B) provides that a fee of $5,000 per calendar year will apply for receipt of Historic SLATE Data, except for qualifying Tax-Exempt Organizations. The data is enabled for unlimited internal use through any number of display applications. As further provided in proposed Rule 7720(d)(1)(B), the fee of $5,000 per calendar year entitles persons or organizations other than qualifying Tax-Exempt Organizations to use Historic SLATE Data in one or more of the following ways: internal operational and processing systems, internal monitoring and surveillance systems, internal price validation, internal portfolio valuation services, internal analytical programs leading to purchase/sale or other trading decisions, and other related activities, and the repackaging of market data for delivery and dissemination outside the organization, such as indices or other derivative products. Bulk redistribution of Historic SLATE Data is not permitted under this subscription type, which is limited to internal use. In addition, any derivative products shall not permit end users to determine underlying SLATE Loan-Level Data and Daily Loan Statistics.

Proposed Rule 7720(d)(2) establishes the fees applicable to qualifying Tax-Exempt Organizations for receipt of Historic SLATE Data. A Tax-Exempt Organization qualifies to receive Historic SLATE Data if it does not redistribute such data in bulk, or it redistributes such data in bulk or otherwise at no charge solely to other Tax-Exempt Organizations that agree to be subject to the same restrictions. Under proposed Rule 7720(d)(2)(A), a single fee of $1,000 will apply to any qualifying Tax-Exempt Organization for development and set-up to begin receiving Historic SLATE Data. The set-up fee is a one-time fee and was established to amount to half of the fee that would be assessed on parties other than qualifying Tax-Exempt Organizations for data set up. Proposed Rule 7720(d)(2)(B) provides that a fee of $2,500 per calendar year will apply to any qualifying Tax-Exempt Organization for receipt of Historic SLATE Data, which is half of the fee that would be assessed on parties other than qualifying Tax-Exempt Organizations for these data. Historic SLATE Data is enabled for unlimited internal use and may be redistributed by a qualifying Tax-Exempt Organization in bulk or otherwise (*e.g.,* unlimited external display) subject to the restrictions in paragraph (d)(2) (*i.e.,* redistributed at no charge solely to other Tax-Exempt Organizations that agree to be subject to the same restrictions prescribed in the rule).

SLATE Cost Recovery

As further discussed below in the Economic Impact Assessment, the proposed fees described herein are designed to permit FINRA to recover costs associated with the operation of the SLATE program, as expressly permitted for an RNSA under the Exchange Act and SEA Rule 10c–1a.[37] FINRA currently estimates an average of approximately $4.5 million in incremental direct ongoing costs per year from 2026 through 2028 (including the incremental direct ongoing costs incurred in 2024 and 2025 to be recovered over the 3-year period),[38] and approximately $4.4 million in annual incremental direct ongoing costs thereafter. In an effort to make SLATE financially self-sustaining on an ongoing basis, the proposed fees are designed to generate an amount of revenue that is calibrated to align with the estimated incremental direct ongoing costs associated with the SLATE program, to enable FINRA to meets its obligations pursuant to the SEA Rule 10c–1a mandate, as further described below.

Specifically, FINRA's incremental direct costs associated with operating the SLATE program include costs for cloud resources (compute and storage), data validation, business rule processing, reference data, data dissemination, billing generation, technology operations monitoring and support, and alert escalation and remediation. Additional costs include staffing related to product management, application management, ongoing business and operational support for the user interface, and administration of participant information and applicable agreements.[39]

FINRA intends to reassess the SLATE reporting fees and data products and associated fees after the commencement of SLATE reporting and dissemination and obtaining additional information regarding reporting volumes and subscription interest. To the extent that FINRA determines that a change to the SLATE fee structure would be appropriate to better align SLATE revenues with the incremental direct ongoing costs incurred in connection with the SLATE program, FINRA would file a proposed rule change with the Commission pursuant to Section 19(b) of the Exchange Act and Rule 19b–4 thereunder.

FINRA has filed the proposed rule change for immediate effectiveness. The Commission's release adopting SEA Rule 10c–1a specified the compliance dates applicable to securities loan reporting and data dissemination.[40] Accordingly, if the Commission approves FINRA's proposed rules establishing the reporting and dissemination requirements, unless an extension is provided pursuant to Commission order, the implementation date of the proposed FINRA rules establishing the securities loan reporting fees will correspond to the commencement of reporting to SLATE, and the implementation date of the proposed FINRA rules establishing the securities loan data products with associated fees will correspond to the commencement of SLATE data

[37] *See* 10c–1a(i); *see also* Adopting Release 88 FR 75644, 75687.

[38] While SEA Rule 10c–1a does not require that securities loan reporting commence until January 2026 or that loan data dissemination commence until April 2026, FINRA has necessarily already begun making financial expenditures in response to the SEC's adoption of Rule 10c–1a so that FINRA will be positioned to comply with all of the obligations applicable to an RNSA under that rule.

[39] To the extent possible, FINRA will leverage existing systems, personnel, and processes in connection with FINRA's SLATE program consistent with FINRA's structure as a not-for-profit self-regulatory organization.

[40] *See supra* note 6.

dissemination. If the SEC extends the compliance dates for SEA Rule 10c–1a's reporting or dissemination requirements, FINRA's proposed rules addressing covered securities loan reporting fees and securities loan data products with associated fees would become effective consistent with the SEC's extended timeframe for reporting and data dissemination, respectively.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(5) of the Act, which requires, among other things, that FINRA rules provide for the equitable allocation of reasonable dues, fees, and other charges among members and issuers and other persons using any facility or system that FINRA operates or controls.[41] FINRA also believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act, which requires, among other things, that FINRA rules are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.[42]

Consistent with Section 984(b) of the Dodd-Frank Act, which mandates that the Commission increase the transparency of information available to brokers, dealers, and investors regarding securities loan activity, on October 13, 2023, the Commission adopted SEA Rule 10c–1a.[43] SEA Rule 10c–1a requires a Covered Person who agrees to a Covered Securities Loan to provide specified information to an RNSA.[44] The RNSA that is collecting the information required to be reported under the rule is then required to make publicly available information regarding reported securities loans, as described in SEA Rule 10c–1a.[45] Because FINRA is an RNSA, FINRA proposed to adopt the SLATE rules and is building a system (the proposed SLATE system) to which Covered Securities Loan information would be reported. SEA Rule 10c–1a sets forth other related requirements for an RNSA, as described in SEA Rule 10c–1a and the Adopting Release.[46] These mandates increase costs to FINRA, as an RNSA, that necessitate funding.

Section 15A(b)(2) of the Act requires that an RNSA be ''so organized and [have] the capacity to be able to carry out the purposes'' of the Act and ''to comply, and . . . to enforce compliance by its members and persons associated with its members,'' with the provisions of the Exchange Act.[47] FINRA therefore believes it is consistent with the Act that FINRA impose reasonable fees that are designed to support FINRA with regard to expenditures to meet its regulatory obligations in connection with the securities loan reporting and transparency initiative. In addition, FINRA notes that SEA Rule 10c–1a itself explicitly provides that the RSNA may establish and collect reasonable fees, pursuant to rules that are promulgated pursuant to Section 19(b) and Rule 19b–4 of the Exchange Act.[48]

As discussed above, and further below in the Economic Impact Assessment, FINRA is establishing a fee structure to implement reasonable fees relating to the SLATE program; specifically: (1) SLATE system connectivity fees; (2) fees in connection with reporting Covered Securities Loan information to SLATE; and (3) SLATE data products and associated fees. The fees being proposed herein are reasonable, including because they are designed to generate an amount of revenue that is calibrated to align with the estimated incremental direct ongoing costs associated with the SLATE program and to enable FINRA to meet its regulatory obligations.

FINRA believes it is equitable, reasonable, and consistent with the Exchange Act that the proposed SLATE system connectivity and reporting fees be assessed directly on the parties that have been designated by the Commission as bearing the underlying regulatory responsibility for reporting securities loan information to an RNSA—*i.e.,* Covered Persons that report to the SLATE system (and their agents).[49] In the Adopting Release, the Commission stated that ''. . . RNSAs may establish and collect reasonable fees, pursuant to rules that are effective pursuant to section 19(b) of the Exchange Act and Rule 19b–4 thereunder, from each person who provides any data set forth in paragraphs (b) through (e) of this section directly to an RNSA.'' [50] The Adopting Release also stated that ''[t]the final rule will also impose direct costs on an RNSA responsible for collecting, maintaining, and distributing the data, who may pass on these costs by imposing fees on entities that provide Rule 10c–1a information to an RNSA and/or consumers of Rule 10c–1a data.'' [51]

FINRA also believes that it is equitable, reasonable, and consistent with the Exchange Act to require that the parties reporting data to SLATE be directly responsible for paying SLATE fees because the reporting process is a primary driver of the costs that the proposed fees are intended to recover. Thus, assessing the SLATE system connectivity and reporting fees on Covered Persons (and their agents) aligns the direct responsibility for SLATE cost recovery with the parties generating the information collection costs.[52]

The proposed SLATE data products are offered on equal terms to similarly situated parties that choose to access the data products. Thus, FINRA believes that the proposed SLATE data fees are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers, as provided for in Section 15A(b)(6).[53] Under the proposal, with one exception (qualifying Tax-Exempt Organizations), the content of the information in the data products and the data products' usage rights are offered on the same terms to interested parties. Thus, any party (except for a qualifying Tax-Exempt Organization) that seeks to access SLATE Loan-Level Data and Daily Loan Statistics will pay a fee depending upon whether such party seeks the right to use the data solely internally, as described in

[41] 15 U.S.C. 78*o*–3(b)(5).

[42] 15 U.S.C. 78*o*–3(b)(6).

[43] *See generally* Adopting Release, 88 FR 75644. *See also* Public Law 111–203, 124 Stat. 1376 (2010).

[44] *See* SEA Rule 10c1–a(a)(1).

[45] *See* SEA Rule 10c–1a(g).

[46] As noted above, SEA Rule 10c–1a anticipates that an RNSA will propose rules consistent with the Commission's mandate. *See* SEA Rule 10c–1a(i). Section 984(a) of the Dodd-Frank Wall Street Reform and Consumer Protection Act (''Dodd-Frank Act'') added section 10(c)(1) to the Exchange Act to provide the Commission with authority over securities lending. *See* 15 U.S.C. 78j(c)(1). Section 984(b) of the Dodd-Frank Act mandates that the Commission increase the transparency of information available to brokers, dealers, and investors with respect to the loan or borrowing of securities. *See* Public Law 111–203, 124 Stat. 1376 (2010).

[47] 15 U.S.C. 78*o*–3(b)(2).

[48] *See* SEA Rule 10c–1a(i).

[49] ''Under the Exchange Act, RNSAs are allowed to adopt rules that impose the equitable allocation of reasonable fees among members and issuers, and other persons that use an RNSA facility or system.'' (citation omitted). *See* Adopting Release, 88 FR 75644, 75687.

[50] *See* Adopting Release, 88 FR 75644, 75687.

[51] *See* Adopting Release, 88 FR 75644, 75693.

[52] FINRA understands that many members shift at least some of the regulatory fees incurred to other parties. For instance, it is regular practice among clearing and trading firms to ''pass through'' the Trading Activity Fee (''TAF'') to the underlying firm executing the trade. Further, FINRA understands that executing firms commonly pass the TAF directly on to their customers. *See* Securities Exchange Act Release No. 90176 (October 14, 2020), 85 FR 66592, 66603 (October 20, 2020) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2020–032). ''The entities that provide Rule 10c–1a information to an RNSA may absorb these costs in the form of lower profits or may pass them on to their customers in the form of increased fees for broker-dealer services or lending program services.'' *See* Adopting Release 88 FR 75644, 75693.

[53] 15 U.S.C. 78*o*–3(b)(6).

proposed Rule 7720(c)(1)(A) ($3,000 per month), or whether such party seeks the right to display the data externally, as described in proposed Rule 7720(c)(1)(B) ($10,000 per month).[54] The higher fee of $10,000 per month proposed in Rule 7720(c)(1)(B) is not unfairly discriminatory (as compared to the $3,000 per month fee for internal use only) given the significantly expanded usage rights authorized under proposed Rule 7720(c)(1)(B), which permits the display of SLATE Loan-Level Data and Daily Loan Statistics through any number of external display applications.[55] All interested parties (except qualifying Tax-Exempt Organizations) will be assessed the same fee, with the same usage rights, for Historic SLATE Data.

Proposed Rule 7720 would apply a lower fee to qualifying Tax-Exempt Organizations for both the SLATE Loan-Level Data and Daily Loan Statistics as well as the Historic SLATE Data. As is the case with other data products offered by FINRA, *e.g.,* TRACE,[56] FINRA offers data products at a reduced fee to qualifying Tax-Exempt Organizations that have received recognition of the exemption from federal income taxes from the Internal Revenue Service.[57] In the proposed rule change, FINRA has established the proposed fees applicable to qualifying Tax-Exempt Organizations as half of the amounts that will be assessed to parties other than qualifying Tax-Exempt Organizations. FINRA also notes that Tax-Exempt Organizations only qualify for the reduced fees offered under the rule if they do not redistribute the data in bulk, or redistribute the data in bulk or otherwise at no charge solely to other Tax-Exempt Organizations that agree to be subject to the same restrictions.[58] FINRA believes this aspect of the proposed rule change is appropriate given the not-for-profit nature of such organizations and therefore is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers, as provided for in Section 15A(b)(6).[59]

FINRA also believes that the amounts of the proposed SLATE fees are equitable, reasonable, and consistent with the Exchange Act. As further discussed in the Economic Impact Assessment, in developing reporting activity estimates, FINRA used data gathered through outreach to industry participants, including data vendors, agent lenders, prime brokers, retail brokers, and beneficial owners. FINRA believes that the proposed SLATE data subscription fees also are reasonable given the usage rights and the use cases for the data. Because the proposed SLATE data products are a new product offering, it is difficult to estimate subscription levels and associated revenue. In addition, based on FINRA's experience, subscribership to data products may be slower initially, with interest building over time. As a result, FINRA has initially sought to rely primarily on revenues through SLATE reporting to offset the costs that FINRA seeks to recover in connection with the SEA Rule 10c–1a mandate. As such, the proposed fees generally are consistent with FINRA's efforts to align its operating expenses with its operating revenues, target break-even cash flows, and continue to responsibly manage expenses driven by mandatory initiatives in a manner consistent with FINRA's public Financial Guiding Principles.[60] The proposed SLATE fees will be applied consistently to all similarly situated parties that are required to report Covered Securities Loans (and their agents) (*i.e.,* SLATE Participants) and to those that choose to subscribe to SLATE data products.[61]

For the reasons discussed herein, FINRA believes that the proposed rule change is consistent with Section 15A(b)(5) of the Exchange Act, including that the proposal provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system that FINRA operates or controls.[62] FINRA likewise believes that the proposed rule change is consistent with Section 15A(b)(6) of the Act, which requires, among other things, that FINRA rules are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.[63]

B. Self-Regulatory Organization's Statement on Burden on Competition

Section 15A(b)(9) of the Act requires that FINRA's rules not impose any burden on competition that is not necessary or appropriate in furtherance of the purpose of the Exchange Act.[64] FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Economic Impact Assessment

FINRA has undertaken an economic impact assessment, as set forth below, to analyze the regulatory need for the proposed rule change, its potential economic impacts, including distributional and competitive effects, and the alternatives considered in assessing how to best meet FINRA's regulatory objectives. The regulatory need is discussed above.

Economic Baseline

In its Adopting Release, the SEC estimated that 609 Covered Persons and Reporting Agents would be affected by SEA Rule 10c–1a, of which 255 were Providing Covered Persons, 248 were Non-Providing Covered Persons, and 106 were Reporting Agents.[65] FINRA has estimated that approximately 125,000 Initial Covered Securities Loan reports and 200,000 Loan Modification reports per day may be reported to SLATE.[66] FINRA estimates that approximately 0.5% of Initial Covered Securities Loan reports and Loan Modification reports could result in corrections, cancellations, or deletions, and approximately 0.5% could be reported late.[67] FINRA anticipates that the volume of erroneous and late reports

[54] *See* proposed Rule 7720(c)(1)(A)–(B).

[55] *See* proposed Rule 7720(c)(1)(B).

[56] *See* Rule 7730(d)(1)(B).

[57] *See* supra note 35.

[58] *See* proposed Rule 7720(c)(2) and (d)(2).

[59] 15 U.S.C. 78*o*–3(b)(6).

[60] *See* FINRA's Financial Guiding Principles, *https://www.finra.org/sites/default/files/finra_financial_guiding_principles_0.pdf.* As discussed above, FINRA intends to reassess the SLATE reporting fees and data products and associated fees after gaining experience with the operation of SLATE and obtaining additional information regarding reporting volumes and subscription interest. To the extent that FINRA determines that a change to the SLATE fee structure would be appropriate to better align SLATE revenues with the incremental direct ongoing costs incurred in connection with the SLATE program, FINRA would file a proposed rule change with the Commission pursuant to Section 19(b) of the Exchange Act and Rule 19b–4 thereunder.

[61] The proposed data products will be offered on the same terms to any similarly situated party that seeks to subscribe.

[62] 15 U.S.C. 78*o*–3(b)(5).

[63] 15 U.S.C. 78*o*–3(b)(6).

[64] 15 U.S.C. 78*o*–3(b)(9).

[65] ''Providing Covered Persons'' would provide information directly to an RNSA while ''Non-Providing Covered Persons'' would use a reporting agent to provide information to an RNSA. *See* Adopting Release, 88 FR 75644, 75718. ''Reporting Agent'' is defined in SEA Rule 10c–1a(j)(4).

[66] The quantity of Loan Modification reports will be impacted by Covered Persons' reporting decisions, among other factors. For example, the extent to which Covered Persons choose to report rates as a spread to benchmark will affect the quantity of Loan Modification reports due to be reported, which in turn will impact fee revenues.

[67] This estimate is based on FINRA's experience with TRACE reporting. As of August 2024, the correction rate was approximately 0.8% for corporate bond reports and 0.68% for U.S. Treasury reports. The rate of late reports was 0.61% for corporate bonds and 0.42% for U.S. Treasury Securities. The correction and late reporting rates may be lower for SLATE reporting because proposed Rule 6530 generally provides a longer timeframe for reporting Covered Securities Loans to SLATE than is provided for corporates and U.S. Treasury Securities under the TRACE reporting regime.

will decrease over time as Covered Persons gain experience with SLATE reporting.

Economic Impacts

The economic impact of the currently proposed reporting fees, data products and associated subscription fees are discussed below.

SLATE Reporting Fees

As discussed above, Covered Persons will incur fees for reporting Initial Covered Securities Loans and Loan Modifications. Specifically, FINRA proposes that, for each Initial Covered Securities Loan report, a SLATE Participant will be subject to a fee of $0.07 per submission and for each Loan Modification report, a SLATE Participant will be subject to a fee of $0.03 per submission. FINRA also proposes that a SLATE Participant will be charged a cancel, correct, or delete fee of $0.10 per canceled, corrected, or deleted Covered Securities Loan report, and a late fee of $0.20 per Initial Covered Securities Loan or Loan Modification that is not reported timely to SLATE.

Developing estimates for the anticipated number and type of SLATE reports is challenging due to the availability of only limited information upon which to base estimates. In developing estimates, FINRA used data gathered through outreach to industry participants, including data vendors, agent lenders, prime brokers, retail brokers, and beneficial owners. These estimates were used to develop the proposed fee structure, which is intended to align SLATE revenues with the incremental direct ongoing costs incurred in connection with the SLATE initiative.

Given the estimated number of reports and proposed reporting fees discussed above, FINRA approximates that annual revenues from reporting fees would be $2,205,000 for Initial Covered Securities Loan reports,[68] $1,512,000 for Loan Modification reports,[69] $40,950 for corrections, cancellations, and deletions,[70] and $81,900 for late reports.[71] SLATE Participants will incur a $25 fee per user per month for connecting to the SLATE web browser. Given the estimated number of Covered Persons and Reporting Agents from the SEC's Adopting Release,[72] FINRA estimates the total connection fees per year would be $365,400.[73] Together, FINRA estimates SLATE reporting fees would total $4,205,250 per year.[74]

FINRA considered the potential impact of the proposed SLATE reporting fee structure on securities lending activities. Covered Persons' securities lending activities will impact the amount of reporting fees that they would incur. Some types of Covered Persons, such as lending agents, may incur relatively larger reporting fees compared to other Covered Persons due to their function in the securities lending market (*e.g.,* agent lenders generally transact as Covered Persons in higher volumes relative to other securities lending market participants). Lending agents may pass along fully or partially the reporting fees to beneficial owners, for instance, in the form of a direct charge or higher fees charged for lending services. The reporting fees also may affect how Covered Persons structure or conduct their securities lending business—*e.g.,* how lending agents determine to structure pool or lending programs. However, Covered Persons' choices are also affected by other factors, including counterparty risk and business models.

SLATE Data Products and Associated Fees

As described above, FINRA is proposing to establish SLATE data products and associated fees.[75] Specifically, FINRA is proposing to make SLATE Loan-Level Data and Daily Loan Statistics available on a subscription basis to qualifying Tax-Exempt Organizations (for $1,500/month) as well as to persons and organizations other than qualifying Tax-Exempt Organizations (for $3,000/month). Also as described above, vendors may subscribe to display externally SLATE Loan-Level Data and Daily Loan Statistics (for $10,000/month). The proposed SLATE data products will enable a broader range of market participants to access comprehensive securities lending data than would otherwise be available in the absence of the proposed data products, which will further enhance market transparency and efficiency. As discussed in the Adopting Release, the broader availability of securities lending information may lead to increased competition for data analytics services as the barriers to entry for providing such services decline and new entrants compete to provide analytics services.[76]

The proposed fees associated with the SLATE Loan-Level Data and Daily Loan Statistics product apply only to market participants that choose to subscribe. Market participants likely will assess the costs and benefits of having access to these data as compared to their existing sources of securities lending data.[77] Vendors externally displaying SLATE Loan-Level Data and Daily Loan Statistics may charge for access to SLATE data. If vendors use securities lending data obtained from FINRA to replace existing, more expensive sources of securities lending data, they may pass some or all of the savings on to their clients.

As described above, in addition to SLATE Loan-Level Data and Daily Loan Statistics, FINRA also will make Historic SLATE Data available: (1) to qualifying Tax-Exempt Organizations (for a $1,000 set-up fee and $2,500 per calendar year); and (2) to persons and organizations other than qualifying Tax-Exempt Organizations (for a $2,000 set-up fee and $5,000 per calendar year). Historic SLATE loan information would facilitate the availability of securities lending data to interested parties, such as academics, in connection with research efforts.[78]

Given the substantial uncertainty in future subscribership for new data products and the likelihood that interest may grow slowly over time, FINRA's

[68] FINRA arrived at $2,205,000 by multiplying the estimated number of daily Initial Loan Reports (125,000) by the proposed fee rate of $0.07 by the number of business days per year (252 days).

[69] FINRA arrived at $1,512,000 by multiplying the estimated number of daily Loan Modification Reports (200,000) by the proposed fee rate of $0.03 by the number of business days per year (252 days).

[70] FINRA arrived at $40,950 by multiplying the sum of the estimated number of daily Initial Loan Reports (125,000) and the estimated number of daily Loan Modification Reports (200,000) by the estimated rate of reports requiring a correction, cancellation, or deletion (0.5%) by the proposed fee rate of $0.10 by the number of business days per year (252 days).

[71] FINRA arrived at $81,900 by multiplying the sum of the estimated number of daily Initial Loan Reports (125,000) and the estimated number of daily Loan Modification Reports (200,000) by the estimated rate of late reports (0.5%) by the proposed fee rate of $0.20 by the number of business days per year (252 days).

[72] *See* Adopting Release, 88 FR 75644, 75718.

[73] FINRA arrived at $365,400 by multiplying the estimated number of Covered Persons and Reporting Agents (609) by an assumed 2 user accounts per Covered Person by the proposed fee rate of $25 per month by 12 months per year.

[74] FINRA arrived at $4,205,250 by adding the estimated annual revenue from reporting fees for Initial Covered Securities Loan Reports ($2,205,000), the estimated annual revenue from reporting fees for Loan Modification Reports ($1,512,000), the estimated annual revenue from correction, cancellation, and deletion fees ($40,950), the estimated annual revenue from fees for late reports ($81,900), and the estimated annual revenue from connection fees ($365,400).

[75] Separate from the SLATE data products and associated fees proposed herein, FINRA intends to make T+1 data, T+20 data, and daily loan statistics available on FINRA's website free of charge for personal, non-commercial purposes only. *See supra* note 21.

[76] *See* Adopting Release, 88 FR 75644, 75712.

[77] For a discussion of the current state of transparency in securities lending, *see* Adopting Release, 88 FR 75644, 75696–75700.

[78] *See* Adopting Release, 88 FR 75644, 75705, 75717.

best and conservative estimation of potential initial future revenues from data product subscriptions is $250,000. Together with the estimated reporting fee revenues discussed above, FINRA estimates approximately $4.2 million in annual revenue from reporting fees and $250,000 in revenue from data product subscriptions for total annual revenue of approximately $4.5 million. This aligns with FINRA's estimated incremental direct ongoing costs of approximately $4.5 million per year from 2026 through 2028, and approximately $4.4 million in incremental direct ongoing costs thereafter.

Alternatives Considered

In developing the proposed rule change, FINRA considered various alternatives and the potential costs and benefits of those alternatives. Among other things, FINRA considered a volume-based reporting fee structure where reporting fees would vary depending on loan size. However, because loan size may not be proportional to the potential revenue from reportable securities loans, a volume-based reporting fee structure may create distortions in the market. For example, the ratio of lending revenue to loan volume for short-term financing or balance sheet management is generally lower than for securities lending transactions used for accessing hard-to-borrow securities. Volume-based reporting fees also could result in a substantial concentration of reporting fees on Covered Persons with a higher share of large-volume loans. Therefore, FINRA believes that a flat fee rate per report will distribute fees in a more equitable manner across market participants.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [79] and paragraph (f)(2) of Rule 19b–4 thereunder.[80] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–FINRA–2024–020 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–FINRA–2024–020. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of FINRA. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to File Number SR–FINRA–2024–020 and should be submitted on or before December 18, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[81]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–27742 Filed 11–26–24; 8:45 am]

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[79] 15 U.S.C. 78s(b)(3)(A).

[80] 17 CFR 240.19b–4(f)(2).

[81] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101699; File No. SR–SAPPHIRE–2024–36]

Self-Regulatory Organizations; MIAX Sapphire, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rule 402, Criteria for Underlying Securities To List and Trade Options on the iShares Bitcoin Trust (the "Trust")

November 21, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 18, 2024, MIAX Sapphire, LLC (''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Exchange Rule 402, Criteria for Underlying Securities. The text of the proposed rule change is available on the Exchange's website at *https://www.miaxglobal.com/markets/us-options/miax-sapphire/rule-filings,* at the Exchange's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Exchange Rule 402, Criteria for Underlying Securities,[3] to allow the Exchange to list and trade options on the iShares Bitcoin Trust (the ''Trust''), designating the Trust as appropriate for options trading on the Exchange.[4] This is a competitive filing based on a similar proposal submitted by Nasdaq ISE, LLC (''ISE'') and approved by the Securities and Exchange Commission (''Commission'').[5]

Current Exchange Rule 402(i)(4) provides that securities deemed appropriate for options trading include shares or other securities (''Exchange Traded Fund Shares'') that are traded on a national securities exchange and are defined as ''NMS stock'' under Rule 600 of Regulation NMS, and that meet specified criteria enumerated in the rule. Sub Section 4 of Exchange Rule 402(i) provides that such shares or other securities:

(4) are issued by the SPDR® Gold Trust or the iShares COMEX Gold Trust or the iShares Silver Trust or the ETFS Silver Trust or the ETFS Gold Trust or the ETFS Palladium Trust or the ETFS Platinum Trust or the Sprott Physical Gold Trust.

In addition, the underlying securities and Exchange Rule 402i, including the commodity based trusts in Exchange Rule 402(i)(4), must meet the requirements of Exchange Rule 402(i), Sections i(5)(i)(A) or (B).

Proposal

The Exchange proposes to amend Exchange Rule 402(i)(4) to expand the list of securities that are appropriate for options trading on the Exchange.

Description of the Trust[6]

The shares are issued by the Trust, a Delaware statutory trust. The Trust operates pursuant to a trust agreement (the ''Trust Agreement'') between the Sponsor, BlackRock Fund Advisors (the ''Trustee'') as the trustee of the Trust and Wilmington Trust, National Association, as Delaware trustee. The Trust issues shares representing fractional undivided beneficial interests in its net assets. The assets of the Trust consist only of bitcoin, held by a custodian on behalf of the Trust except under limited circumstances when transferred through the Trust's prime broker temporarily (described below), and cash. Coinbase Custody Trust Company, LLC (the ''Bitcoin Custodian'') is the custodian for the Trust's bitcoin holdings, and maintains a custody account for the Trust (''Custody Account''); Coinbase, Inc. (the ''Prime Execution Agent''), an affiliate of the Bitcoin Custodian, is the prime broker for the Trust and maintains a trading account for the Trust (''Trading Account''); and Bank of New York Mellon is the custodian for the Trust's cash holdings (the ''Cash Custodian'' and together with the Bitcoin Custodian, the ''Custodians'') and the administrator of the Trust (the ''Trust Administrator''). Under the Trust Agreement, the Trustee may delegate all or a portion of its duties to any agent, and has delegated the bulk of the day to day responsibilities to the Trust Administrator and certain other administrative and record-keeping functions to its affiliates and other agents. The Trust is not an investment company registered under the Investment Company Act of 1940, as amended.

The investment objective of the Trust is to reflect generally the performance of the price of bitcoin. The Trust seeks to reflect such performance before payment of the Trust's expenses and liabilities. The shares are intended to constitute a simple means of making an investment similar to an investment in bitcoin through the public securities market rather than by acquiring, holding and trading bitcoin directly on a peer-to-peer or other basis or via a digital asset exchange. The shares have been designed to remove the obstacles represented by the complexities and operational burdens involved in a direct investment in bitcoin, while at the same time having an intrinsic value that reflects, at any given time, the investment exposure to the bitcoin owned by the Trust at such time, less the Trust's expenses and liabilities. Although the shares are not the exact equivalent of a direct investment in bitcoin, they provide investors with an alternative method of achieving investment exposure to bitcoin through the public securities market, which may be more familiar to them.

Custody of the Trust's Bitcoin

An investment in the shares is backed by bitcoin held by the Bitcoin Custodian on behalf of the Trust. All of the Trust's bitcoin will be held in the Custody Account, other than the Trust's bitcoin which is temporarily maintained in the Trading Account under limited circumstances, *i.e.,* in connection with creation and redemption Basket[7] activity or sales of bitcoin deducted from the Trust's holdings in payment of Trust expenses or the Sponsor's fee (or, in extraordinary circumstances, upon liquidation of the Trust). The Custody Account includes all of the Trust's bitcoin held at the Bitcoin Custodian, but does not include the Trust's bitcoin temporarily maintained at the Prime Execution Agent in the Trading Account from time to time. The Bitcoin Custodian will keep all of the private keys associated with the Trust's bitcoin held in the Custody Account in ''cold storage''.[8] The hardware, software,

[3] The Exchange notes that its affiliate exchanges, MIAX Options and MIAX Pearl, submitted substantively identical proposals. The Exchange notes that all the rules of Chapter III of the MIAX Options Exchange, including Rules 307 and 309, are incorporated by reference to MIAX Pearl and MIAX Sapphire. The Exchange also notes that all of the rules of Chapter III of the MIAX Options Exchange, including Rules 307 and 309, and the rules of Chapter IV of the MIAX Options Exchange, including Rule 402, are incorporated by reference to MIAX Emerald.

[4] On January 10, 2024, the Commission approved proposals by NYSE Arca, Inc., The Nasdaq Stock Market LLC, and Cboe BZX Exchange, Inc. to list and trade the shares of 11 bitcoin-based commodity-based trust shares and trust units, including the iShares Bitcoin Trust. *See* Securities Exchange Act Release No. 99306 (Jan. 10, 2024), 89 FR 3008 (Jan. 17, 2024) (order approving File Nos. SR–NYSEARCA–2021–90; SR–NYSEARCA–2023–44; SR–NYSEARCA–2023–58; SR–NASDAQ–2023–016; SR–NASDAQ–2023–019; SR–CboeBZX–2023–028; SR–CboeBZX–2023–038; SR–CboeBZX–2023–040; SR–CboeBZX–2023–042; SR–CboeBZX–2023–044; SR–CboeBZX–2023–072) (''Bitcoin ETP Order'').

[5] *See* Securities Exchange Act Release No. 101128 (September 20, 2024), 89 FR 78942 (September 26, 2024) (SR–ISE–2024–03) (Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing of Amendment Nos. 4 and 5 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment Nos. 1, 4, and 5, to Permit the Listing and Trading of Options on the iShares Bitcoin Trust).

[6] *See* Securities Exchange Act Release No. 99306 (Jan. 10, 2024), 89 FR 3008 (Jan. 17, 2024) (order approving File Nos. SR–NYSEARCA–2021–90; SR–NYSEARCA–2023–44; SR–NYSEARCA–2023–58; SR–NASDAQ–2023–016; SR–NASDAQ–2023–019; SR–CboeBZX–2023–028; SR–CboeBZX–2023–038; SR–CboeBZX–2023–040; SR–CboeBZX–2023–042; SR–CboeBZX–2023–044; SR–CboeBZX–2023–072)(Order Granting Accelerated Approval of Proposed Rule Changes, as Modified by Amendments Thereto, To List and Trade Bitcoin-Based Commodity-Based Trust Shares and Trust Units) for a complete description of the Trust.

[7] The Trust issues and redeems Shares only in blocks of 40,000 or integral multiples thereof. A block of 40,000 Shares is called a ''Basket.'' These transactions take place in exchange for Bitcoin.

[8] The term ''cold storage'' refers to a safeguarding method by which the private keys corresponding to the Trust's bitcoins are generated and stored in an offline manner, subject to layers of procedures

systems, and procedures of the Bitcoin Custodian may not be available or cost-effective for many investors to access directly.

The Exchange believes that offering options on the Trust will benefit investors by providing them with an additional, relatively lower cost investing tool to gain exposure to spot Bitcoin as well as a hedging vehicle to meet their investment needs in connection with Bitcoin products and positions. Similar to other commodity-based trusts on which options may be listed on the Exchange (*e.g.,* SPDR® Gold Trust, the iShares COMEX Gold Trust, the iShares Silver Trust, or the ETFS Gold Trust),[9] the Trust essentially offers the same objectives and benefits to investors as do other commodity-based trusts on which options may be listed on the Exchange.

Options on the Trust will trade in the same manner as options on other ETFs on the Exchange. Exchange Rules that currently apply to the listing and trading of all options on ETFs on the Exchange, including, for example, Rules that govern listing criteria, expirations, exercise prices, minimum increments, position and exercise limits (including as proposed in the filing submitted by Exchange's affiliate, MIAX Options), margin requirements, customer accounts and trading halt procedures, will apply to the listing and trading of options on the Trust on the Exchange. Today, these rules apply to options on the various commodities-based trusts deemed appropriate for options trading on the Exchange pursuant to Exchange Rule 402(i)(4).

The Exchange's initial listing standards for ETFs on which options may be listed and traded on the Exchange will apply to the Trust. Pursuant to Exchange Rule 402(a), a security (which includes ETFs) on which options may be listed and traded on the Exchange must be duly registered (with the Commission) and be an NMS stock (as defined in Rule 600 of Regulation NMS under the Act,) and be characterized by a substantial number of outstanding shares that are widely held and actively traded. Exchange Rule 402(i) requires that, in relevant part, ETFs must either (1) meet the criteria and standards set forth in Exchange Rule 402(a) or Exchange Rule 402(b), or (2) be available for creation or redemption each business day from or through the issuer in cash or in kind at a price related to net asset value, and the issuer must be obligated to issue ETFs in a specified aggregate number even if some or all of the investment assets required to be deposited have not been received by the issuer, subject to the condition that the person obligated to deposit the investments has undertaken to deliver the investment assets as soon as possible and such undertaking is secured by the delivery and maintenance of collateral consisting of cash or cash equivalents satisfactory to the issuer, as provided in the respective prospectus.

Options on the Trust will also be subject to the Exchange's continued listing standards set forth in Exchange Rule 403(g), for ETFs deemed appropriate for options trading pursuant to Exchange Rule 402(i). Specifically, Exchange Rule 403(g) provides that ETFs that were initially approved for options trading pursuant to Exchange Rule 402(i) shall be deemed not to meet the requirements for continued approval, and the Exchange shall not open for trading any additional series of option contracts of the class covering that such ETFs, if the ETFs are delisted from trading pursuant to Exchange Rule 403(b)(4), are halted or suspended from trading in their primary market. Additionally, options on ETFs may be subject to the suspension of opening transactions in any of the following circumstances: (1) in the case of options covering ETFs approved for trading under Exchange Rule 402(i)(5)(i)(A), in accordance with the terms of paragraphs (b)(1), (2), and (3) of Exchange Rule 403; (2) in the case of options covering ETFs approved for trading under Exchange Rule 402(i)(5)(i)(B), following the initial twelve-month period beginning upon the commencement of trading in the ETFs on a national securities exchange and are defined as an NMS stock, there are fewer than 50 record and/or beneficial holders of such ETFs for 30 or more consecutive trading days; (3) the value of the index or portfolio of securities, non-U.S. currency, or portfolio of commodities including commodity futures contracts, options on commodity futures contracts, swaps, forward contracts and/or options on physical commodities and/or financial instruments and money market instruments on which the ETFs are based is no longer calculated or available; or (4) such other event shall occur or condition exist that in the opinion of the Exchange makes further dealing in such options on the Exchange inadvisable.

Options on the Trust would be physically settled contracts with American-style exercise.[10] Consistent with current Exchange Rule 404, which governs the opening of options series on a specific underlying security (including ETFs), the Exchange will open at least one expiration month for options on the Trust[11] and may also list series of options on the Trust for trading on a weekly,[12] monthly,[13] or quarterly[14] basis. The Exchange may also list long-term equity option series (''LEAPS'') that expire from 12 to 39 months from the time they are listed.[15]

Pursuant to Exchange Rule 404, Interpretation and Policy .06, which governs strike prices of series of options on ETFs, the interval between strike prices of series of options on ETFs approved for options trading pursuant to Exchange Rule 402(i) shall be fixed at a price per share which is reasonably close to the price per share at which the underlying security is traded in the primary market at or about the same time such series of options is first open for trading on the Exchange, or at such intervals as may have been established on another options exchange prior to the initiation of trading on the Exchange. With respect to the Short Term Options Series or Weekly Program, during the month prior to expiration of an option

designed to enhance security. Private keys are generated by the Bitcoin Custodian in offline computers that are not connected to the internet so that they are more resistant to being hacked.

[9] *See* Exchange Rule 402(i)(4).

[10] *See* Exchange Rule 401, which provides that the rights and obligations of holders and writers are set forth in the Rules of the Options Clearing Corporation (''OCC''); *see also* OCC Rules, Chapters VIII (which governs exercise and assignment) and Chapter IX (which governs the discharge of delivery and payment obligations arising out of the exercise of physically settled stock option contracts).

[11] *See* Exchange Rule 404(b). The monthly expirations are subject to certain listing criteria for underlying securities described within Exchange Rule 404 and its Interpretations and Policies. Monthly listings expire the third Friday of the month. The term ''expiration date'' (unless separately defined elsewhere in the OCC By-Laws), when used in respect of an option contract (subject to certain exceptions), means the third Friday of the expiration month of such option contract, or if such Friday is a day on which the exchange on which such option is listed is not open for business, the preceding day on which such exchange is open for business. *See* OCC By-Laws Article I, Section 1. Pursuant to Exchange Rule 404(c), additional series of options of the same class may be opened for trading on the Exchange when the Exchange deems it necessary to maintain an orderly market, to meet customer demand or when the market price of the underlying stock moves more than five strike prices from the initial exercise price or prices. Pursuant to Exchange Rule 404(e), new series of options on an individual stock may be added until the beginning of the month in which the options contract will expire. Due to unusual market conditions, the Exchange, in its discretion, may add a new series of options on an individual stock until the close of trading on the business day prior to expiration.

[12] *See* Exchange Rule 404, Interpretations and Policies .02.

[13] *See* Exchange Rule 404, Interpretations and Policies .13.

[14] *See* Exchange Rule 404, Interpretations and Policies .03.

[15] *See* Exchange Rule 406(a).

class that is selected for the Short Term Option Series Program, the strike price intervals for the related non-Short Term Option (''Related non-Short Term Option'') shall be the same as the strike price intervals for the Short Term Option.[16] Specifically, the Exchange may open for trading Short Term Option Series at strike price intervals of (i) $0.50 or greater where the strike price is less than $100, and $1 or greater where the strike price is between $100 and $150 for all option classes that participate in the Short Term Options Series Program; (ii) $0.50 for option classes that trade in one dollar increments and are in the Short Term Option Series Program; or (iii) $2.50 or greater where the strike price is above $150.[17] Additionally, the Exchange may list series of options pursuant to the $1 Strike Price Interval Program,[18] the $0.50 Strike Program,[19] and the $2.50 Strike Price Program.[20] Pursuant to Exchange Rule 510, where the price of a series of options for the Trust is less than $3.00, the minimum increment will be $0.05, and where the price is $3.00 or higher, the minimum increment will be $0.10 [21] consistent with the minimum increments for options on other ETFs listed on the Exchange. Any and all new series of Trust options that the Exchange lists will be consistent and comply with the expirations, strike prices, and minimum increments set forth in Rules 404 and 510, as applicable.

Position and exercise limits for options on ETFs, including options on the Trust, are determined pursuant to the Exchange's affiliate MIAX Options Rules 307 and 309, respectively. Position and exercise limits for ETF options vary according to the number of outstanding shares and the trading volumes of the underlying ETF over the past six months, where the largest in capitalization and the most frequently traded ETFs have an option position and exercise limit of 250,000 contracts (with adjustments for splits, re-capitalizations, etc.) on the same side of the market; and smaller capitalization ETFs have position and exercise limits of 200,000, 75,000, 50,000 or 25,000 contracts (with adjustments for splits, re-capitalizations, etc.) on the same side of the market. The Exchange further notes that the Exchange's affiliate MIAX Options Rule 1502, which governs margin requirements applicable to trading on the Exchange, including options on ETFs, will also apply to the trading of the Trust options. Notwithstanding the position limits in the Exchange's affiliate MIAX Options Rule 307(d) and exercise limits in the Exchange's affiliate MIAX Options Rule 309, the Exchange proposes the position and exercise limits for the options on the Trust to be 25,000 contracts on the same side pursuant to proposed Supplementary Material .01 to the Exchange's affiliate MIAX Options Rule 307 and proposed Supplementary Material .01 to the Exchange's affiliate MIAX Options Rule 309.

The Exchange represents that the same surveillance procedures applicable to all other options on other ETFs currently listed and traded on the Exchange will apply to options on the Trust. Also the Exchange represents that it has the necessary systems capacity to support the new option series. The Exchange believes that its existing surveillance and reporting safeguards are designed to deter and detect possible manipulative behavior which might potentially arise from listing and trading options on ETFs, including the proposed Trust options.

Today, the Exchange has an adequate surveillance program in place for options. The Exchange intends to apply those same program procedures to options on the Trust that it applies to the Exchange's other options products.[22] The Exchange's staff will have access to the surveillance programs conducted by its affiliate exchanges, MIAX Options and MIAX Pearl with respect to trading in the shares of the underlying Trust when conducting surveillances for market abuse or manipulation in the options on the Trust. Additionally, the Exchange is a member of the Intermarket Surveillance Group (''ISG'') under the Intermarket Surveillance Group Agreement. ISG members work together to coordinate surveillance and investigative information sharing in the stock, options, and futures markets. In addition to obtaining surveillance data from MIAX Options and MIAX Sapphire, the Exchange will be able to obtain information regarding trading in the shares of the underlying Trust from Nasdaq, LLC and other markets through ISG. In addition, the Exchange has a Regulatory Services Agreement with the Financial Industry Regulatory Authority (''FINRA''). Pursuant to a multi-party 17d–2 joint plan, all options exchanges allocate regulatory responsibilities to FINRA to conduct certain options-related market surveillance that are common to rules of all options exchanges.[23]

The underlying shares of spot bitcoin ETPs, including the Trust, are also subject to safeguards related to addressing market abuse and manipulation. As the Commission stated in Bitcoin ETP Order:

Each Exchange has a comprehensive surveillance-sharing agreement with the CME via their common membership in the Intermarket Surveillance Group. This facilitates the sharing of information that is available to the CME through its surveillance of its markets, including its surveillance of the CME bitcoin futures market.[24]

The Exchange states that, given the consistently high correlation between the CME bitcoin futures market and the spot bitcoin market, as confirmed by the Commission through robust correlation analysis, the Commission was able to conclude that such surveillance sharing agreements could reasonably be ''expected to assist in surveilling for fraudulent and manipulative acts and practices in the specific context of the [Bitcoin ETPs].'' [25]

In light of surveillance measures related to both options and futures as well as the underlying Trust,[26] the Exchange believes that existing surveillance procedures are designed to deter and detect possible manipulative behavior which might potentially arise from listing and trading the proposed options on the Trust. Further, the Exchange represents that it will implement any new surveillance

[16] *See* Exchange Rule 404, Interpretations and Policies .02(e).

[17] *Id.*

[18] *See* Exchange Rule 404, Interpretation and Policy .01.

[19] *See* Exchange Rule 404, Interpretation and Policy .04.

[20] *See* Exchange Rule 404(f).

[21] *See* Exchange Rule 510.

[22] The surveillance program includes real-time patterns for price and volume movements and post-trade surveillance patterns (*e.g.,* spoofing, marking the close, pinging, phishing).

[23] Section 19(g)(1) of the Act, among other things, requires every SRO registered as a national securities exchange or national securities association to comply with the Act, the rules and regulations thereunder, and the SRO's own rules, and, absent reasonable justification or excuse, enforce compliance by its members and persons associated with its members. See 15 U.S.C. 78q(d)(1) and 17 CFR 240.17d–2. Section 17(d)(1) of the Act allows the Commission to relieve an SRO of certain responsibilities with respect to members of the SRO who are also members of another SRO (''common members''). Specifically, Section 17(d)(1) allows the Commission to relieve an SRO of its responsibilities to: (i) receive regulatory reports from such members; (ii) examine such members for compliance with the Act and the rules and regulations thereunder, and the rules of the SRO; or (iii) carry out other specified regulatory responsibilities with respect to such members.

[24] *See supra* note 4.

[25] *See* Bitcoin ETP Order, 89 FR at 3010–11.

[26] *See* Securities Exchange Act Release No. 99295 (January 8, 2024), 89 FR 2321, 2334–35 (January 12, 2024) (SR–NASDAQ–2023–016) (Notice of Filing of Amendment No. 1 to a Proposed Rule Change To List and Trade Shares of the iShares Bitcoin Trust Under Nasdaq Rule 5711(d)).

procedures it deems necessary to effectively monitor the trading of options on the Trust.

The Exchange has also analyzed its capacity and represents that it believes the Exchange and Options Price Reporting Authority or ''OPRA'' have the necessary systems capacity to handle the additional traffic associated with the listing of new series that may result from the introduction of options on the Trust up to the number of expirations currently permissible under the Rules. Because the proposal is limited to one class, the Exchange believes any additional traffic that may be generated from the introduction of the Trust options will be manageable. Finally, the Exchange proposes a technical amendment to Exchange Rule 402(i)(4) to amend the name ''ETFS Gold Trust'' to ''Aberdeen Standard Physical Gold Trust.'' In 2018 ETFS Gold Trust was renamed.[27] At this time, the Exchange proposes to amend the name of the ETF to reflect its current name.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[28] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [29] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section (6)(b)(5) [30] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes that the proposal to list and trade options on the Trust will remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, protect investors because offering options on the Trust will provide investors with a greater opportunity to realize the benefits of utilizing options on an ETF based on spot bitcoin, including cost efficiencies and increased hedging strategies. The Exchange believes that offering options on a competitively priced ETF based on spot bitcoin will benefit investors by providing them with an additional, relatively lower-cost risk management tool, allowing them to manage, more easily, their positions and associated risks in their portfolios in connection with exposure to spot bitcoin. Today, the Exchange lists options on other commodity ETFs structured as a trust, which essentially offer the same objectives and benefits to investors, and for which the Exchange has not identified any issues with the continued listing and trading of options on those ETFs.

The Exchange also believes the proposal to permit options on the Trust will remove impediments to and perfect the mechanism of a free and open market and a national market system, because options on the Trust will comply with current Exchange Rules. Options on the Trust must satisfy the initial listing standards and continued listing standards currently in the Exchange Rules, applicable to options on all ETFs, including options on other commodity ETFs already deemed appropriate for options trading on the Exchange pursuant to Exchange Rule 402(i)(4). Further, Exchange Rules that currently govern the listing and trading of options on ETFs, including permissible expirations, strike prices, minimum increments, position and exercise limits (including as proposed in the filing submitted by Exchange's affiliate, MIAX Options), and margin requirements, will govern the listing and trading of options on the Trust. The proposed position and exercise limits for options on the Trust is 25,000 contracts. These position and exercise limits are the lowest position and exercise limits available in the options industry, are extremely conservative and more than appropriate given the Trust's market capitalization, average daily volume, and high number of outstanding shares. The proposed position limit, and exercise limit, is consistent with the Act as it addresses concerns related to manipulation and protection of investors because the position limit (and exercise limit) is extremely conservative and more than appropriate given the Trust is actively traded.

The Exchange represents that it has the necessary systems capacity to support options on the Trust. The Exchange believes that its existing surveillance and reporting safeguards are designed to deter and detect possible manipulative behavior which might arise from listing and trading options on ETFs, including the Trust options. Today, the Exchange has an adequate surveillance program in place for options. The Exchange intends to apply those same program procedures to options on the Trust that it applies to the Exchange's other options products.[31] The Exchange's staff will have access to the surveillance programs conducted by its affiliate exchanges, MIAX Options and MIAX Sapphire with respect to the underlying Trust when conducting surveillances for market abuse or manipulation in the options on the Trust. The Exchange will review activity in the underlying Trust when conducting surveillances for market abuse or manipulation in the options on the Trust. Additionally, the Exchange is a member of the ISG under the Intermarket Surveillance Group Agreement. ISG members work together to coordinate surveillance and investigative information sharing in the stock, options, and futures markets. In addition to obtaining surveillance data from MIAX Options and MIAX Sapphire, the Exchange will be able to obtain information from ISE and other markets through ISG. In addition, the Exchange has a Regulatory Services Agreement with FINRA. Pursuant to a multi-party 17d–2 joint plan, all options exchanges allocate regulatory responsibilities to FINRA to conduct certain options-related market surveillance that are common to rules of all options exchanges.[32]

The underlying shares of spot bitcoin ETPs, including the Trust, are also

[27] Effective October 1, 2018 ETFS Gold Trust was renamed Aberdeen Standard Gold ETF Trust. *https://www.sec.gov/Archives/edgar/data/1450923/000138713118005292/ex10-2.htm.*

[28] 15 U.S.C. 78f(b).

[29] 15 U.S.C. 78f(b)(5).

[30] *Id.*

[31] The surveillance program includes real-time patterns for price and volume movements and post-trade surveillance patterns (*e.g.,* spoofing, marking the close, pinging, phishing).

[32] Section 19(g)(1) of the Act, among other things, requires every SRO registered as a national securities exchange or national securities association to comply with the Act, the rules and regulations thereunder, and the SRO's own rules, and, absent reasonable justification or excuse, enforce compliance by its members and persons associated with its members. See 15 U.S.C. 78q(d)(1) and 17 CFR 240.17d–2. Section 17(d)(1) of the Act allows the Commission to relieve an SRO of certain responsibilities with respect to members of the SRO who are also members of another SRO (''common members''). Specifically, Section 17(d)(1) allows the Commission to relieve an SRO of its responsibilities to: (i) receive regulatory reports from such members; (ii) examine such members for compliance with the Act and the rules and regulations thereunder, and the rules of the SRO; or (iii) carry out other specified regulatory responsibilities with respect to such members.

subject to safeguards related to addressing market abuse and manipulation. As the Commission stated in Bitcoin ETP Order:

Each Exchange has a comprehensive surveillance-sharing agreement with the CME via their common membership in the Intermarket Surveillance Group. This facilitates the sharing of information that is available to the CME through its surveillance of its markets, including its surveillance of the CME bitcoin futures market.[33]

The Exchange states that, given the consistently high correlation between the CME bitcoin futures market and the spot bitcoin market, as confirmed by the Commission through robust correlation analysis, the Commission was able to conclude that such surveillance sharing agreements could reasonably be ''expected to assist in surveilling for fraudulent and manipulative acts and practices in the specific context of the [Bitcoin ETPs].'' [34]

In light of surveillance measures related to both options and futures as well as the underlying Trust,[35] the Exchange believes that existing surveillance procedures are designed to deter and detect possible manipulative behavior which might potentially arise from listing and trading the proposed options on the Trust. Further, the Exchange represents that it will implement any new surveillance procedures it deems necessary to effectively monitor the trading of options on the Trust.

Finally, the Commission has previously approved the listing and trading of options on other commodity ETFs structured as a trust, such as SPDR® Gold Trust,[36] the iShares COMEX Gold Trust [37] the iShares Silver Trust,[38] the ETFS Gold Trust,[39] and the ETFS Silver Trust.[40]

Further, the Exchange's proposal to amend the name ''ETFS Gold Trust'' to ''Aberdeen Standard Physical Gold Trust'' in Exchange Rule 402(i)(4) is consistent with the Act and the protection of investors as this amendment reflects the current name of this product.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. In this regard and as indicated above, the Exchange notes that the rule change is being proposed as a competitive response to filings submitted by ISE.[41]

The Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act as options on the Trust will be subject to initial listing standards and continued listing standards the same as other options on ETFs listed on the Exchange. Further, options on the Trust will be subject to Exchange Rules that currently govern the listing and trading of options on ETFs, including permissible expirations, strike prices, minimum increments, position and exercise limits (including as proposed in the filing submitted by Exchange's affiliate, MIAX Options), and margin requirements. Options on the Trust will be equally available to all market participants who wish to trade such options. Also, and as stated above, the Exchange already lists options on other commodity ETFs structured as a trust.

The Exchange does not believe that the proposal to list to list and trade options on the Trust will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. To the extent that permitting options on the Trust to trade on the Exchange may make the Exchange a more attractive marketplace to market participants, such market participants are free to elect to become market participants on the Exchange. Additionally, other options exchanges are free to amend their listing rules, as applicable, to permit them to list and trade options on the Trust. The Exchange believes that the proposed rule change may relieve any burden on, or otherwise promote, competition as it is designed to increase competition for order flow on the Exchange in a manner that is beneficial to investors by providing them with a lower-cost option to hedge their investment portfolios. The Exchange notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues that offer similar products. Ultimately, the Exchange believes that offering options on the Trust for trading on the Exchange will promote competition by providing investors with an additional, relatively low-cost means to hedge their portfolios and meet their investment needs in connection with spot bitcoin prices and bitcoin related products and positions.

Finally, the Exchange's proposal to amend the name ''ETFS Gold Trust'' to ''Aberdeen Standard Physical Gold Trust'' in Exchange Rule 402(i)(4) does not impose an undue burden on competition as this amendment reflects the current name of this product.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [42] and Rule 19b–4(f)(6) thereunder.[43] Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act [44] and subparagraph (f)(6) of Rule 19b–4 thereunder.[45]

[33] *See supra* note 4.

[34] *See* Bitcoin ETP Order, 89 FR at 3010–11.

[35] *See* Securities Exchange Act Release No. 99295 (January 8, 2024), 89 FR 2321, 2334–35 (January 12, 2024) (SR–NASDAQ–2023–016) (Notice of Filing of Amendment No. 1 to a Proposed Rule Change To List and Trade Shares of the iShares Bitcoin Trust Under Nasdaq Rule 5711(d)).

[36] *See* Securities Exchange Act Release No. 57897 (May 30, 2008), 73 FR 32061 (June 5, 2008) (SR–Amex–2008–15; SR–CBOE–2005–11; SR–ISE–2008–12; SR–NYSEArca–2008–52; and SRPhlx–2008–17) (Order Granting Approval of a Proposed Rule Change, as Modified, and Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Changes, as Modified, Relating to Listing and Trading Options on the SPDR Gold Trust).

[37] *See* Securities Exchange Act Release No. 59055 (December 4, 2008), 73 FR 75148 (December 10, 2008) (SR–Amex–2008–68; SR–BSE–2008–51; SR–CBOE–2008–72; SR–ISE–2008–58; SRNYSEArca–2008–66; and SR–Phlx–2008–58) (Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Changes Relating to the Listing and Trading Options on Shares of the iShares COMEX Gold Trust and the iShares Silver Trust).

[38] *Id.*

[39] *See* Securities Exchange Act Release No. 61483 (February 3, 2010), 75 FR 6753 (February 10, 2010) (SR–CBOE–2010–007; SR–ISE–2009–106; SR–NYSEAmex–2009–86; and SR–NYSEArca–2009–110) (Order Granting Approval of Proposed Rule Changes and Notice of Filing and Order Granting Accelerated Approval of a Proposed Rule Change Relating to Listing and Trading Options on the ETFS Gold Trust and the ETFS Silver Trust).

[40] *Id.*

[41] *See supra* note 5.

[42] 15 U.S.C. 78s(b)(3)(A)(iii).

[43] 17 CFR 240.19b–4(f)(6).

[44] 15 U.S.C. 78s(b)(3)(A)(iii).

[45] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time

A proposed rule change filed under Rule 19b–4(f)(6) [46] under the Act does not normally become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[47] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Commission previously approved the listing of options on iShares Bitcoin Trust.[48] The Exchange has provided information regarding the underlying iShares Bitcoin Trust, including, among other things, information regarding trading volume, the number of beneficial holders, and the market capitalization of the iShares Bitcoin Trust. The proposal also establishes position and exercise limits for options on the iShares Bitcoin Trust and provides information regarding the surveillance procedures that will apply to iShares Bitcoin Trust options. The Commission believes that waiver of the operative delay could benefit investors by providing an additional venue for trading iShares Bitcoin Trust options. Therefore, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.[49]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

as designated by the Commission. The Exchange has satisfied this requirement.

[46] 17 CFR 240.19b–4(f)(6).

[47] 17 CFR 240.19b–4(f)(6)(iii).

[48] *See* Securities Exchange Act Release No. 101128 (September 20, 2024), 89 FR 78942 (September 26, 2024) (SR–ISE–2024–03) (Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing of Amendment Nos. 4 and 5 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment Nos. 1, 4, and 5, to Permit the Listing and Trading of Options on the iShares Bitcoin Trust).

[49] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–SAPPHIRE–2024–36 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–SAPPHIRE–2024–36. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–SAPPHIRE–2024–36 and should be submitted on or before December 18, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[50]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–27744 Filed 11–26–24; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101695; File No. SR–FICC–2024–007]

Self-Regulatory Organizations; Fixed Income Clearing Corporation; Order Approving Proposed Rule Change, as Modified by Partial Amendment No. 1, To Modify the GSD Rules (i) Regarding the Separate Calculation, Collection and Holding of Margin for Proprietary Transactions and That for Indirect Participant Transactions, and (ii) To Address the Conditions of Note H to Rule 15c3–3a

November 21, 2024.

On March 14, 2024, Fixed Income Clearing Corporation (''FICC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change SR–FICC–2024–007 pursuant to Section 19(b) of the Securities Exchange Act of 1934 (''Exchange Act'') [1] and Rule 19b–4 [2] thereunder to modify FICC's Government Securities Division (''GSD'') Rulebook (''GSD Rules'') to calculate, collect, and hold margin for transactions that a direct GSD participant enters into for its own benefit (''proprietary transactions'') separately from margin a direct participant submits to FICC on behalf of indirect participants and to address conditions of Note H to Rule 15c3–3a under the Exchange Act (the ''Proposed Rule Change'').[3] The Proposed Rule Change was published for public comment in the **Federal Register** on March 28, 2024.[4]

[50] 17 CFR 200.30–3(a)(12), (59).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 99149 (Dec. 13, 2023), 89 FR 2714 (Jan. 16, 2024) (S7–23–22) (''Adopting Release,'' and the rules adopted therein as ''Treasury Clearing Rules''). *See also* 17 CFR 240.15c3–3a.

[4] Securities Exchange Act Release No. 99844 (March 22, 2024), 89 FR 21603 (Mar. 28, 2024) (File No. SR–FICC–2024–007) (''Notice of Filing''). FICC also filed a related Advance Notice with the Commission pursuant to Section 806(e)(1) of Title VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act, entitled the Payment, Clearing, and Settlement Supervision Act of 2010 and Rule 19b–4(n)(1)(i) under the Exchange Act. 12 U.S.C. 5465(e)(1). 15 U.S.C. 78s(b)(1) and 17 CFR 240.19b–4, respectively. The Advance Notice was

Continued

On April 24, 2024, pursuant to Section 19(b)(2) of the Exchange Act,[5] the Commission designated a longer period within which to approve, disapprove, or institute proceedings to determine whether to approve or disapprove the Proposed Rule Change.[6] On June 21, 2024, pursuant to Section 19(b)(2)(B) of the Exchange Act,[7] the Commission instituted proceedings to determine whether to approve or disapprove the Proposed Rule Change.[8] On September 18, 2024, the Commission extended the time period for Commission action on the proceedings to determine whether to disapprove the Proposed Rule Change.[9] On October 25, 2024, FICC filed Partial Amendment No. 1 to the Proposed Rule Change.[10] The Proposed Rule Change, as modified by Partial Amendment No. 1, is referred to herein as the ''Proposed Rule Change.''

The Commission has received comments regarding the substance of the Proposed Rule Change.[11] The Commission also received a letter from FICC responding to the comments.[12]

For the reasons discussed below, the Commission is approving the Proposed Rule Change.

I. Description of the Proposed Rule Change

A. Background and Terminology

FICC, through its GSD, is a central counterparty and provider of clearance and settlement services for the U.S. government securities markets. As a central counterparty in the U.S. government securities markets, FICC novates transactions between two counterparties, effectively becoming the buyer to every seller and the seller to every buyer, and guarantees the settlement of the novated transactions. This means that FICC is exposed to a number of risks arising from such transactions, including counterparty credit risk. FICC seeks to maintain sufficient resources (*i.e.,* margin) to cover its credit exposures to its participants fully with a high degree of confidence and mitigate potential losses from a default of a direct GSD participant, which is generally referred to as a Netting Member under the GSD Rules [13] (and in this Order).

On December 13, 2023, the Commission adopted amendments to the standards applicable to covered clearing agencies that clear transactions in U.S. Treasury securities (''Treasury CCAs''), such as FICC.[14] These amendments require Treasury CCAs to establish, implement, maintain, and enforce written policies and procedures reasonably designed to, among other things, calculate, collect, and hold margin for direct participants' proprietary positions separately and independently from margin calculated, collected, and held for indirect participants that rely on the services provided by the direct participant to access the Treasury CCA's payment, clearing, or settlement facilities.[15] The Commission also amended its broker-dealer customer protection rule (''Rule 15c3–3'') [16] and the customer and proprietary accounts of broker-dealer (''PAB'' reserve formulas thereunder (''Rule 15c3–3a'') [17] to permit margin required and on deposit with Treasury CCAs to be included under certain conditions as a debit in the reserve formulas.[18]

The GSD Rules describe how FICC provides clearance and settlement services to both direct participants and indirect participants, the latter of which rely on the services provided by direct participants to access FICC's clearance and settlement facilities. Currently, the GSD Rules allow indirect participants to access GSD's clearing services through a Netting Member (that is, a direct participant) via two models: the correspondent clearing/prime broker services [19] and the Sponsored Service.[20] The primary difference between the two models is that an indirect participant who becomes a Sponsored Member via the Sponsored Service model must establish an indirect, limited purpose FICC membership, whereas the correspondent clearing/prime broker services do not require an indirect member to establish any relationship with FICC.[21]

The correspondent clearing/prime broker services allow a Netting Member to submit eligible transactions to FICC on behalf of an indirect participant (referred to as the ''Executing Firm''), record these transactions in the same account as the proprietary transactions that the Netting Member (referred to as a ''Submitting Member'') enters into for its own benefit, and net the indirect participants' transactions against the Netting Member's proprietary transactions for purposes of calculating the Netting Member's margin requirements. Unlike the Sponsored Service, FICC has no relationship with the Executing Firm, and all obligations (*i.e.,* margin and settlement) under the GSD Rules remain with the Submitting Member.[22]

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published in the **Federal Register** on March 28, 2024. Securities Exchange Act Release No. 99845 (Mar. 22, 2024), 89 FR 21586 (Mar. 28, 2024) (File No. SR–FICC–2024–802). Upon publication of notice of filing of the Advance Notice, the Commission extended the review period of the advance notice for an additional 60 days because the Commission determined that the advance notice raised novel and complex issues. On April 24, 2024, the Commission requested additional information from FICC pursuant to Section 806(e)(1)(D) of the Clearing Supervision Act, which tolled the Commission's period of review of the Advance Notice until 120 days from the date the information requested by the Commission was received by the Commission. *See* 12 U.S.C. 5465(e)(1)(D). A memo regarding the Request for Additional Information and the tolled period of review is available at *https://www.sec.gov/comments/sr-ficc-2024-802/srficc2024802-462751-1210414.pdf.* On September 24, 2024, the Commission requested additional information from FICC pursuant to Section 806(e)(1)(D) of the Clearing Supervision Act, which tolled the Commission's period of review of the Advance Notice until 120 days from the date the information requested by the Commission was received by the Commission. On October 21, 2024, the Commission received FICC's response to the Commission's September 24, 2024 request for additional information. *See* 12 U.S.C. 5465(e)(1)(E)(ii) and (G)(ii). A memo regarding receipt of FICC's response to the Request for Additional Information is available at *https://www.sec.gov/comments/sr-ficc-2024-802/srficc2024802-539295-1544222.pdf.*

[5] 15 U.S.C. 78s(b)(2).

[6] Securities Exchange Act Release No. 100022 (Apr. 24, 2024), 89 FR 34289 (Apr. 30, 2024) (File No. SR–FICC–2024–007).

[7] 15 U.S.C. 78s(b)(2)(B).

[8] Securities Exchange Act Release No. 100401 (Jun. 21, 2024), 89 FR 53690 (Jun. 27, 2024) (File No. SR–FICC–2024–007).

[9] Securities Exchange Act Release No. 101082 (Sep. 18, 2024), 89 FR 77949 (Sep. 24, 2024) (File No. SR–FICC–2024–007).

[10] Securities Exchange Act Release No. 101454 (Oct. 28, 2024), 89 FR 87441 (Nov. 1, 2024) (File No. SR–FICC–2024–007) (''Notice of Partial Amendment'').

[11] Comments on the Proposed Rule Change are available at *https://www.sec.gov/comments/sr-ficc-2024-007/srficc2024007.htm.* Comments on the Advance Notice are available at *https://www.sec.gov/comments/sr-ficc-2024-802/srficc2024802.htm.* Because the proposals contained in the Proposed Rule Change and the Advance Notice are the same, the Commission considers all comments received on the proposal, regardless of whether the comments are submitted with respect to the Advance Notice or the Proposed Rule Change. The comment letters to the Proposed Rule Change and Advance Notice also contained comments on the substance of another FICC proposed rule change, FICC–2024–005. The Commission will only be addressing comments relevant to this proposal and will address the comments on the other proposed rule change in a separate order.

[12] *See* Letter from Laura Klimpel, Managing Director, Head of Fixed Income and Financing Solutions, Depository Trust & Clearing Corporation, (Aug. 1, 2024) (''FICC Letter'').

[13] The GSD Rules are available at *https://www.dtcc.com/~/media/Files/Downloads/legal/rules/ficc_gov_rules.pdf.* Terms not otherwise defined herein are defined in the GSD Rules.

[14] *See supra* note 3.

[15] 17 CFR 240.17ad–22(e)(6)(i).

[16] 17 CFR 240.15c3–3.

[17] 17 CFR 240.15c3–3a.

[18] *See supra* note 3.

[19] *See* GSD Rule 8, *supra* note 13.

[20] *See generally* GSD Rule 3A, *supra* note 13.

[21] *See* Securities Exchange Act Release No. 99817 (Mar. 21, 2024), 89 FR 21362, at 21364 (Mar. 27, 2024) (File No. SR–FICC–2024–005).

[22] *Id.* at 21365; *see also* GSD Rule 8, *supra* note 13.

Under a proposed rule change being approved concurrently, FICC is renaming the prime broker/correspondent clearing model to be known as the Agent Clearing Service and providing further specificity around the operation of that service.[23] In that service, the Netting Member which serves as the direct participant to FICC would be referred to as the Agent Clearing Member, and the indirect participant would be referred to as an Executing Firm Customer. An Executing Firm Customer would have no direct relationship to FICC. This separate change would require that a Netting Member using the Agent Clearing Service submit transactions for Executing Firm Customers through an Agent Clearing Member Omnibus Account, to be recorded separately from its other clearing activity, including its proprietary activity. It would also add a definition for transactions eligible to be submitted by an Agent Clearing Member on behalf of its Executing Firm Customers (''Agent Clearing Transactions'').

In addition, in the Sponsored Service, both currently and in a concurrently approved proposed rule change,[24] Netting Members that are approved to be Sponsoring Members are able to sponsor certain indirect participants, referred to as Sponsored Members, into GSD membership and submit transactions on behalf of those Sponsored Members. A Sponsored Member is the legal counterparty to FICC for any submitted transactions.[25] However, the Sponsoring Member unconditionally guarantees to FICC the Sponsored Member's performance under a Sponsoring Member Guaranty, which guarantees to FICC the payment and performance of a Sponsored Member's obligations to FICC.[26] Therefore, reliance upon the Sponsoring Member Guaranty necessarily involves FICC's reliance upon the financial resources of the Sponsoring Member.

Unlike the correspondent clearing/prime broker services, transactions by the Sponsoring Member's Sponsored Members (''Sponsored Member Trades'') are not netted, for margining purposes, against transactions of the Sponsoring Member or another Sponsored Member. Instead, FICC records Sponsored Member Trades in a Sponsored Member Omnibus Account, and calculates margin requirements for each Sponsored Member individually on a gross basis (*i.e.,* without netting their transactions against transactions of the Sponsoring Member or another Sponsored Member).[27]

B. Proposed Changes

In the Proposed Rule Change, FICC seeks to address the Commission's new margin and account separation requirements and the conditions for including margin in the broker-dealer reserve formulas discussed in part I.A above.[28] As described in greater detail below, the Proposed Rule Change would (1) provide for the separate and independent calculation, collection, and holding of margin for proprietary transactions of a Netting Member from margin submitted to FICC by a Netting Member to support the transactions of an indirect participant (*i.e.,* either an Executing Firm Customer or a Sponsored Member); (2) establish segregated accounts for direct and indirect participants, including establishing a minimum $1 million cash margin requirement for each Segregated Indirect Participant; (3) consolidate the methodology for calculating the margin requirements, including definitions of relevant terms and components for calculating margin requirements from various sections of the current GSD Rules into a single margin component schedule (''Margin Component Schedule''), specify how the various components relate to different types of margin, and make certain changes to the margin methodology, including revising the Margin Liquidity Adjustment (''MLA Charge'')[29] definition, providing a method for allocating net unsettled positions to individual indirect participants for calculating margin requirements, and revising and clarifying the calculation of the Excess Capital Premium (''ECP'') component[30] of the Clearing Fund; and (4) modify the terms relating to transactions submitted by Inter-Dealer Broker Netting Members[31] to FICC for clearance and settlement (''Brokered Transactions'').

1. Separate Calculation, Collection, and Holding of Margin

The Proposed Rule Change would provide for the separate and independent calculation, collection, and holding of (i) margin deposited by a Netting Member to support its proprietary transactions, and (ii) margin deposited by a Netting Member to support the transactions of an indirect participant, that is, either an Executing Firm Customer or a Sponsored Member. To facilitate the separate and independent calculation, collection, and holding proprietary and indirect participant margin, FICC would establish proprietary accounts to record the proprietary transactions that the Netting Member enters into for its own benefit and separate indirect participant accounts to record transactions that the Netting Member submits on behalf of an indirect participant, which could be either a Sponsored Member or an Executing Firm Customer.

For proprietary transactions, the accounts would include Dealer Accounts, which would be available for all Netting Members, and Cash Broker Accounts and Repo Broker Accounts, which would only be available for Inter-Dealer Broker Netting Members.[32] Cash

[23] *See* Order, FICC–2024–005, *available at https://www.sec.gov/rules-regulations/self-regulatory-organization-rulemaking/ficc.*

[24] *See id.*

[25] *See* GSD Rule 3A, section 7 (describing novation of Sponsored Member Trades) and 2 (identifying membership types), *supra* note 13.

[26] *See* GSD Rules 3A (describing the operation of the Sponsoring Member Guaranty) and 1 (defining the Sponsoring Member Guaranty), *supra* note 13.

[27] *See* GSD Rule 3A, Section 10(c), *supra* note 13.

[28] *See supra* note 3.

[29] The MLA Charge is a margin component designed to address the market impact costs of liquidating a defaulted Netting Member's portfolio that may increase when that portfolio includes large net unsettled positions in a particular group of securities with a similar risk profile or in a particular asset type, thereby causing those costs to be higher than the amount collected for the Netting Member's volatility charge, which is designed to capture the market price risk associated with liquidating each Netting Member's portfolio at a 99th percentile level of confidence. *See* GSD Rule 1 (defining Margin Liquidity Adjustment Charge), *supra* note 13; *see also* Securities Exchange Act Release No. 89560 (Aug. 14, 2020), 85 FR 51503 (Aug. 20, 2020) (File No. SR–FICC–2020–09) (approving the MLA charge as a new component of the margin methodology); Securities Exchange Act Release No. 98558 (Sep. 27, 2023), 88 FR 68179 (Oct. 3, 2023) (File No. SR–FICC–2023–012) (approving revisions to ECP charge).

[30] The ECP is a margin component that allows FICC to collect additional margin if a member's exposure to FICC, based on its clearing activity, is out of proportion to its capital levels. It is designed to mitigate the heightened default risk a member could pose to FICC if it operates with lower capital levels relative to its margin requirements. *See* Margin Component Schedule (defining Excess Capital Premium), *supra* note 13; *see also* Securities Exchange Act Release No. 54457 (Sep. 15, 2006), 71 FR 55239 (Sep. 21, 2006) (File Nos. SR–FICC–2006–03 and SR–NSCC–2006–03) (approving the ECP charge as a new component of the margin methodology); Securities Exchange Act Release No. 96786 (Feb. 7, 2023), 88 FR 8013 (Feb. 7, 2023) (File No. SR–NSCC–2022–005) (approving revisions to ECP charge).

[31] An Inter-Dealer Broker is defined as a Person which is in the business of buying and selling securities as agent on behalf of dealers and is registered under Section 15 or Section 15C of the Exchange Act. GSD Rule 1 (defining Inter-Dealer Broker), *supra* note 13. An Inter-Dealer Broker Netting Member must meet that definition and certain applicable membership requirements. *See id.* and Rule 2A (setting forth membership requirements).

[32] Under the proposed changes, ''Cash Broker Account'' would be a proprietary account maintained by FICC for an Inter-Dealer Broker Netting Member to record Brokered Transactions, other than Brokered Repo Transactions, submitted to the Corporation by the Inter-Dealer Broker

Continued

Broker Accounts would be available for recording an Inter-Dealer Broker Netting Member's Brokered Transactions (other than Brokered Repo Transactions), and Repo Broker Accounts would be for purposes of recording an Inter-Dealer Broker Netting Member's Brokered Repo Transactions.

For indirect participant transactions, FICC would establish Indirect Participants Accounts to record transactions that a Netting Member submits to FICC on behalf of Sponsored Members and Executing Firm Customers. These Indirect Participants Accounts would include Sponsoring Member Omnibus Accounts for recording Sponsored Member Trades and Agent Clearing Member Omnibus Accounts for recording Agent Clearing Transactions submitted on behalf of Executing Firm Customers. In addition, the proposal would permit a Sponsoring Member or Agent Clearing Member to designate any of its Indirect Participants Accounts as a segregated customer account (a ''Segregated Indirect Participants Account''). Such designation, as further described in part I.B.2 below, would give Netting Members a mechanism to direct FICC to calculate and segregate margin deposited in connection with the relevant Segregated Indirect Participants Account in accordance with the conditions described in Note H to Rule 15c3–3a.[33]

The proposal would require each Netting Member to deposit two forms of margin: the Required Fund Deposit and the Segregated Customer Margin Requirement. The Required Fund Deposit, which would be deposited to the Clearing Fund, would be the sum of each Netting Member's proprietary accounts (*e.g.,* Dealer Accounts and Broker Accounts) and indirect participant accounts (*e.g.,* Agent Clearing Omnibus Accounts and Sponsoring Member Omnibus Accounts) not designated as Segregated Indirect Participants Accounts. The Segregated Customer Margin Requirement, which would be excluded from the Clearing Fund, would be the sum of the Netting Member's Sponsoring Member Omnibus Accounts designated as Segregated Indirect Participants Accounts and Agent Clearing Member Omnibus Accounts designated as Segregated Indirect Participants Accounts.

FICC's proposal would also provide that a Netting Member's Margin Portfolio, which is utilized to determine a Netting Member's margin requirement, cannot include both proprietary and indirect participant accounts. As a result, the transactions a Netting Member submits to FICC on behalf of an indirect participant either as a Sponsoring Member or an Agent Clearing Member would no longer be netted against a Netting Member's proprietary transactions for calculating a Netting Member's margin requirements.[34] Since proprietary transactions and transactions submitted for indirect participants would not be recorded in the same type of account, these changes would result in margin for a Netting Member's proprietary transactions being calculated separately and independently from margin calculated for the transactions that the Netting Member submits on behalf of indirect participants.

To help ensure that margin for proprietary transactions is calculated, collected, and held separately and independently of margin for indirect participant transactions, FICC would require each Netting Member, at the time it submits a transaction to FICC for clearance and settlement, to designate the account in which the particular transaction should be recorded using a separate Deposit ID, which is an existing operational mechanism used by Netting Members to identify the type of account for which a margin deposit is being made. The use of these separate Deposit IDs would result in margin for each type of account being separately transferred to FICC and recorded on FICC's books as separate margin amounts for each account type. The proposal would also require FICC to report a Netting Member's Required Fund Deposit and Segregated Customer Margin Requirement twice daily and specify the amount of margin attributable to each Required Fund Deposit Portion or Segregated Indirect Participants Account so that the Netting Member can transfer the different margin amounts separately.

In addition, the proposal would eliminate the concept of a Permitted Margin Affiliate, which allows a Netting Member to include accounts of an affiliate that is also a Netting Member in the same Margin Portfolio as its accounts and net their transactions for margin calculation purposes. FICC states that no Netting Member currently has a Permitted Margin Affiliate, so keeping this option in the rules in conjunction with the proposed changes to establish separate and independent calculation, collection, and holding of margin would introduce unnecessary complexity in FICC's rules.[35]

2. Segregation of Customer Margin

FICC is proposing several changes to allow for the segregation of customer margin in a manner that satisfies the conditions for recording a debit in the customer reserve formula under Note H to Exchange Act Rule 15c3–3a.[36] First, to satisfy Section (b)(2)(i) of Note H to Rule 15c3–3a,[37] FICC would calculate the margin requirements applicable to any segregated account on a gross basis (*i.e.,* FICC would treat each indirect participant as if it were a separate Netting Member for margin calculations and would not net the transactions of one indirect participant against the transactions of another indirect participant). Second, to satisfy Section (b)(2)(iii) of Note H to Rule 15c3–3a,[38] FICC would establish Segregated Customer Margin Custody Accounts for eligible customers on its books and records. These accounts would segregate the margin deposited for transactions in that account from any margin for a Netting Member's proprietary positions, both on FICC's own books and records and at FICC's custodians. FICC would only be able to use such segregated margin to secure or satisfy the obligations of the customer for whom such margin is held, and it would not be considered part of the mutualized Clearing Fund. FICC would not be able to apply such margin to the proprietary obligations of the Netting Member that deposited it with FICC, to the obligations of any other Netting Member or indirect participant, or to any lien or claim against FICC.[39] FICC would

Netting Member. ''Repo Broker Account'' would be a proprietary account maintained by the FICC for an Inter-Dealer Broker Netting Member in its capacity as a Repo Broker to record Brokered Repo Transactions submitted to the Corporation by the Inter-Dealer Broker Netting Member.

[33] 17 CFR 240.15c3–3a.

[34] The Proposed Rule Change would also specify the types of accounts in which Netting Members may record transactions to identify the purpose and use of these accounts. FICC's ''Accounts'' are not custodial accounts in which FICC holds assets, but rather a mechanism for FICC to record and group transactions. These records are utilized by FICC in its calculation of a Netting Member's margining, settlement, and other obligations. Proprietary Accounts would include ''Dealer Accounts,'' which would be available for all Netting Members, and ''Cash Broker Accounts'' and ''Repo Broker Accounts,'' which would only be available for Inter-Dealer Broker Netting Members. Non-Proprietary Accounts would include, in the case of a Sponsoring Member, Sponsoring Member Omnibus Accounts for purposes of recording Sponsored Member Trades, and, in the case of an Agent Clearing Member, Agent Clearing Member Omnibus Accounts for purposes of recording Agent Clearing Transactions of its Executing Firm Customers.

[35] *See* Notice of Filing, *supra* note 4, at 21608.

[36] *See id.*, at 21608 (citing 17 CFR 240.15c3–3a).

[37] *Id.* at 21608–09.

[38] *Id.* at 21609.

[39] *See* FICC Letter at 35 (describing this as ''an express prohibition on FICC using Segregated Customer Margin held in respect of one Segregated Indirect Participant for the obligations of any other

provide written notice to any Netting Member that is a broker-dealer that any Segregated Customer Margin Custody Account is being held for the exclusive benefit of the customers and is being kept separate from any other accounts maintained by the broker-dealer or any other Netting Member at FICC, as required by Section (b)(2)(iii)(C) of Note H.[40]

Further, as amended, the proposal would clarify that any interest earned on Segregated Customer Margin consisting of cash must be paid to the Netting Member on behalf of, and as agent for, its Segregated Indirect Participant.[41]

Moreover, to comply with the custody requirements of (b)(2)(iv) of Note H,[42] FICC would require segregated margin accounts to be held at either a bank within the meaning of the Exchange Act that is insured by the Federal Deposit Insurance Corporation and is a qualified custodian under the 1940 Act, or the Federal Reserve Bank of New York.[43] FICC would require these accounts to be segregated from any other account of FICC and used exclusively to hold Segregated Customer Margin, in accordance with Section (b)(2)(iv)(A) of Note H. Moreover, each of these accounts would be subject to (i) a written notice of the bank or Federal Reserve Bank that the account is being held by the bank or Federal Reserve Bank pursuant to Rule 15c3–3 and is being kept separate from and not commingled with any other accounts maintained by FICC or any other person at the bank or Federal Reserve Bank and (ii) a written contract between FICC and the bank or Federal Reserve Bank which would provide that the Segregated Customer Margin in the account is subject to no right, charge, security interest, lien, or claim in favor of the bank or Federal Reserve Bank or any person claiming through the bank or Federal Reserve Bank, in accordance with Sections (b)(2)(iv)(B) and (C) of Note H.[44] FICC would also only allow Segregated Customer Margin consisting of cash to be invested in U.S. Treasury securities with a maturity of one year or less, in accordance with Section (b)(2)(ii) of Note H.[45]

Finally, to satisfy Section (b)(2)(v) of Note H,[46] FICC would provide specific procedures to allow Netting Members to request the return of excess segregated margin. FICC notes that these changes would allow broker-dealer Netting Members to collect margin from customers and deposit it with FICC and to provide all customers, including those that access FICC through non-broker-dealers, the ability to segregate margin they deposit.[47] FICC would have the ability to retain some or all of the excess segregated customer margin if the Netting Member had an outstanding payment or margin obligation to FICC for transactions of any Segregated Indirect Participant. FICC could not retain the excess segregated customer margin for a Segregated Indirect Participant when FICC has determined, in its sole discretion, that such outstanding payment or margin obligation is unrelated to the transactions of that Segregated Indirect Participant.[48] FICC states that these aspects of the Proposed Rule Change would allow for the segregation of certain customer margin in a manner that satisfies the conditions for a broker-dealer to record a debit in the customer reserve formula under Note H to Rule 15c3–3a.[49]

a. $1 Million Minimum Cash Margin Requirement

FICC is also proposing a minimum $1 million cash margin requirement for each Segregated Indirect Participant Account, similar to the $1 million minimum cash margin requirement currently applicable to each Netting Member.[50] FICC conducts daily backtesting to evaluate whether each Netting Member's margin is sufficient to cover FICC's credit exposures to that member based on a simulated liquidation of the member's portfolio on that day. FICC's daily backtesting of the sufficiency of Clearing Fund deposits has shown a heightened risk of backtesting deficiencies (*i.e.,* the projected liquidation losses to FICC due to a Netting Member's default would be greater than the member's margin) for members with lower deposits.[51] Because FICC is required to calculate the margin requirements for Segregated Indirect Participants on a gross basis, as if each Segregated Indirect Participant were a separate Margin Portfolio, and Segregated Customer Margin would not be available to address losses from other direct or indirect participants, FICC believes it is also appropriate to apply the same minimum cash requirement to each Segregated Indirect Participant that it applies to each Margin Portfolio.[52] Moreover, FICC believes that the $1 million cash requirement is the appropriate minimum amount to optimize the balance between financial impact of the requirement to participants and FICC's ability to continue to meet its regulatory obligation to maintain a backtesting performance coverage ratio above its 99 percent coverage target.[53] FICC states that the $1 million minimum is supported by its prior analyses of the appropriate minimum margin requirement for Netting Members.[54] FICC further describes this minimum requirement as critical to ensuring that the account segregation does not expose FICC and its participants to undue loss. FICC explains that the Segregated Customer Margin posted by an individual Segregated Indirect Participant needs to be enough, on its own, to address losses arising from the Segregated Indirect Participant's positions, and that, otherwise, such losses may be mutualized.[55]

However, FICC, in its sole discretion, would have the ability to adjust the amount of the minimum $1 million margin requirement if FICC determines that a different minimum charge would be appropriate and consistent with achieving its backtesting coverage target.[56] FICC would notify Netting Members of any such adjustment to the minimum margin requirement through an Important Notice.[57] In discussing this proposed ability, FICC states that it will review the $1 million floor for Segregated Customer Margin as part of ongoing internal surveillance and risk management monitoring procedures.[58] FICC further states that it would be prudent to have the ability to adjust the $1 million floor proactively to the extent that FICC identifies as part of these reviews that activity levels, margin performance observed through backtesting, and other measures indicate that FICC would be able to continue to

person'' and stating that, as a result, the default of one Segregated Indirect Participant should not generally cause another segregated Indirect participant to lose its margin).

[40] *Id.* at 21610.

[41] *See* Notice of Partial Amendment, *supra* note 10, at 87443.

[42] *See* Notice of Filing, *supra* note 4, at 21607.

[43] *See* Notice of Partial Amendment, *supra* note 10, at 87443.

[44] *See* Notice of Filing, *supra* note 4, at 21607.

[45] *Id.*

[46] *Id.*

[47] *Id.* at 21606.

[48] *See* Notice of Partial Amendment, *supra* note 10, at 87443.

[49] *See* Notice of Filing, *supra* note 4, at 21606.

[50] Like the current requirement for Netting Member Required Fund Deposits, the proposal would require that a minimum of 40 percent of the Segregated Customer Margin Requirement be satisfied with cash and/or Eligible Clearing Fund Treasury Securities.

[51] *See* Notice of Filing, *supra* note 4, at 21611.

[52] *Id.*

[53] *Id.;* FICC Letter at 28–29.

[54] *See* FICC Letter at 28–29.

[55] *Id.* at 29.

[56] *See* Notice of Partial Amendment, *supra* note 10, at 87443.

[57] *Id.*

[58] *See* FICC Letter at 30.

manage the risks presented to it and meet its regulatory risk management obligations (including, for example, its 99% backtesting coverage target) with a lower minimum Segregated Customer Margin Requirement (that is, an amount below $1 million).[59]

3. Margin Component Schedule

To improve the clarity and transparency of its margin components and Clearing Fund calculation methodology,[60] FICC would move the margin calculation methodology, including the relevant defined terms, into a new Margin Component Schedule. Currently, the terms and information concerning the margin calculation methodology, as well as the relevant definitions, appear in several different locations.[61] FICC states that its methodology and the included components would continue to be substantively the same as the methodology under the current Rules.[62]

The new Margin Component Schedule would set out the methodology for calculating margin amounts. That Margin Component Schedule would provide for FICC to perform substantially the same calculation it currently performs when determining a Netting Member's Required Fund Deposit, except that (i) the calculation would be performed on a Segregated Indirect Participant-by-Segregated Indirect Participant basis as though each Segregated Indirect Participant represented a separate Margin Portfolio and (ii) FICC would not impose an ECP on Segregated Indirect Participant Accounts. Specifically, for Required Fund Deposit calculations, the margin amount shall equal the VaR Charge, plus or minus the Blackout Period Exposure Adjustment (as applicable), plus the Portfolio Differential Charge, with the following potential additional charges, as applicable: the Backtesting Charge, the Holiday Charge, the MLA Charge, the ECP, and the Intraday Supplemental Fund Deposit.[63] For Segregated Customer Margin Requirement calculations, the margin amount shall equal the VaR Charge, plus or minus the Blackout Period Exposure Adjustment (as applicable), plus the Portfolio Differential Charge, with the following potential additional charges, as applicable: the Backtesting Charge, the Holiday Charge, the MLA Charge, and the Intraday Supplemental Fund Deposit.

For both types of calculations, the Margin Component Schedule addresses the applicable minimum cash margin requirements ($1 million for each Netting Member and Segregated Indirect Participant)[64] and FICC's authority to require increased deposits as appropriate, including the use of a special charge. FICC would not add Segregated Customer Margin to Section 4 of the Margin Component Schedule, which describes FICC's ability to impose increased Required Fund Deposits under certain circumstances.[65] However, when determining whether to increase the Required Fund Deposit of a Netting Member under the circumstances described in Section 4, FICC would consider the risk presented by a Netting Member from the activity it submits to FICC, including activity of indirect participants.[66]

a. MLA Charge

FICC would amend the definition of the MLA Charge to account for the use of Segregated Indirect Participant Accounts. Specifically, the definition would provide that, if a Segregated Indirect Participant clears through multiple Accounts[67] (including Accounts of different Netting Members), then the MLA Charge for transactions in a Segregated Indirect Participants Account would be the greater of (i) an amount calculated for only the transactions maintained in that Account (*i.e.,* excluding the other Accounts where the Segregated Indirect Participant's transactions are recorded) and (ii) an amount calculated on a consolidated portfolio basis (*i.e.,* taking into account the transactions in each of the Accounts). This would be the same methodology currently used for Sponsored Members clearing through multiple Accounts.[68]

b. Allocation of Net Unsettled Positions

The Proposed Rule Change would also provide a method for allocating net unsettled positions to individual indirect participants for calculating margin requirements. Specifically, as amended, FICC would modify the definition of Current Net Settlement Positions in Rule 1 to provide that, for calculating margin requirements and not for purposes of calculating the Net Settlement Position under GSD Rule 11, positions that are not clearly allocable to an individual Sponsored Member or Segregated Indirect Participant (other than Sponsored GC Trades), because one or more transactions recorded for indirect participants did not settle on the original Scheduled Settlement Date, would be allocated *pro rata* to Sponsored Members or Segregated Indirect Participants that had positions in the same direction and CUSIP as the un-allocable Current Net Unsettled Positions at the end of the preceding business day. FICC states that this situation could arise if a transaction recorded in a Sponsoring Member Omnibus Account or Segregated Indirect Participants Account fails to settle and that such failure to settle would not occur with Sponsored GC Trades.[69] FICC believes this methodology facilitates a reasonable and fair allocation for purposes of calculating gross margin requirements.[70]

c. Calculation of Excess Capital Premium

In addition, the Proposed Rule Change would amend the terms related to the ECP component of the Clearing Fund, which is used to collect additional margin if a Netting Member's exposure to FICC through its clearing activity is out of proportion to its capital. Currently, the ECP applicable to a Netting Member equals the Netting Member's ''Excess Capital Ratio'' (*i.e.,* its VaR Charge divided by its Netting Member Capital) multiplied by its ''Excess Capital Differential'' (*i.e.,* the amount by which a Netting Member's VaR Charge exceeds its Netting Member Capital). However, FICC currently reserves the right to collect less than

[59] *Id.* at 31.

[60] *See* Notice of Filing, *supra* note 4, at 21612.

[61] FICC would move the calculation methodology from Rule 4, Sections 1b, and 2a, Rule 3, Section 14, and Rule 3A, Section 10 to the new Margin Component Schedule. FICC would move the definitions from Rule 1 to Section 5 of the Margin Component Schedule.

[62] *See* Notice of Filing, *supra* note 4, at 21612.

[63] This method does not represent a change from the current method of calculating Required Fund Deposits, but merely moves the description from current Rule 4 to the new Margin Component Schedule.

[64] *See supra* Section I.B.2.a for a description of the proposed $1 million minimum cash margin requirement for each Segregated Indirect Participant Account.

[65] *See* Notice of Filing, *supra* note 4, at 21609.

[66] *Id.*

[67] FICC proposed to amend the definition of Account to be an account maintained by FICC for a Member to record transactions submitted by the member. FICC states that this change would clarify that Accounts are recordkeeping mechanisms for FICC to determine which transactions should be netted against each other, but are not custodial accounts through which FICC holds assets for a Netting Member. *See* Notice of Filing, *supra* note 4, at 21608.

[68] *See* GSD Rule 1 (defining MLA Charge, including for Sponsored Members sponsored by multiple Sponsoring Members), *supra* note 13; Securities Exchange Act Release No. 98558 (Sep. 27, 2024), 89 FR 68179 (Oct. 3, 2023) (File No. SR–FICC–2023–012).

[69] *See* Notice of Filing, *supra* note 4, at 21612–13; Notice of Partial Amendment, *supra* note 10, at 87443.

[70] *See* Notice of Filing, *supra* note 4, at 21613.

this amount or to return some or all of this amount.[71]

The changes would seek to make the calculation of the ECP component clearer and more predictable by (i) capping the amount of the ECP at two times the amount by which a Netting Member's VaR Charge exceeds its Netting Capital,[72] (ii) specifying the Netting Member Capital amounts used to calculate the ECP (that is, the Net Capital amount from each Netting Member's most recent Form X–17–A–5 (Financial and Operational Combined Uniform Single Report (''FOCUS Report'')) or the Equity Capital amount on its most recent Consolidated Report of Condition and Income (''Call Report'')), (iii) providing that FICC may calculate the premium based on updated available information, and (iv) permitting FICC, in its discretion, to waive the amount of the ECP and setting forth a specific procedure for doing so. Regarding the waiver procedure, only a Managing Director in FICC's Group Chief Risk Office would be able to grant a waiver of an ECP in certain situations. These situations would be limited to exigent circumstances or other unexpected events. When deciding whether to grant a waiver, FICC would consider the degree to which a Netting Member's capital position and trading activity compare or correlate to the exigent circumstances and whether FICC can effectively manage the risk exposure from the Netting Member without collecting the ECP.[73] Any waiver would be documented in a written report made available to the Netting Member. FICC states that these changes are substantially similar to changes recently adopted by the National Securities Clearing Corporation (''NSCC'') and they would enhance the ability of Netting Members to identify what their ECP will be and to ensure such amount is accurately calibrated.[74]

In addition, the Proposed Rule Change would revise the definitions of Excess Capital Ratio and Excess Capital Differential to exclude the VaR Charge for Segregated Indirect Participants. FICC is proposing this change because each indirect participant would be responsible for satisfying its own respective VaR Charge, not the Netting Member, and the Excess Margin Charge is designed to address the risk that a Netting Member with low capital relative to value-at-risk is not able to perform its obligations.[75] FICC states that including the VaR Charge that is calculated for an indirect participant and is satisfied by the capital of that indirect participant in the calculation of the Netting Member's ECP could result in assessing an ECP for that Netting Member that is greater than the amount required to mitigate the risk this margin component is designed to address.[76] FICC also states that this change is designed to ensure that the ECP does not result in differential treatment of Netting Members that act as intermediaries for Segregated Indirect Participants.

4. Modification of Terms for Brokered Transactions

The Proposed Rule Change would modify the terms relating to Brokered Transactions. FICC's rules currently cap the amount of loss allocation that may be applied to Inter-Dealer Broker Netting Members and Non-IDB Repo Brokers submitting Brokered Transactions. FICC would revise the definition of Brokered Transactions to include only the side of the transactions submitted to FICC for novation by an Inter-Dealer Broker Netting Member and entered into on the Inter-Dealer Broker Netting Member's own trading platform.[77] As a result, the favorable loss allocation treatment for Brokered Transactions would apply only to the transactions that present limited risk since an Inter-Dealer Broker is standing between two counterparties in those transactions and is therefore completely flat (that is, subject to offsetting exposures).[78] Since FICC believes the favorable loss allocation treatment is appropriate only for Inter-Dealer Broker Netting Members submitting Brokered Transactions, it would delete the term ''Non-IDB Repo Broker'' from its rules.[79] FICC states that these changes would improve FICC's risk management and promote access by ensuring that its differential treatment of different parties and transactions has a sound risk management justification.[80]

In addition, the proposed changes would provide that transactions entered into on inter-dealer brokers and similar platforms may be cleared using the Sponsored Service or the Agent Clearing Service.[81]

II. Discussion and Commission Findings

Section 19(b)(2)(C) of the Exchange Act[82] directs the Commission to approve a proposed rule change of a self-regulatory organization if it finds that such proposed rule change is consistent with the requirements of the Exchange Act and rules and regulations thereunder applicable to such organization. After carefully considering the Proposed Rule Change, the Commission finds that the Proposed Rule Change is consistent with the requirements of the Exchange Act and the rules and regulations thereunder applicable to FICC. In particular, the Commission finds that the Proposed Rule Change is consistent with Sections 17A(b)(3)(F) and (b)(3)(I) of the Exchange Act[83] and Rules 17ad–22(e)(4)(i), (e)(6)(i), (e)(6)(iii), (e)(18)(ii), (e)(18)(iii), (e)(18)(iv)(C), (e)(19), and (e)(23)(ii) thereunder.[84]

A. Consistency With Section 17A(b)(3)(F) of the Exchange Act

Section 17A(b)(3)(F) of the Exchange Act[85] requires the rules of a clearing agency to, among other things, promote the prompt and accurate clearance and settlement of securities transactions and assure the safeguarding of securities and funds which are in the custody or control of the clearing agency or for which it is responsible, and protect investors and promote the public interest.

1. Separate Calculation and Collection of Margin for Proprietary and Customer Accounts

The proposed changes to require the separate and independent calculation and collection of margin for Netting Members' proprietary transactions and indirect participants' transactions, as described in Section I.B.1., should allow FICC to better identify and measure the unique risk profiles of each Netting

[71] *See* GSD Rule 1 (defining Excess Capital Ratio and Excess Capital Differential) and Rule 3, Section 14 (describing the Excess Capital Premium), *supra* note 13.

[72] In addition, FICC would amend the definition of Netting Member Capital to refer to a Netting Member's Net Capital, Net Assets, or Equity Capital to link the calculation to the appropriate regulatory framework for each Netting Member and add the term Equity Capital to clarify that a Netting Member's most recent Call Report, or financial statements or equivalent reporting if a Netting Member is not required to file a Call Report, will be used for the calculation of the Excess Capital Premium.

[73] *See* Notice of Filing, *supra* note 4, at 21613.

[74] *See* Securities Exchange Act Release No. 96786 (Feb. 1, 2023), 88 FR 8013 (Feb. 7, 2023) (SR–NSCC–2022–005).

[75] *Id.*

[76] *Id.*

[77] *See* Notice of Partial Amendment, *supra* note 10, at 87444.

[78] *See* Notice of Filing, *supra* note 4, at 21614.

[79] *Id.*

[80] *See* Notice of Filing, *supra* note 4, 21604.

[81] Notice of Partial Amendment, *supra* note 10, at 87444; *see also* FICC Letter at 22–23.

[82] 15 U.S.C. 78s(b)(2)(C).

[83] 15 U.S.C. 78q–1(b)(3)(F) and 15 U.S.C. 78q–1(b)(3)(I).

[84] 17 CFR 240.17ad–22(e)(4)(i), (e)(6)(i), (e)(6)(iii), (e)(18)(ii), (e)(18)(iii), (e)(18)(iv)(C), (e)(19), and (e)(23)(ii).

[85] 15 U.S.C. 78q–1(b)(3)(F).

Member and indirect participant. This proposed change would ensure that an indirect participant's positions are no longer netted against a Netting Member's positions, that margin is collected with respect to the indirect participant's positions specific to those transactions, and that interest on an indirect participant's cash margin would be paid to the Netting Member for the benefit of, and as agent for, the indirect participant. As discussed in more detail in Section II.C.1 below, this should enhance FICC's ability to calculate and collect the appropriate margin from each direct and indirect participant and, therefore, meet its settlement obligations in the event of a Netting Member or indirect participant default. By doing so, the Proposed Rule Change should better ensure that, in the event of a default, FICC's operation of its critical clearance and settlement services would not be disrupted because of insufficient financial resources and, therefore, it would be able to continue providing prompt and accurate clearance and settlement of securities transactions, consistent with Section 17A(b)(3)(F).[86]

The separate and independent calculation and collection of margin for proprietary and indirect participants' transactions should allow FICC to better identify and measure the unique risk profiles of each Netting Member and indirect participant, enhancing FICC's ability to calculate and collect sufficient margin from each Netting Member and indirect participant to cover potential losses from a Netting Member or indirect participant default, thereby reducing the likelihood that FICC, Netting Members, or indirect participants would incur losses resulting from a default. As a result, the proposed changes should limit FICC's risk to a Netting Member or indirect participant default and thereby enhance its ability to safeguard securities and funds in its control and for which it is responsible.

2. $1 Million Minimum Cash Margin Requirement

For the reasons discussed below in more detail in Section II.C.2., the proposed $1 million minimum cash margin requirement for Segregated Indirect Participants, which could be adjusted by FICC if it determines that a different minimum amount would be appropriate and consistent with achieving its backtesting coverage target, should help ensure that each indirect participant provides sufficient margin to cover its potential obligations to FICC, thereby helping to allow FICC to meet its settlement obligations in the event of a default and to protect FICC, non-defaulting Netting Members, indirect participants, and the market from losses from an indirect participant default. Accordingly, the proposed $1 million minimum cash margin requirement should assure the safeguarding of securities and funds which are in the custody or control of FICC.

In addition, as indicated by FICC's backtesting results, and discussed further in Section II.C.2 below, the $1 million minimum margin requirement should enhance FICC's ability to collect the appropriate margin from each indirect participant and, therefore, meet its settlement obligations in the event of a default. FICC's flexibility to adjust the minimum margin amount if it determines that a different amount would be appropriate and consistent with achieving its backtesting coverage target is also consistent with ensuring that each indirect participant provides sufficient margin to cover its obligations to FICC. Achieving backtesting coverage targets is essential to ensuring that the margin collected would be sufficient for FICC to cover its credit exposures to its Netting Members and indirect participants fully with a high degree of confidence, as required for a covered clearing agency such as FICC.[87] As defined in the Covered Clearing Agency Standards, backtesting is an ex-post comparison of actual outcomes with expected outcomes derived from the use of margin models,[88] and it is a key analytical mechanism for a CCP to consider the effectiveness of its margin model. FICC's ability to adjust the minimum margin amount would apply only where it would be appropriate and consistent with achieving its backtesting coverage target. This ability would, therefore, be limited to circumstances where its backtesting coverage target requirements are not being met or the amount of margin being collected exceeds the amount needed to cover the indirect participant's exposure to FICC.

Based on FICC's representations, the Commission understands that FICC generally intends to use this ability to adjust the minimum margin requirement below $1 million if a lower minimum would suffice to reduce backtesting deficiencies comparably to the $1 million.[89] As part of its ongoing supervision of FICC, the Commission will continue to monitor the performance of the $1 million minimum margin requirement, including as its performance compares to backtesting, and will engage with FICC regarding any changes to that requirement and the supporting analysis for such changes, to help ensure that FICC is appropriately exercising that discretion consistent with the requirements imposed upon it by the rule (*i.e.,* that it determines that any such adjustments would be appropriate and consistent with achieving its backtesting coverage target).[90] For example, not meeting backtesting coverage requirements would be an indication that the minimum margin amount is insufficient to cover FICC's credit exposure to its Netting Members and indirect participants, whereas, on the contrary, higher backtesting performance could indicate that the margin collected exceeds the exposure to FICC.

Therefore, the $1 million minimum margin requirement should help ensure that, in the event of a Segregated Indirect Participant default, FICC's operation of its critical clearance and settlement services would not be disrupted because of insufficient financial resources and it can continue providing prompt and accurate clearance and settlement of securities transactions.

3. Margin Component Schedule

The proposed changes in section I.B.3 regarding the calculation of margin for segregated and non-segregated accounts should help ensure that FICC collects margin sufficient to cover its exposures with respect to both direct and indirect participants. Requiring that the margin requirement for a Segregated Indirect Participant Account be calculated in generally the same manner as a Netting Member's requirement, which the Commission generally has reviewed and approved as part of FICC's rules,[91]

[86] *Id.*

[87] 17 CFR 240.17ad–22(e)(6).

[88] 17 CFR 240.17ad–22(a).

[89] *See* FICC Letter at 3, 30–31.

[90] In addition, the requirements applicable to FICC as a self-regulatory organization under Section 19(b) of the Exchange Act and as a designated financial market utility under Title VIII of the Payment, Clearing, and Supervision Act (12 U.S.C. 5465(e)) would continue to apply. Thus, for example, if FICC were to amend the $1 million minimum margin requirement to an amount that would materially alter the level or nature of risk presented, FICC would be obligated to submit an advance notice of such change with the Commission.

[91] *See, e.g.,* Self-Regulatory Organizations; Fixed Income Clearing Corporation; Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To Implement Changes to the Required Fund Deposit Calculation in the Government Securities Division Rulebook, Exchange Act Release No. 83362 (June 1, 2018), 83 FR 26514 (June 7, 2018) (approving changes to how FICC calculates the Value at Risk component of its margin methodology, addition of the new ''Blackout Period Exposure adjustment'' component to the margin methodology, eliminating certain existing components, and revising additional components).

should help ensure that FICC collects margin sufficient to cover its exposures with respect to both direct and indirect participants, as discussed further in Sections II.C.3 and II.D.3 below. In addition, by doing so, these proposed changes should help ensure that, in the event of such a default, FICC's operation of its critical clearance and settlement services would not be disrupted because of insufficient financial resources and, therefore, it could continue providing prompt and accurate clearance and settlement of securities transactions, consistent with Section 17A(b)(3)(F).[92] For the same reasons, these proposed changes should also help ensure that FICC is able to continue to meet its obligation in the event of a default, without accessing non-defaulting Netting Members' or indirect participants' margin deposits, thereby helping FICC ensure that it can safeguard the funds and securities within its custody or control, consistent with Section 17A(b)(3)(F).[93]

In addition, the proposed changes described in Section I.B.4 to consolidate the terms relating to margin calculation into a single location and refine the description of FICC's margin methodology should help FICC's Netting Members and indirect participants better understand and anticipate their margin requirements. This improved understanding of the potential margin requirements should, in turn, facilitate prompt and accurate clearance and settlement by removing potential ambiguity or confusion about market participants' obligations to FICC. Similarly, the improved transparency provided by the proposed centralized margin component schedule and enhanced descriptions of FICC's margin components, such as the MLA Charge, should provide Netting Members, indirect participants, and the public with more clarity about the calculation and application of FICC's margin components and resolve potential ambiguity about when certain components would or would not apply, which is consistent with promoting the public interest.

4. Allocation of Net Unsettled Positions

The proposed changes described in Section I.B.3.b. to adopt a method for allocating net unsettled positions to individual indirect participants for calculating margin requirements should reduce the potential exposure to FICC arising from indirect participant transactions that fail to settle by ensuring that FICC has a mechanism to collect margin for such transactions. Further, these proposed changes should make clear that such obligations are allocated only to participants that are outside the Sponsored GC service, since such fails to deliver do not occur in that service. By accounting for risks arising from net unsettled positions, the proposed changes should enhance FICC's risk management and its ability to assure the safe return of funds and securities, consistent with Section 17A(b)(3)(F).[94]

5. Calculation of Excess Capital Premium

The proposed changes to the calculation of the ECP described in Section I.B.3.c. above are consistent with promoting robust risk management, because the changes should help ensure that FICC continues to collect margin sufficient to address the heightened default risk presented by a Netting Member operating with lower capital levels relative to its margin requirements. Based on its review of the Proposed Rule Change, including the detailed impact analysis submitted as a confidential exhibit, FICC's margin coverage would not be impacted by this change and FICC would continue to collect sufficient margin to manage its potential exposure to its Netting Members.

In addition, the proposed changes to the calculation of the ECP should result in a simplified and more straightforward method for calculating the ECP, based on understandable metrics with which FICC's Netting Members are familiar. Using a clearly defined source for determining Netting Member Capital in the calculation of the ECP would result in a more consistent calculation across different types of Netting Members. Moreover, capping the Excess Capital Ratio at 2.0 would provide transparency to Netting Members so they can understand how the ECP will be calculated, and it also would align FICC's cap with the recently approved changes to the ECP calculation at NSCC.[95] By improving the consistency and predictability of the ECP, the proposed enhancements would also improve FICC's ability to collect margin amounts that reflect the risks posed by its Netting Members such that, in the event of Netting Member default, FICC's operations would not be disrupted, and non-defaulting Netting Members and indirect participants would not be exposed to losses they cannot anticipate or control. In this way, the proposed rule change is designed to promote the prompt and accurate clearance and settlement of securities transactions and to assure the safeguarding of securities and funds which are in the custody or control of NSCC or for which it is responsible, consistent with Section 17A(b)(3)(F) of the Exchange Act.[96]

The proposed changes set forth in section I.B.3.c should improve transparency and understanding of the FICC's governance and application of the ECP. For example, FICC's proposal would describe the exigent circumstances in which FICC may waive the ECP, describe what information FICC would consider when determining whether to waive the charge, and specify the approval necessary to waive the charge. Moreover, using commonly understood inputs as the determinants of the ECP (*i.e.,* the FOCUS or Call Report) and capping the Excess Capital Ratio at 2.0 should help Netting Members better anticipate and plan for a potential ECP. These proposed changes should help FICC's members better anticipate their required margin because of the use of simplified inputs to the calculation of the ECP and the imposition of a cap on the applicable Excess Capital Ratio. This improved understanding of the potential margin requirements should, in turn, facilitate prompt and accurate clearance and settlement by removing potential ambiguity or confusion about a member's obligations to FICC.

Similarly, the improved transparency provided by this Proposed Rule Change both with respect to a Netting Member's margin obligations and the process by which FICC would consider waiver of an ECP should provide Netting Members and the public with more clarity about the nature and application of the ECP and resolve potential ambiguity about when the ECP would or would not apply, which is consistent with promoting the public interest.

6. Modification of Terms for Brokered Transactions

The proposed changes described in Section I.B.4. to revise the definition of Brokered Transactions to include only the side of the transactions submitted to FICC for novation by an Inter-Dealer Broker Netting Member and entered into on the Inter-Dealer Broker Netting Member's own trading platform should enhance FICC's risk management by providing favorable loss allocation

[92] 15 U.S.C. 78q–1(b)(3)(F).

[93] *Id.*

[94] 15 U.S.C. 78q–1(b)(3)(F).

[95] *See* Securities Exchange Act Release No. 96786 (Feb. 1, 2023), 88 FR 8013 (Feb. 7, 2023) (SR–NSCC–2022–005); *see also id.* (discussing the view that capping the ratio at 2.0 strikes an appropriate balance between addressing the heightened default risk without imposing overly burdensome Excess Capital Premium charges).

[96] 15 U.S.C. 78q–1(b)(3)(F).

treatment only to transactions that present limited risk to FICC. As a result, these changes should help ensure that FICC has sufficient prefunded financial resources to continue meeting its obligations in the event of a default, which will facilitate the safeguarding of securities and funds which are in the custody or control of FICC, consistent with Section 17A(b)(3)(F).[97]

For these reasons, the proposed changes are consistent with Section 17A(b)(3)(F) of the Exchange Act.[98]

B. Consistency With Section 17A(b)(3)(I) of the Exchange Act

Section 17A(b)(3)(I) of the Exchange Act requires that the rules of a clearing agency, such as FICC, do not impose any burden on competition not necessary or appropriate in furtherance of the Exchange Act.[99] Section 17A(b)(3)(I) does not require the Commission to make a finding that FICC chose the option that imposes the least possible burden on competition. Rather, the Exchange Act requires that the Commission find that the Proposed Rule Change does not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Exchange Act, which involves balancing the competitive effects of the proposed rule change against all other relevant considerations under the Exchange Act.[100]

The Commission received comments regarding the impacts the Proposed Rule Change may have on competition. Several commenters state that the $1 million minimum Segregated Customer Margin Requirement for each Segregated Indirect Participant could discourage small firms from using the Segregated Indirect Participant Accounts.[101] Several commenters state that the requirement would increase costs for small firms and limit execution counterparties,[102] and several additional commenters state that FICC's proposed $1 million margin requirement is arbitrarily too high.[103]

In response to concerns about increased costs to relatively small indirect participants, FICC states that the margin segregation regime under the proposal is entirely voluntary.[104] To the extent the $1 million floor is too costly for certain indirect participants, FICC states that they can choose to post margin to a Netting Member in a non-segregated account that could require them to post lower margin or no margin at all.[105] Further, FICC amended the Margin Segregation Proposal to provide that the minimum margin floor will be set at an amount of $1 million but could be adjusted by FICC if it determines that a different minimum amount would be appropriate and consistent with achieving its backtesting coverage target, and it would require that FICC's members would be notified of any such adjustment to the applicable minimum charge by an Important Notice.[106] Specifically, FICC states that it would review the $1 million floor for Segregated Customer Margin as part of ongoing internal surveillance and risk management monitoring procedures.[107] FICC also stated that it would be prudent to have the ability to adjust the $1 million floor proactively to the extent that FICC identifies, as part of these reviews, that activity levels, margin performance observed through backtesting, and other measures indicate that FICC would be able to continue to manage the risks presented to it and meet its regulatory risk management obligations (including, for example, its 99% backtesting coverage target) with a lower minimum Segregated Customer Margin Requirement.[108]

The Commission acknowledges the commenters' concerns that the $1 minimum margin requirement could result in increased costs for small firms that choose to utilize the proposed margin segregation regime, which may weaken those firms' competitive positions relative to others. In addition, the Commission acknowledges that FICC could, potentially, adjust the minimum margin requirement to an amount above $1 million; however, under the proposal, FICC would only be able to do so if it determines that a different amount would be appropriate and consistent with achieving its backtesting coverage target. As part of its ongoing supervision of FICC, the Commission will continue to monitor the performance of the $1 million minimum margin requirement, including as its performance compares to backtesting, and will engage with FICC regarding any changes to that requirement and the supporting analysis for such changes, to help ensure that FICC is appropriately exercising that discretion consistent with the requirements imposed upon it by the rule (*i.e.,* that it determines that any such adjustments would be appropriate and consistent with achieving its backtesting coverage target). In addition, the Commission acknowledges that firms are not required to use a segregated account to participate at FICC and may choose to access FICC through a different type of account. Although some firms who choose to use segregated accounts could experience a burden on competition because of these potentially higher costs, the Commission concludes that any such burden to these firms is necessary and appropriate in furtherance of the Exchange Act [109] for the following reasons.

As discussed in Section I.A above, FICC seeks to maintain sufficient resources (*i.e.,* margin) to cover its credit exposures to its Netting Members and indirect participants fully with a high degree of confidence and uses backtesting to determine when a Netting Member or indirect participant's margin

[97] *Id.*

[98] *Id.*

[99] 15 U.S.C. 78q–1(b)(3)(I).

[100] *See* Bradford National Clearing Corp., 590 F.2d 1085, 1105 (D.C. Cir. 1978).

[101] *See* Letter from Katherine Darras, General Counsel, International Swaps and Derivatives Association (Apr. 17, 2024) (''ISDA Letter I'') at 4; Letter from Jennifer W. Han, Executive Vice President, Chief Counsel and Head of Global Regulatory Affairs, Managed Funds Association (Apr. 17, 2024) (''MFA Letter I'') at 6–7; Letter from Jennifer W. Han, Executive Vice President, Chief Counsel and Head of Global Regulatory Affairs, Managed Funds Association (Nov. 12, 2024) (''MFA Letter II'') at 7; Letter from Jiri Krol, Deputy Chief Executive Officer, Global Head of Government Affairs, Alternative Investment Management Association (Apr. 23, 2024) (''AIMA Letter'') at 6–7; Letter at 10; Letter from William C. Thum, Managing Director and Assistant General Counsel, Securities Industry and Financial Markets Association, Asset Management Group (May 24, 2024) (''SIFMA AMG Letter'') at 8; Letter from Joanna Mallers, Secretary, Futures Industry of America, Principal Traders Group (Oct. 11, 2024) (''FIA PTG Letter II'') at 2–3.

[102] *See* AIMA Letter at 6 (stating that the requirement will have myriad negative effects on customers and market liquidity generally, and that, for a customer with multiple clearing relationships and multiple segregated accounts, the need to maintain at $1 million cash in each account will increase costs for customers and prevent them from utilizing that capital in more productive ways); Letter from Joanna Mallers, Secretary, Futures Industry of America, Principal Traders Group (Apr. 17, 2024) (''FIA PTG Letter I'') at 7; FIA PTG Letter II at 2–3; SIFMA AMG Letter at 8–9. In addition, one commenter stated that, with the proposed deletion of the requirement to be a qualified institutional buyer (''QIB'') to be a Sponsored Member, these market participants may not be able to afford the $1 million cash requirement because QIBs, by definition, manage more than $100 million in securities on a discretionary basis, so it follows that the $1 million minimum could represent a sizable portion of a non-QIB's assets, potentially disincentivizing the non-QIB from pursuing indirect access to FICC. AIMA at 6–7.

[103] *See* Letter from Sarah A. Bessin, Deputy General Counsel and Nhan Nguyen, Associate General Counsel, Investment Company Institute (Jun. 20, 2024) (''ICI Letter'') at 12; MFA Letter I at 6–7; MFA Letter II at 6–7.

[104] *See* FICC Letter at 30.

[105] *Id.*

[106] *See* Notice of Partial Amendment, *supra* note 10, at 87443.

[107] *See* FICC Letter at 30.

[108] *Id.* at 31.

[109] 15 U.S.C. 78q 1(b)(3)(I). Specifically, as discussed in greater detail in Section II.C and II.H below, the Proposed Rule Change is necessary and appropriate to further the policy goals under Rule 17Ad 22(e)(4)(i) and (e)(19). 17 CFR 240.17Ad 22(e)(4)(i) and (e)(19).

would have been insufficient to cover FICC's credit exposure to that Netting Member or indirect participant. As described in Section II.C.2 below, the impact studies conducted by FICC prior to and after implementation of the $1 million Netting Member minimum margin requirement demonstrate that a $1 million margin floor has a material impact on reducing the number of backtesting deficiencies experienced by FICC's Netting Members, thereby increasing the number of Netting Members for which FICC maintained sufficient coverage at a confidence level of at least 99 percent. Since FICC would only be able to use Segregated Customer Margin posted by an individual Segregated Indirect Participant to satisfy that customer's obligations, the Segregated Customer Margin posted by each individual Segregated Indirect Participant would need to be sufficient on its own to address losses arising from the Segregated Indirect Participant's position. Therefore, adding the proposed $1 million floor for Segregated Customer Margin should enable FICC to better manage its credit exposure to a Segregated Indirect Participant by ensuring FICC holds sufficient collateral to cover that exposure, reducing the likelihood that FICC or non-defaulting parties would incur losses resulting from a Segregated Indirect Participant default. Moreover, if the $1 million floor is cost prohibitive for certain indirect participants, they can continue to access FICC's services by submitting activity through a Sponsoring Member Omnibus Account or Agent Clearing Member Omnibus Account that is not segregated, since the proposed margin segregation regime is entirely voluntary.

Therefore, the Commission concludes that any competitive burden imposed by the Proposed Rule Change is necessary and appropriate in furtherance of the Exchange Act. Accordingly, the Commission finds that the Proposed Rule Change is consistent with the requirements of Section 17A(b)(3)(I) of the Exchange Act.[110]

A. Consistency With Rule 17ad–22(e)(4)(i)

Rule 17ad–22(e)(4)(i) requires that FICC establish, implement, maintain and enforce written policies and procedures reasonably designed to effectively identify, measure, monitor, and manage its credit exposures to participants and those arising from its payment, clearing, and settlement processes, including by maintaining sufficient financial resources to cover its credit exposure to each participant fully with a high degree of confidence.[111]

1. Separate Calculation and Collection of Margin for Proprietary and Customer Accounts

The proposed changes to require the separate and independent calculation and collection of margin for Netting Members' proprietary transactions and indirect participants' transactions, as described in Section I.B.1., are consistent with Rule 17ad–22(e)(4)(i).[112] The separate calculation and collection of margin from Netting Members and indirect participants should allow FICC to better identify and measure the unique risk profile of each participant, enhancing FICC's ability to calculate and collect the appropriate margin from each direct and indirect participant. As a result, the proposed changes should help ensure that FICC has sufficient margin to cover potential losses from a Netting Member or indirect participant default, thereby reducing the probability that FICC, non-defaulting Netting Members, or non-defaulting indirect participants would incur losses resulting from a default.

2. $1 Million Minimum Cash Margin Requirement

The proposed minimum $1 million cash margin requirement for each Segregated Indirect Participant Account, as described in Section I.B.2.a, is consistent with Rule 17ad–22(e)(4)(i). Several commenters state that FICC lacks a sufficient basis or justification for the required $1 million minimum margin amount.[113] Specifically, one commenter stated that using the amount applicable to Netting Members is not an appropriate basis for establishing a minimum for indirect participants, and also stated that the requirement lacks any support or analysis as to the level of margin attributable to a typical fund's positions in cleared Treasury repo, which is data FICC should have readily available.[114] An additional commenter stated the requirement seems arbitrary, and not practical or necessary, especially in the current done-with model, to force every segregated customer to be subject to the same minimum requirement as a Netting Member.[115]

In addition, commenters state that FICC should adopt a lower minimum requirement ($100,000 to $250,000), a dynamic minimum based on average exposure subject to a $250,000 cap, or a minimum set by the relevant Netting Member.[116] Commenters also state that FICC should determine a minimum deposit based on the individual client and the risk that such client presents to FICC and other market participants.[117]

In response, FICC states that the $1 million floor for Segregated Indirect Participants is the same floor FICC already has in place for its Netting Members.[118] FICC states that its impact study, conducted in 2022 when adopting the rule applicable to Netting Members, demonstrated that a $1 million floor would protect FICC and its participants from incurring a loss in the event of a Netting Member failure because the study indicated that a $1 million floor would provide an adequate buffer for additional repo activity due to increases in repo interest rates and would have mitigated 65 out of 396 backtesting deficiencies (16%) during the period from July 1, 2021 to June 30, 2022.[119] FICC further states that it analyzed alternative minimum margin amounts, such as $500,000, and, based on the results of its analysis, the $1 million floor provided the appropriate balance of improving backtesting performance and margin coverage while minimizing the impact on Netting Members.[120]

FICC also states that the backtesting data from the period after the $1 million minimum floor was implemented indicated a ''material reduction of backtesting deficiencies at FICC.'' [121] From December 5, 2022 to June 30, 2024, FICC states that the $1 million floor eliminated 24 backtesting deficiencies, a 12% reduction.[122] Further, during a period of 12-month period of moderate market volatility from July 1, 2023 to June 30, 2024, FICC states that the $1 million floor

[110] 15 U.S.C. 78q–1(b)(3)(I).

[111] 17 CFR 240.17ad–22(e)(4)(i).

[112] *See id.*

[113] *See* ISDA Letter I at 4; ICI Letter at 12; AIMA Letter at 6–7; MFA Letter II at 6.

[114] ICI Letter at 12.

[115] AIMA Letter at 6. *See also* MFA Letter II at 7.

[116] AIMA Letter at 7; MFA Letter I at 7; SIFMA AMG Letter at 9.

[117] ISDA I at 4; *see also* MFA Letter II at 7 (stating that the requirement should be determined based on a participant's particular risk profile, including its planned and historical clearing activity).

[118] *See* FICC Letter at 28; Securities Exchange Act Release No. 96136 (Oct. 24, 2022), 87 FR 65268 (Oct. 28, 2022) (SR–FICC–2022–006) (''FICC–2022–006 Order''). The impact study contains an analysis of backtesting results on a member-by-member basis over a twelve-month period ending June 30, 2022, and it includes, for both the then-current rule and the proposed $1 million minimum rule, the number of backtesting deficiencies and the level of coverage obtained. It contains the same analysis for a $500,000 minimum as well, including the same data points on a member-by-member basis.

[119] *See* FICC Letter at 28.

[120] *Id.*

[121] *See* FICC Letter at 29.

[122] *Id.*

eliminated 15 backtesting deficiencies, a 22% reduction.[123]

FICC further states that the $1 million floor is appropriate because the Segregated Customer Margin posted by each individual Segregated Indirect Participant needs to be sufficient on its own to address losses arising from the Segregated Indirect Participant's positions.[124] This is because Segregated Customer Margin is not subject to loss mutualization under the proposal, so FICC can only use Segregated Customer Margin posted by an individual Segregated Indirect Participant to satisfy that customer's obligations. As a result, each Segregated Indirect Participant's portfolio would present a risk to FICC that is equivalent to the risk of a proprietary portfolio of an individual Netting Member.[125] If the Segregated Customer Margin is insufficient, losses would need to be mutualized, with harm to FICC, its non-defaulting Netting Members, and, potentially, the market as a whole.[126]

In addition, FICC stated that the risk cited by the Commission of inconsistent activity giving rise to dramatic changes in risk exposure, discussed by the Commission in the FICC–2022–006 Order,[127] is arguably more pronounced for indirect participants than for Netting Members.[128] First, indirect participants may clear through multiple Netting Members and shift their activity through different Netting Members, which can present risks to FICC since FICC cannot use the Segregated Customer Margin posted by the Segregated Indirect Participant through one Netting Member to address the Segregated Indirect Participant's transactions cleared by another Netting Member.[129] As a result, FICC states that, even if the Segregated Indirect Participant's overall activity remains steady, FICC could see dramatic shifts in its risk simply because the Segregated Indirect Participant shifts the Netting Members it uses as its intermediary at FICC.[130] Second, FICC states that it does not have the same general understanding of indirect participants' business that it has for its Netting Members, since it does not collect the same information on individual customers' business or finances that it does for its Netting Members.[131] As a result, FICC states that it is less likely to know when there may be significant swings in indirect participant risk exposures as it would for its Netting Members and, since indirect participants are likely to have a far more diverse array of business models and interest rate considerations than FICC's Netting Members, they could engage in inconsistent activity that could increase risk exposure to FICC.[132] According to FICC, the possibility of inconsistent activity among indirect participants is potentially greater.[133]

The Commission disagrees with commenters who stated that using the same minimum as Netting Members is not appropriate for Segregated Indirect Participants. As stated in Section I.A. above, FICC and non-defaulting Netting Members and indirect participants may be subject to losses should the Segregated Customer Margin of an indirect participant be insufficient to satisfy losses caused by the liquidation of that indirect participant's portfolio. This potential exposure both to FICC and non-defaulting Netting Members and indirect participants makes it essential that FICC determine margin amounts for Segregated Indirect Participant Accounts that are reasonably designed to ensure that FICC has sufficient margin to cover the losses of a defaulting Segregated Indirect Participant.

The analyses conducted by FICC both in connection with the 2022 change to the required minimum margin amount for Netting Members and after the implementation of that requirement, which the Commission has reviewed and analyzed, support the use of the $1 million margin requirement for Segregated Indirect Participant Accounts. The Commission agrees that these studies demonstrate that a $1 million margin floor has a material impact on reducing the number of backtesting deficiencies experienced by FICC's Netting Members, which would likely help FICC better manage its credit exposure to its Netting Members and indirect participants and credit exposures arising from its payment, clearing, and settlement processes.

Consideration of the appropriate Netting Member minimum is directly relevant to what is appropriate for Segregated Indirect Participant Accounts because FICC would treat such accounts the same as Netting Member accounts in the event of a default of that individual customer.[134] Even though a Segregated Indirect Participant would be the customer of a Sponsoring Member or an Agent Clearing Member, each Segregated Indirect Participant Account would need to provide sufficient margin to independently cover its losses in the event of a default. FICC will determine the appropriate margin for each Segregated Indirect Participant Account as if it were a separate Netting Member. As discussed above, indirect participants may increase risk by clearing through different Netting Members, which would provide FICC with less insight into their overall portfolio. Accordingly, it is appropriate for the minimum amount to be the same for both Netting Members and indirect participants.

In response to commenters who proposed an alternative amount or approach, the Commission also has reviewed and analyzed the analysis of alternative minimum amounts that FICC conducted, which show that there would still be potential for higher amounts of backtesting deficiencies using a $500,000 alternative minimum, making the alternatives proposed by commenters ($100,000, $250,000 or a dynamic minimum with a $250,000 cap) not reasonably designed to allow FICC to collect sufficient margin to cover its exposures. As discussed above, FICC's backtesting data from December 5, 2022 to June 30, 2024 indicates that increasing the minimum margin amount from $100,000 to $1 million eliminated 24 Netting Member backtesting deficiencies, a 12% reduction.[135] Further, during a 12-month period of moderate market volatility from July 1, 2023 to June 30, 2024, the $1 million floor eliminated 15 backtesting deficiencies, a 22% reduction.[136]

Because FICC is not able to predict how many indirect participants may elect to submit activity to FICC through a Segregated Indirect Participants Account or the size or volume of that activity, margin requirements for each Segregated Indirect Participant would be calculated in the same manner as for Netting Members.[137] FICC's impact studies of Netting Members provide a reasonable approximation of the risks FICC may face if the minimum margin amount is set below $1 million.

[123] *Id.*

[124] *Id.*

[125] *Id.*

[126] *Id.*

[127] FICC–2022–006 Order, *supra* note 118, at 65270.

[128] *See* FICC Letter at 30.

[129] *Id.*

[130] *Id.*

[131] *Id.*

[132] *Id.*

[133] *Id.*

[134] This also makes the 2022 impact study relevant to this determination because FICC would calculate margin requirements for each Segregated Indirect Participant in the same manner as margin requirements for each Netting Member. The Commission reviewed and analyzed that impact study when approving the current minimum applicable to Netting Members, and the same analysis should apply here as well.

[135] *See* FICC Letter at 29.

[136] *Id.*

[137] *See* Notice of Filing, *supra* note 4, at 21595.

Therefore, the proposed $1 million floor is appropriate to increase the probability that the margin amount collected by FICC is sufficient to cover FICC's credit exposure to Segregated Indirect Participants and protect non-defaulting parties from experiencing losses. However, as described above in Section I.B.2.a., if FICC determines that a different minimum charge would be appropriate and consistent with achieving its backtesting coverage target, FICC would have the ability to adjust the minimum charge of $1 million margin requirement. This added flexibility should allow FICC to continue to collect the appropriate amount of margin to cover its credit exposure to each participant fully with a high degree of confidence, as demonstrated by FICC's meeting its backtesting coverage targets, while minimizing the burden on indirect participants.

Moreover, the Commission disagrees that allowing the Netting Member to determine a minimum would be appropriate. It is unclear what basis a Netting Member would use to determine such a minimum in a way that would ensure that the amount is sufficient to meet FICC's regulatory obligations and minimize backtesting deficiencies because a Netting Member would not be able to replicate FICC's backtesting or calculate FICC's regulatory obligations.

The Commission disagrees that determining a minimum deposit on a case-by-case basis would be feasible for every Segregated Indirect Participant. FICC has stated that it does not know how many Segregated Indirect Participants will participate in FICC. At this time, there are over 2500 Sponsored Members at FICC,[138] and it is likely that additional indirect participants will want to access clearing going forward in light of the Treasury Clearing rules. Determining a minimum for even half the current Sponsored Members on a case-by-case basis would be extremely burdensome for FICC and would require the submission of detailed financial information by each Sponsored Member to inform FICC of its planned business activities, and it is unclear how or on what basis such a minimum would be adjusted over time. Establishment of a minimum requirement is appropriate to ensure that FICC can meet its obligations under Rule 17ad–22(e)(4)(i), and reliance upon the minimum for Netting Members is appropriate because, as discussed above, FICC has to treat each Segregated Indirect Participant as a stand-alone account for risk management purposes to segregate its margin appropriately.

For these reasons, the $1 million minimum margin requirement should help ensure that FICC has sufficient margin to cover potential losses from a Segregated Indirect Participant default, thereby reducing the probability that FICC, non-defaulting Netting Members, and non-defaulting indirect participants would incur losses resulting from a default. Moreover, as described above in Section I.B.2.a., FICC would have the ability to adjust the amount of the minimum $1 million margin requirement if FICC determines that a different minimum charge would be appropriate and consistent with achieving its backtesting coverage target. The Commission agrees with FICC that it should continue to assess the performance of this minimum requirement with respect to FICC's backtesting coverage requirements, as it provided in the Amendment to this filing, to ensure that FICC is not collecting more margin than is necessary to meet its regulatory obligations to cover its exposure to its participants.[139] Although the Commission recognizes that FICC could use this ability to increase the $1 million minimum to some greater amount, it would only be able to do so if determines that a different minimum charge would be appropriate and consistent with achieving its backtesting coverage target.

3. Margin Component Schedule

The proposed changes in section I.B.3 regarding the calculation of margin for segregated and non-segregated accounts should ensure that FICC collects margin sufficient to cover its exposures with respect to both direct and indirect participants. Requiring that the margin requirement for a Segregated Indirect Participant Account be calculated in generally the same manner as a Netting Member's requirement, which the Commission has reviewed and approved as part of FICC's rules, should help ensure that FICC collects margin sufficient to cover its exposures with respect to both direct and indirect participants. By doing so, this portion of the Advance Notice should better ensure that, in the event of a Netting Member's or indirect participant's default, FICC has sufficient margin to cover potential losses from the default, thereby reducing the probability that FICC, non-defaulting Netting Members, and non-defaulting indirect participants would incur losses resulting from a default. Collecting the same margin components for a Segregated Indirect Participant Account as those used for a Netting Member Account is appropriate because FICC has to risk-manage each Segregated Indirect Participant Account individually, and application of the existing margin methodology would help ensure that FICC collects sufficient margin to cover its exposures to participants for all Accounts. FICC has, however, taken into account how the ECP should apply differently when determining a Segregated Customer Margin Requirement, which is appropriate for the reasons discussed in Section II.C.3 below, and the changes related to the ECP Charge would ensure that Segregated Indirect Participants are not required to post additional margin to account for the capital position of its Netting Member.

Accordingly, for the reasons discussed above, the Proposed Rule Change is reasonably designed to enable FICC to effectively identify, measure, monitor, and manage its credit exposure to Netting Members and indirect participants, consistent with Rule 17ad–22(e)(4)(i).[140]

B. Consistency With Rule 17ad–22(e)(6)(i)

Rule 17ad–22(e)(6)(i) requires FICC to establish, implement, maintain and enforce written policies and procedures reasonably designed to cover its credit exposures to its participants by establishing a risk-based margin system that, at a minimum, considers, and produces margin levels commensurate with, the risks and particular attributes of each relevant product, portfolio, and market, and, if the covered clearing agency provides central counterparty services for U.S. Treasury securities, calculates, collects, and holds margin amounts from a direct participant for its proprietary positions in Treasury securities separately and independently from margin calculated and collected from that direct participant in connection with U.S. Treasury securities transactions by an indirect participant that relies on the services provided by the direct participant to access the covered clearing agency's

[138] *See* GSD Member Directories, *available at https://www.dtcc.com/client-center/ficc-gov-directories.*

[139] One commenter states that FICC should not delay recalibration of the minimum margin requirement to a later date. MFA Letter II at 6–7. However, as the Commission discussed above, the minimum margin requirement is appropriate, based on the data available at this time. The Commission will continue to monitor implementation of this requirement going forward once more data regarding the use of segregated accounts is available.

[140] *See id.*

payment, clearing, or settlement facilities.[141]

1. Separation of Proprietary and Customer Margin

The proposed changes to separate proprietary and customer margin are consistent with Rule 17ad–22(e)(6)(i). First, to help ensure that proprietary transactions and transactions submitted to FICC on behalf of indirect participants are margined separately, FICC would require that each margin portfolio contain only transactions from the same account type and that Netting Members use separate Deposit IDs for different transaction types. Second, FICC would calculate each Segregated Indirect Participant's margin requirement separately on a gross basis as though each Segregated Indirect Participant were a separate Netting Member. Finally, FICC would create a separate ''Segregated Customer Margin Custody Account'' for each Netting Member that contains deposits of Segregated Customer Margin for indirect participants, with interest earned on cash margin paid to each Segregated Indirect Participant's Netting Member for the benefit of, and as an agent for, the Segregated Indirect Participant. Collectively, these proposed changes should ensure that a Netting Member's proprietary transactions are not netted with indirect participant transactions for margin calculations and that margin for indirect participant transactions is collected and held separately and independently from margin for a Netting Member's proprietary transactions. Moreover, by calculating each Segregated Indirect Participant's margin requirement separately from Netting Members and other Segregated Indirect Participants, the proposed changes should allow FICC to better isolate the risk profiles of individual indirect participants from Netting Members, which should help FICC better understand and monitor each individual participant's risk exposures.[142]

One commenter expressed concern that the proposal would not fully eliminate fellow customer risk because it would allow for the *pro rata* allocation of Current Net Settlement positions among Segregated Indirect Participant positions held in the same Segregated Indirect Participants Account.[143] In response, FICC explained that, due to the requirement in the Treasury Clearing Rules that margin for customer positions be calculated separately from margin for a Netting Member's proprietary positions, FICC would not be able to allocate the margin obligations from Current Net Settlement Positions to a Netting Member's portfolio.[144] As a result, such margin must be allocated to customer positions and FICC states that, when it is not aware of the allocation of Current Net Settlement Positions among customers, it is most equitable to allocate such positions *pro rata* to customers who were long or short the relevant securities.[145] The Commission agrees that allocating the positions to the Netting Member's account would be inconsistent with Rule 17ad–22(e)(6)(i) because it would impermissibly net proprietary transactions against indirect participant transactions. The Commission further agrees that the positions must be allocated to ensure that FICC is able to appropriately risk-manage those positions (that is, to collect appropriate margin). The Commission further agrees with FICC's approach of limiting such *pro rata* allocations only to customers engaging in non-Sponsored GC Trades because settlement failures do not occur with respect to Sponsored GC Trades. Therefore, in the event that the positions are not allocated, a *pro rata* allocation among customers is appropriate.

Accordingly, the proposed changes in the Proposed Rule Change would be consistent with Rule 17ad–22(e)(6)(i) because they should help ensure that FICC calculates, collects, and holds margin for a Netting Member's proprietary positions separately from the margin for positions the member clears for customers.[146]

5. Margin Component Schedule

The proposed changes to establish a Margin Component Schedule, which would consolidate the terms and information relating to margin calculation throughout the Rules into a single schedule, are consistent with Rule 17ad–22(e)(6)(i). Under the proposed Margin Component Schedule, FICC would perform substantially the same calculation it currently performs when determining a Netting Member's Required Fund Deposit and include the methodology for calculating a Netting Member's Segregated Customer Margin Requirement. By including a methodology to calculate each Segregated Indirect Participant's margin requirement separately from Netting Members and other Segregated Indirect Participants, the proposed changes should help ensure that FICC calculates, collects, and holds margin for a Netting Member's proprietary positions separately from the margin for positions the member clears for customers. Moreover, calculating margin requirements for each Segregated Indirect Participant should allow FICC to better isolate the risk profiles of individual indirect participants from Netting Members, which should help FICC better understand and monitor each individual participant's risk exposures and thereby collect margin commensurate with the risks of each Netting Member and indirect participant portfolio.

A commenter states that FICC should confirm that segregation of margin for indirect participants does not magnify risk for Netting Members. Specifically, the commenter states that it is not clear whether the Required Fund Deposit to be posted by Netting Members incorporates any exposure associated with Segregated Indirect Participant Accounts and expresses concern as to whether FICC's rules allow FICC to collect additional margin to cover any enhanced risk that may arise relating to the Netting Member's obligations to FICC for its clients who are indirect participants generally or who choose segregation specifically.[147] However, FICC's proposed rules establish that the calculation of a Netting Member's Required Fund Deposit excludes the exposure of its Segregated Indirect Participants.[148] FICC's rules do permit FICC to collect increased Required Fund Deposits from Netting Members if ''necessary to protect [FICC] and its Members from Legal Risk,'' which, FICC states, would include the consideration

[141] 17 CFR 240.17ad–22(e)(6)(i).

[142] Commenters requested clarification that FICC's funds-only settlement amounts are settlement payments rather than margin. *See* ISDA Letter at 6; Letter from Katherine Darras, General Counsel, International Swaps and Derivatives Association (July 18, 2024) (''ISDA Letter II'') at 6; SIFMA Letter at 4; Letter from Walt L. Lukken, President and Chief Executive Officer, Futures Industry of America (Apr. 18, 2024) (''FIA Letter'') at 11. The Proposed Rule Change does not make any amendments to the funds-only settlement process at FICC. *See* GSD Rule 13. This aspect of FICC's rules is, therefore, not relevant to this Proposed Rule Change. However, FICC clarified that it views such payments as constituting settlements that discharge outstanding payment obligations, rather than as margin or collateral. FICC Letter at 43. The Commission agrees with this clarification, based upon its knowledge of FICC's margin and payment flows and the applicable GSD Rules.

[143] *See* SIFMA AMG Letter at 10.

[144] *See* FICC Letter at 36.

[145] *Id.*

[146] 17 CFR 240.17ad–22(e)(6)(i).

[147] ISDA Letter I at 7; ISDA Letter II at 6.

[148] *Compare* proposed Margin Component Schedule section 2 (regarding Required Fund Deposits) *with* section 3 (regarding Segregated Customer Margin).

of the Netting Members' indirect participants.[149]

This commenter also states the fact that the ability to prefund margin for a customer is only temporary puts pressure on the Netting Member's own Required Fund Deposits, which ''it seems would still cover the obligations of all its clients'' and also on the Netting Member and the broader FICC membership, in the event of a failure by any Segregated Indirect Participant.[150] However, the Netting Member's Required Fund Deposits would not be calculated based on the obligations of its clients, and, in the event of the default of an indirect participant, FICC would use the Segregated Customer Margin for only that indirect participant. Therefore, the Commission disagrees that the inability to permanently prefund the customer's margin requirement puts additional pressure on the Netting Member's own Required Fund Deposits.

Another commenter states that FICC should explain why it is appropriate to calculate a segregated customer's margin requirement as if it were a Netting Member, even though the margin calculation for FICC Netting Members covers both initial margin and guaranty fund contributions (and customers are not expected to be contributing to the guaranty fund).[151] However, FICC does not maintain a separate guaranty fund into which a Netting Member contributes for its customers. The Segregated Customer Margin Requirement must be sufficient to cover the exposures to FICC arising from that particular customer's activity because, under the segregation system proposed by the Proposed Rule Change which would allow broker-dealers participating in FICC to comply with the conditions of Note H to Rule 15c3–3, FICC would not be able to use the margin collected from a Segregated Indirect Participant for any reason unrelated to the Segregated Indirect Participant. Therefore, calculating each Segregated Customer Margin Requirement in this manner is appropriate to ensure that FICC has appropriate resources to cover each customer's exposures. Therefore, this aspect of the Proposed Rule Change is consistent with Rule 17ad–22(e)(6)(i) under the Exchange Act.

[149] *See* proposed Margin Component Schedule section 4; *see also* Notice of Filing, *supra* note 4, at 21593.

[150] *See* ISDA Letter I at 7.

[151] *See* Letter from Joanna Mallers, Secretary, Futures Industry of America, Principal Traders Group (Apr. 17, 2024) (''FIA PTG Letter I'') at 8.

6. Excess Capital Premium

The proposed changes to the calculation of the ECP charge are consistent with Rule 17ad–22(e)(6)(i). FICC's margin deposits are made up of risk-based components (as margin) that are calculated and assessed daily to limit FICC's exposures to Netting Members. FICC's proposed changes to use clearly defined sources in the calculation of the ECP charge would collectively make the calculation clearer and more predictable to Netting Members, while continuing to apply an appropriate risk-based charge designed to mitigate the risks presented to FICC. Similarly, the proposal to cap the Excess Capital Ratio at 2.0 would allow FICC to appropriately address the risks it faces without imposing an overly burdensome ECP and would reduce the circumstances in which FICC may waive the charge, resulting in a more transparent margining methodology. Finally, the proposed rule change would clarify the exigent circumstances under which FICC may determine that it is appropriate to waive the ECP charge. Overall, these proposed changes would improve the effectiveness of the calculation of the ECP and, therefore, allow FICC to more effectively address the increased default risks presented by Netting Members that operate with lower capital levels relative to their margin requirements.

In addition, FICC proposes to exclude VaR Charges for Segregated Indirect Participants Accounts when determining a Netting Member's Excess Capital Differential, in order to take into account the fact that each indirect participant would be responsible for satisfying its own respective VaR Charge. Not including these Segregated Indirect Participants Accounts when determining the Excess Capital Differential, and, therefore, the ECP Charge, is consistent with the purpose of the Excess Premium Charge. This charge is designed to address the risk that a Netting Member with low capital relative to its value-at-risk to FICC is not able to perform its obligations. Because the Netting Member's capital is not used to meet the indirect participant's obligation to FICC, excluding the indirect participant VaR Charges from the determination of the ECP should result in FICC collecting margin commensurate with the risks and particular attributes of each relevant portfolio.

Taken together, the proposed changes enhance the ability of the ECP to produce margin levels commensurate with the risks FICC faces related to its Netting Members' operating capital levels. Therefore, this aspect of the Proposed Rule Change is consistent with Rule 17ad–22(e)(6)(i) under the Exchange Act.

C. Consistency With Rule 17ad–22(e)(6)(iii)

Rule 17ad–22(e)(6)(iii) requires that FICC establish, implement, maintain and enforce written policies and procedures reasonably designed to cover its credit exposures to its participants by establishing a risk-based margin system that, at a minimum, calculates margin sufficient to cover its potential future exposure to members in the interval between the last margin collection and the close out of positions following a member default.[152]

As summarized in Section I.B.3 above, FICC employs daily backtesting to determine the adequacy of each Netting Member's Required Fund Deposit, paying particular attention to members that have backtesting deficiencies below the 99% confidence target. Such backtesting deficiencies highlight exposure that could subject FICC to potential losses if a Netting Member defaults. As discussed in Section II.C.2, FICC's impact study during the period from July 1, 2021 to June 30, 2022 demonstrated that a $1 million floor would have protected FICC and its participants by reducing the possibility of incurring a loss in the event of a Netting Member failure by mitigating 16% of backtesting deficiencies.[153] Moreover, after the $1 million floor was implemented for Netting Members, FICC states that it eliminated 22% of backtesting deficiencies during a 12-month period of moderate market volatility from July 1, 2023 to June 30, 2024.[154]

Therefore, adding the proposed $1 million minimum requirement for Segregated Customer Margin, and the ability to adjust the minimum million margin requirement to achieve FICC's backtesting coverage target, should better ensure that FICC maintains sufficient margin to cover its potential future exposure to its indirect participants in the interval between the last margin collection and the close out of positions following an indirect participant default. This should, thereby, reduce the likelihood FICC or non-defaulting Netting Members or indirect participants would incur losses as a result. Accordingly, FICC's proposed $1 million minimum requirement for Segregated Customer

[152] 17 CFR 240.17ad–22(e)(6)(iii).

[153] *See* FICC Letter at 28.

[154] *Id.*

Margin would be consistent with Rule 17ad–22(e)(6)(iii).[155]

D. Consistency With Rule 17ad–22(e)(18)(ii)

Rule 17ad–22(e)(18)(ii) requires that FICC establish, implement, maintain and enforce written policies and procedures reasonably designed to establish objective, risk-based, and publicly disclosed criteria for participation, which require participants to have sufficient financial resources and robust operational capacity to meet obligations arising from participation in the clearing agency.[156] The proposed changes to consolidate FICC's margin methodology in a single location, identify the particular Required Fund Deposit Portions and Segregated Customer Margin Requirements, and clarify the calculation of the Excess Capital Premium and circumstances in which FICC would waive the application of such premium should enhance FICC's public disclosure of the risk-based margin obligations that Netting Members and their indirect participants would have as a result of their participation in FICC's clearance and settlement services. This improved public disclosure should allow Netting Members and their indirect participants to better understand how their activity would impact margin calculations, which are designed to ensure that participants have sufficient financial resources and robust operational capacity to meet obligations to FICC. Accordingly, the proposed changes would be consistent with Rule 17ad–22(e)(18)(ii).[157]

E. Consistency With Rule 17ad–22(e)(18)(iii)

Rule 17ad–22(e)(18)(iii) requires that FICC establish, implement, maintain and enforce written policies and procedures reasonably designed to establish objective, risk-based, and publicly disclosed criteria for participation, which monitor compliance with its participant requirements on an ongoing basis.[158] The proposed changes would require Netting Members to designate the specific account type when submitting transactions and to identify any Sponsored Member or Executing Firm Customer for whom the transaction is submitted. These changes should enhance FICC's ability to monitor which transactions are being entered into by which entities and assess the specific risks associated with those entities. This enhanced monitoring of participant activity should allow FICC to better monitor participants' compliance with FICC's Rules. Accordingly, the proposed changes would be consistent with Rule 17ad–22(e)(18)(iii) because they should enhance FICC's ability to monitor compliance with its participant requirements on an ongoing basis.[159]

F. Consistency With Rule 17ad–22(e)(18)(iv)(C)

Rule 17ad–22(e)(18)(iv)(C) requires that FICC establish, implement, maintain and enforce written policies and procedures reasonably designed to ensure that it has appropriate means to facilitate access to clearance and settlement services of all eligible secondary market transactions in U.S. Treasury securities, including those of indirect participants.[160]

As discussed above in Section II.B.3, by improving the transparency of FICC's account offerings and margin calculation methodology, the proposed changes should enhance market participants' understanding of how margin is calculated and their options for posting margin, thereby facilitating access to FICC's clearance and settlement services. In addition, the proposed changes should offer greater optionality to Netting Members and indirect participants, which should allow Netting Members and indirect participants to adopt a margining arrangement that aligns with their business objectives and regulatory, operational, and practical constraints. By enhancing transparency of FICC's margin framework and account options and offering greater optionality to participants concerning the type of account they transact in and how their margin is posted, the proposal should facilitate access to FICC's clearance and settlement systems.

Several commenters proposed that FICC should require Netting Members to offer account segregation to customers.[161] One such commenter specified that this should include bank Netting Members, who would not face the same restrictions on the use of customer margin as broker-dealer customers subject to Rule 15c3–3 and therefore may not be as incentivized to provide segregated account services.[162]

FICC did not propose a requirement that its Netting Members offer segregated accounts to their customers. Therefore, the Commission is not addressing any changes related to such a requirement in this Proposed Rule Change. Nothing in the Treasury Clearing Rules or Rule 15c3–3 requires a covered clearing agency, like FICC, to require its Netting Members to provide certain services. Moreover, certain Netting Members may have regulatory or other reasons not to offer segregation, and, if required to offer such services, may choose to cease providing customer clearing services, which could, in turn, increase concentration in the market and reduce liquidity.[163] Any such requirement could constitute a burden on competition that would not be permissible under Section 17A(b)(3)(I) of the Exchange Act.

Additionally, a commenter urged FICC to allow indirect participants to post margin directly to FICC without intermediation from a Netting Member.[164] The Treasury Clearing Rules do not require FICC to provide this function, and FICC did not propose such a method for direct posting of margin.[165] Accordingly, the Commission is not addressing any changes related to such a requirement in this Proposed Rule Change.

One commenter sought clarification whether Netting Members other than broker-dealers can elect segregation for their customers.[166] Based on the Proposed Rule Change, the Commission understands, and FICC confirmed,[167] that any Sponsoring Member or Agent Clearing Member, regardless of whether registered as broker-dealers, would be able to designate an account as a Segregated Indirect Participants Account.

The same commenter also sought clarification whether a customer may segregate margin obtained through a margin financing arrangement.[168] Based

[155] 17 CFR 240.17ad–22(e)(6)(iii).

[156] 17 CFR 240.17ad–22(e)(4)(18)(ii).

[157] *Id.*

[158] 17 CFR 240.17ad–22(e)(18)(iii).

[159] 17 CFR 240.17ad–22(e)(18)(iii).

[160] 17 CFR 240.17ad–22(e)(18)(iv)(C).

[161] Specifically, one commenter stated that for indirect participants, having a ''right'' to direct their Netting Member to segregate their margin is highly desirable because it would allow an indirect participant to have certainty that margin that it posts receives the protection afforded by segregation. SIFMA AMG Letter at 6. Another such commenter stated that, despite what a customer may desire with respect to margin and segregation, there could be incentives for direct participants to finance the margin for their customers' transactions (and thereby earn extra fees for doing so) instead of the customer financing or posting that margin, and for the direct participant to accept the customer's margin without offering the option of segregation (and thereby avoid the additional operational and other costs associated with segregation), which would still be permissible if FICC were not to require its Netting Members to offer account segregation. MFA Letter I at 4.

[162] SIFMA AMG Letter at 6.

[163] FICC Letter at 33.

[164] *See* ICI Letter at 13.

[165] *See supra* note 3 at 2751.

[166] FIA–PTG Letter at 7–9.

[167] FICC Letter at 39.

[168] FIA–PTG Letter at 7–9.

on the Proposed Rule Change, the Commission understands, and FICC confirmed,[169] that such segregation would be permissible under FICC's rules.

This commenter also asked why excess margin would only be returned on request and states that an indirect participant should not have to request a return of its excess margin.[170] The Treasury Clearing Rules do not require FICC to provide this function, and FICC did not propose such a function. Accordingly, the Commission is not addressing any changes related to such a requirement in this Proposed Rule Change. Moreover, when it adopted the amendments to Rule 15c3–3, the Commission declined to adopt a requirement to ''push'' excess margin to direct participants.[171]

Another commenter suggested that FICC allow customer margin to be segregated, even when customers do not post the full amount of the margin needed to cover their positions.[172] FICC states that allowing customer margin to be segregated when customers do not post the full amount of margin would lead to disparities that would put broker-dealer Netting Members at competitive disadvantage to other Netting Members.[173] The Treasury Clearing Rules do not require FICC to provide this function, and FICC did not propose such a function. Any changes to FICC's rules to impose such a requirement would have to be filed with the Commission pursuant to Section 19(b)[174] of the Exchange Act, as well as, potentially, in an advance notice filed pursuant to Section 806(e) of the Clearing Supervision Act.[175] Therefore, the Commission is not addressing any changes related to such a requirement in this Proposed Rule Change.

Finally, one commenter urged FICC to address the cross-border implications of the proposal and provide a framework for compliance by non-U.S. Netting Members and indirect participants.[176] Specifically, this commenter was concerned that the U.S. Treasury clearing mandate will adversely impact foreign customers that are limited in their ability, or prohibited entirely, to post margin in connection with transactions involving U.S. Treasury securities.[177] However, nothing in the Proposed Rule Change would require a particular market participant to post margin in connection with transactions involving U.S. Treasury securities. Indirect participants remain able to access FICC's central clearing services through access models that do not require the direct posting of margin to FICC (*e.g.,* via the non-segregated versions of FICC's Sponsored and Agent Clearing Services), which should allow flexibility for market participants to determine the most effective way to access FICC indirectly regardless of potential regulatory or other constraints on the ability to post margin directly.

Accordingly, the proposed changes would be consistent with Rule 17ad–22(e)(18)(iv)(C).[178]

G. Consistency With Rule 17ad–22(e)(19)

Rule 17ad–22(e)(19) requires that FICC establish, implement, maintain and enforce written policies and procedures reasonably designed to identify, monitor, and manage the material risks to the covered clearing agency arising from arrangements in which firms that are indirect participants in FICC rely on the services provided by direct participants to access FICC's clearance and settlement facilities.[179] The proposed changes described in Section I.B.1 would require that each margin portfolio contains only transactions from the same account type, Netting Members use separate Deposit IDs for different transaction types, each Segregated Indirect Participant's margin requirement be calculated separately on a gross basis as though each Segregated Indirect Participant were a separate Netting Member, and Segregated Customer Margin for each indirect participant be deposited into a separate interest-earning Segregated Customer Margin Custody Account. These changes should enhance FICC's ability to isolate the risk profiles of individual indirect participants from Netting Members, which should help FICC better understand and monitor each individual participant's risk exposures. In addition, the calculation and collection of Segregated Customer Margin on a gross basis, as described in Section I.B.1 and 1.B.2, and the establishment of a $1 million cash floor for Segregated Customer Margin, as described in Section I.B.2.a, should help ensure that FICC will have sufficient margin to manage the risk to FICC during an indirect participant default.

Accordingly, the proposed changes would be consistent with Rule 17ad–22(e)(19) because they should enhance FICC's ability to identify, monitor, and manage the material risks to FICC associated with indirect participants relying on Netting Members to access FICC's clearance and settlement services.[180]

H. Consistency With Rule 17ad–22(e)(23)(ii)

Rule 17ad–22(e)(23)(ii) requires that FICC establish, implement, maintain and enforce written policies and procedures providing sufficient information to enable participants to identify and evaluate the risks, fees, and other material costs they incur by participating in FICC.[181] The proposed changes described in Section I.B.3 to consolidate and clarify FICC's margin calculation methodology in the proposed Margin Component Schedule, adopt a method for allocating net unsettled positions to individual indirect participants for purposes of calculating margin requirements and to clarify the calculation of the ECP should make it easier for both Netting Members and indirect participants to identify and price the potential margining costs

[169] FICC Letter at 40.

[170] *See* FIA PTG Letter I at 7–9.

[171] *See* Treasury Clearing Adopting Release, *supra* note 3, at 2767 (removing, in response to commenters, the requirement that the covered clearing agency have procedures to return customer position margin to the broker-dealer that is no longer needed to meet a current margin requirement resulting from positions in U.S. Treasury securities of the broker-dealer's customers no later than the close of the next business day after the day the customer position margin is no longer needed for this purpose because such a requirement may add significant operational burdens to covered clearing agencies for U.S. Treasury securities and because the debit is limited to margin required and on deposit at the covered clearing agency and therefore does not include the excess margin).

[172] *See* MFA Letter I at 6.

[173] *See* FICC Letter at 32. Specifically, FICC stated that the Treasury Clearing Rules, in particular the amendments to Exchange Act Rule 15c3–3a, provide that a broker-dealer may record a debit in the customer and PAB reserve formulas for margin it collects from customers and on-posts to FICC, but only if the broker-dealer collects from the customer the full amount of margin required for the customer's positions. Accordingly, a broker-dealer is effectively precluded from collecting from customers only a portion of the margin that their positions require and on-posting that amount to FICC. Were FICC to allow segregation of customer margin even if the customer did not fully fund its margin obligations, such segregation would effectively allow non-broker-dealer Netting Members to offer what broker-dealers cannot, *i.e.,* permitting their customers to post a portion of the margin required by FICC and on-post that margin to FICC. This ability would place such Netting Members at a competitive advantage relative to broker-dealer Netting Members.

[174] 15 U.S.C. 78s(b)(1).

[175] *See supra* note 3 at 2751.

[176] *See* SIFMA AMG Letter at 12–13.

[177] *See id.* (citing Article 15(2) of the European Union's Money Market Fund Regulation, which it describes as prohibiting European Money Market Mutual Funds from pledging any assets received under reverse repos and certain restrictions on Undertakings for Collective Investments in Transferable Securities and similar investment vehicles related to their ability to post margin that will be held on deposit at FICC).

[178] 17 CFR 240.17ad–22(e)(18)(iv)(C).

[179] 17 CFR 240.17ad–22(e)(19).

[180] 17 CFR 240.17ad–22(e)(19).

[181] 17 CFR 240.17ad–22(e)(23)(ii).

associated with how each chooses to submit transactions to FICC for clearance and settlement.

Accordingly, the proposed changes would be consistent with Rule 17ad–22(e)(23)(ii) because they should enhance the ability of Netting Members and indirect participants to identify and evaluate the costs to access FICC's clearance and settlement services.[182]

I. Other Comments Received

Commenters submitted several comments that were not related to the Proposed Rule Change. Commenters stated that FICC should publish a roadmap and/or expedite their plans with the Chicago Mercantile Exchange (''CME'') for expanding their cross-margining framework.[183] The Proposed Rule Change does not address the cross-margining agreement between FICC and CME. The current cross-margining agreement between FICC and CME is part of FICC's rulebook, and therefore any changes to the agreement would have to be filed with the Commission pursuant to Section 19(b) [184] of the Exchange Act.[185] Therefore, the Commission cannot approve or disapprove any changes related to the cross-margining agreement at this time. Cross-margining is not required by the recently adopted Treasury Clearing Rules.

However, the Commission historically has supported and approved cross-margining at clearing agencies and recognizes the potential benefits of cross-margining systems, which include freeing capital through reduced margin requirements, reducing clearing costs by integrating clearing functions, reducing clearing agency risk by centralizing asset management, and harmonizing liquidation procedures.[186] The Commission continues to believe that market participants can benefit from cross-margining arrangements and encourages U.S. Treasury CCAs to consider the potential of such benefits. FICC states, in its response letter regarding the Proposed Rule Change, that it is actively pursuing an end-user level cross-margining arrangement with CME. The Commission would consider any proposal arising from such pursuit in due course, if such a proposal were to be filed with the Commission.

Several commenters requested that FICC provide a legal analysis on the enforceability of the proposed changes, including the protection of segregated customer margin in the event of a Netting Member default.[187] In response, FICC states that it has prepared an analysis on the treatment of Segregated Customer Margin in the event of a FICC or Netting Member insolvency and that this analysis confirmed that, as long as customers and their Netting Members make clear that their relationship is a custodial one, Segregated Customer Margin would be reserved for customers and would not form part of FICC's or the Netting Member's general estate upon either institution's insolvency.[188] FICC states that it has made this analysis available to indirect participants upon request on a non-reliance basis.[189] This analysis addresses the commenters' request, and the Commission does not believe that any further action is necessary to respond to the commenters, who can use this analysis to inform their consideration whether to utilize a segregated account.

IV. Conclusion

On the basis of the foregoing, the Commission finds that the Proposed Rule Change is consistent with the requirements of the Exchange Act and in particular with the requirements of Section 17A of the Exchange Act [190] and the rules and regulations promulgated thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Exchange Act [191] that proposed rule change SR–FICC–2024–007, be, and hereby is, APPROVED.[192]

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[193]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–27763 Filed 11–26–24; 8:45 am]

BILLING CODE 8011–01–P

[182] 17 CFR 240.17ad–22(e)(23)(ii).

[183] *See* AIMA Letter at 5; FIA PTG Letter I at 15; MFA Letter I at 10; MFA Letter II at 5–6; SIFMA AMG Letter at 10.

[184] 15 U.S.C. 78s(b)(1).

[185] *See supra* note 3 at 2751.

[186] Treasury Clearing Adopting Release, at 2751 at n. 362 and accompanying text.

[187] *See* AIMA Letter at 7; MFA Letter I at 8–9; SIFMA AMG Letter at 11.

[188] FICC Letter at 41.

[189] *Id.*

[190] 15 U.S.C. 78q–1.

[191] 15 U.S.C. 78s(b)(2).

[192] In approving the Proposed Rule Change, the Commission considered its impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[193] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101687; File No. SR–ISE–2024–52]

Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Fees for Connectivity and Co-Location Services

November 21, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 8, 2024, Nasdaq ISE, LLC (''ISE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's fees for connectivity and co-location services, as described further below.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/ise/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the Exchange's fees relating to connectivity and co-location

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

services.[3] Specifically, the Exchange proposes to raise its fees for connectivity and co-location services in General 8 as well as certain fees related to its Testing Facilities in Options 7, Section 8 by 10%, with certain exceptions.

General 8, Section 1 includes the Exchange's fees that relate to connectivity, including fees for cabinets, external telco/inter-cabinet connectivity fees, fees for connectivity to the Exchange, fees for connectivity to third party services, fees for market data connectivity, fees for cabinet power install, and fees for additional charges and services. General 8, Section 2 includes the Exchange's fees for direct connectivity services, including fees for direct circuit connection to the Exchange, fees for direct circuit connection to third party services, and fees for point of presence connectivity. With the exception of the Exchange's GPS Antenna fees and the Cabinet Proximity Option Fee for cabinets with power density >10kW,[4] the Exchange proposes to increase its fees throughout General 8 by 10%.

In addition to increasing fees in General 8, the Exchange also proposes to increase certain fees in Options 7, Section 8, which relate to the Testing Facility. Options 7, Section 8(I) provides that subscribers to the Testing Facility located in Carteret, New Jersey shall pay a fee of $1,000 per hand-off, per month for connection to the Testing Facility. The hand-off fee includes either a 1Gb or 10Gb switch port and a cross connect to the Testing Facility. In addition, Options 7, Section 8(I) provides that subscribers shall also pay a one-time installation fee of $1,000 per hand-off. The Exchange proposes to increase these aforementioned fees by 10% to require that subscribers to the Testing Facility shall pay a fee of $1,100 per hand-off, per month for connection to the Testing Facility and a one-time installation fee of $1,100 per hand-off.

The proposed increases in fees would enable the Exchange to maintain and improve its market technology and services to remain competitive with its peers. Over the years, customer demand for more sophisticated, higher-throughput, lower-latency, and higher-power connectivity solutions has increased. The Exchange continues to invest in maintaining, improving, and enhancing its connectivity and co-location products, services, and facilities—for the benefit and often at the behest of its customers. Such enhancements include refreshing hardware and expanding Nasdaq's existing co-location facility to offer customers additional space and power. Nevertheless, and with the exception of fees that were established as part of a new service in 2017 (and have remained unchanged since their adoption), the Exchange has not increased any of the fees included in the proposal since prior to 2017, and many of the fees date back to between 2010 and 2014. For each of the connectivity products and services that pre-date 2017, inflation (as measured using the ''Data PPI'' metric described below) has been between roughly 15–17%, and in no instance has such inflation been less than 10%. Nevertheless, the Exchange proposes to increase its fees only with respect to the 10% inflation that has occurred since 2017.

As discussed below, the Exchange proposes to adjust its fees by an industry- and product-specific inflationary measure. It is reasonable and consistent with the Act for the Exchange to recoup its investments, at least in part, by adjusting its fees. Continuing to operate at fees frozen at 2010–2017 levels impacts the Exchange's ability to enhance its offerings and the interests of market participants and investors.

The fee increases the Exchange proposes are based on an industry-specific Producer Price Index (''PPI''), which is a tailored measure of inflation.[5] As a general matter, the Producer Price Index is a family of indexes that measures the average change over time in selling prices received by domestic producers of goods and services. PPI measures price change from the perspective of the seller. This contrasts with other metrics, such as the Consumer Price Index (''CPI''), that measure price change from the purchaser's perspective.[6] About 10,000 PPIs for individual products and groups of products are tracked and released each month.[7] PPIs are available for the output of nearly all industries in the goods-producing sectors of the U.S. economy—mining, manufacturing, agriculture, fishing, and forestry—as well as natural gas, electricity, and construction, among others. The PPI program covers approximately 69 percent of the service sector's output, as measured by revenue reported in the 2017 Economic Census.

For purposes of this proposal, the relevant industry-specific PPI is the Data Processing and Related Services PPI (''Data PPI''), which is an industry net-output PPI that measures the average change in selling prices received by companies that provide data processing services.

The Data PPI was introduced in January 2002 by the Bureau of Labor Statistics (''BLS'') as part of an ongoing effort to expand Producer Price Index coverage of the services sector of the U.S. economy and is identified as NAICS—518210 in the North American Industry Classification System.[8] According to the BLS ''[t]he primary output of NAICS 518210 is the provision of electronic data processing services. In the broadest sense, computer services companies help their customers efficiently use technology. The processing services market consists of vendors who use their own computer systems—often utilizing proprietary software—to process customers' transactions and data. Companies that offer processing services collect, organize, and store a customer's transactions and other data for record-keeping purposes. Price movements for the NAICS 518210 index are based on changes in the revenue received by companies that provide data processing services. Each month, companies provide net transaction prices for a specified service. The transaction is an actual contract selected by probability, where the price-determining characteristics are held constant while the service is repriced. The prices used in index calculation are the actual

[3] The Exchange initially filed the proposed pricing change on March 1, 2024 (SR–ISE–2024–09). On April 29, 2024, the Exchange withdrew that filing and submitted SR–ISE–2024–16. The Exchange withdrew that filing on June 27, 2024 and replaced it with SR–ISE–2024–23. The Exchange withdrew SR–ISE–2024–23 and replaced it with SR–ISE–2024–44 on September 10, 2024. On October 11, 2024, the Exchange replaced SR–ISE–2024–44 with SR–ISE–2024–50. The instant filing replaces SR–ISE–2024–50.

[4] The Exchange proposes to exclude the GPS Antenna fees from the proposed fee increase because, unlike the other fees in General 8, the Exchange recently increased its GPS Antenna fees. *See* Securities Exchange Act Release No. 34–99131 (December 11, 2023), 88 FR 86979 (December 15, 2023) (SR–ISE–2023–33). The Exchange also proposes to exclude the Cabinet Proximity Option Fee for cabinets with power density >10kW from the proposed fee increase because the Exchange recently established such fee. *See* Securities Exchange Act Release No. 34–100209 (May 22, 2024), 89 FR 46512 (May 29, 2024) (SR–ISE–2024–19). Similarly, the Exchange proposes to exclude from the proposed fee increase those fees that the Exchange recently established for services in its new NY11–4 expansion facility. *See* Securities Exchange Act Release No. 34–101266 (October 7, 2024), 89 FR 82654 (October 11, 2024) (SR–ISE–2024–47).

[5] *See https://fred.stlouisfed.org/series/PCU51825182#0.*

[6] *See https://www.bls.gov/ppi/overview.htm.*

[7] *See Id.*

[8] *NAICS appears in table 5 of the PPI Detailed Report and is available at https://data.bls.gov/timeseries/PCU518210518210.*

prices billed for the selected service contract.'' [9]

The Exchange believes the Data PPI is an appropriate measure to be considered in the context of the proposed rule change to modify the fee for its connectivity products because the Exchange uses its ''own computer systems'' and ''proprietary software,'' *i.e.,* its own data center and proprietary matching engine software, respectively, to collect, organize, store and report customers' transactions in U.S. equity securities on the Exchange's proprietary trading platform. In other words, the Exchange is in the business of data processing and related services.

For purposes of this proposed rule change, the Exchange examined the Data PPI value for the period from January 2017 to August 2024. The Data PPI had a starting value of 105.6 in January 2017 and an ending value of 116.022 in August 2024, a 10.422% increase. This indicates that companies who are also in the data storage and processing business have generally increased prices for a specified service covered under NAICS 518210 by an average of 10.422% during this period. Based on that percentage change, the Exchange proposes to make a one-time fee increase of only 10%, which reflects an increase covering roughly the entire period since the last price adjustments to these fees were made.

The Exchange further believes the Data PPI is an appropriate measure for purposes of the proposed rule change on the basis that it is a stable metric with limited volatility, unlike other consumer-side inflation metrics. In fact, the Data PPI has not experienced a greater than 2.16% increase for any one calendar year period since Data PPI was introduced into the PPI in January 2002. The average calendar year change from January 2002 to December 2023 was .62%, with a cumulative increase of 15.67% over this 21-year period. The Exchange believes the Data PPI is considerably less volatile than other inflation metrics such as CPI, which has had individual calendar-year increases of more than 6.5%, and a cumulative increase of over 73% over the same period.[10]

The Exchange believes the Data PPI, and significant investments into, and enhanced performance of, the Exchange support the reasonableness of the proposed fee increases.[11]

These proposed fee increases will be immediately effective upon filing. However, going forward and until December 1, 2024, the Exchange will waive all fees set forth herein to the extent that such fees exceed the levels that would have been charged for the same products and services purchased during that time period, had such fees been calculated at the rates set forth in SR–ISE–2024–44 (*i.e.,* pricing reflective of a 5.5% increase from prior fee levels). This waiver is reasonable, equitable, and not unfairly discriminatory because it will afford all customers in excess of the 30-day prior notice period for fee changes set forth in the Exchange's service terms.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[12] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[13] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

This belief is based on two factors. First, the current fees do not properly reflect the quality of the services and products, as fees for the services and products in question have been static in nominal terms, and therefore falling in real terms due to inflation. Second, the Exchange believes that investments made in enhancing the capacity and speed of Exchange systems increase the performance of the services and products.

The Proposed Rule Change Is Reasonable

As noted above, the Exchange has not increased any of the fees included in the proposal since 2017 or earlier. However, in the years following the last fee increases, the Exchange has made significant investments in upgrades to its connectivity products, services, and facilities, enhancing the quality of its services. In other words, Exchange customers have greatly benefitted, while the Exchange's ability to recoup its investments has been hampered. Between 2017 and 2024, the inflation rate is 3.64% per year, on average, producing a cumulative inflation rate of 28.43%.[14] Using the more targeted inflation number of Data PPI, the cumulative inflation rate was 10.422%. The exchange believes the Data PPI is a reasonable metric to base this fee increase on because it is targeted to producer-side increases in the data processing industry.

Notwithstanding inflation, as noted above, the Exchange has not increased its fees at all for over seven years for the subject services. The proposed fee changes represent a modest increase from the current fees. The Exchange believes the proposed fee increase is reasonable in light of the Exchange's continued expenditure in maintaining a robust technology ecosystem. Furthermore, the Exchange continues to invest in maintaining and enhancing its connectivity products—for the benefit and often at the behest of its customers and global investors. Such enhancements include refreshing all aspects of the technology ecosystem including software, hardware, and network while introducing new and innovative products and expanded and modernized facilities.[15] The goal of the enhancements discussed above, among other things, is to provide faster, higher-capacity, and more modern connectivity products and services. Accordingly, the Exchange continues to expend resources to innovate and modernize technology so that it may benefit its members in offering its connectivity products and services.

The Proposed Fees Are Equitably Allocated and Not Unfairly Discriminatory

The Exchange believes that the proposed fee increases are equitably allocated and not unfairly discriminatory because they would apply to all market participants that choose to purchase connectivity products and services from the Exchange. Any participant that chooses to purchase the Exchange's connectivity products and services would be subject to the same Fee Schedule, regardless of what type of business they operate or

[9] *See https://www.bls.gov/ppi/factsheets/producer-price-index-for-the-data-processing-and-related-servicesindustry-naics-518210.htm.*

[10] *See https://www.usinflationcalculator.com/inflation/consumer-price-index-and-annual-percent-changesfrom-1913-to-2008/.*

[11] *See supra* discussion of connectivity product and facility improvements. Additionally, other exchanges have filed for increases in certain fees, based in part on comparisons to inflation. See, *e.g.,* Securities Exchange Act Release Nos. 34–100004 (April 22, 2024), 89 FR 32465 (April 26, 2024) (SR–CboeBYX–2024–012); and 34–100398 (June 21, 2024), 89 FR 53676 (June 27, 2024) (SR–BOX–2024–16)l; Securities Exchange Act Release No. 34–100994 (September 10, 2024), 89 FR 75612 (September 16, 2024) (SR–NYSEARCA–2024–79).

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(4) and (5).

[14] *See https://www.officialdata.org/us/inflation/2017?amount=1.*

[15] *See, e.g.,* Securities Exchange Act Release No.34–101076 (September 18, 2024), 89 FR 77951(September 24, 2024) (SR–ISE–2024–45 (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Expand [the Exchange's] Co-Location Services).

the use they plan to make use of the products and services. Additionally, the fee increase would be applied uniformly to market participants without regard to Exchange membership status or the extent of any other business with the Exchange or affiliated entities. The Exchange also believes that the proposal represents an equitable allocation of reasonable dues, fees and other charges because Exchange fees have fallen in real terms during the relevant period. Finally, the Exchange believes that the proposed fee changes are not unfairly discriminatory because the fees would be assessed uniformly across all market participants, in the same manner they are today, that voluntarily purchase the Exchange's connectivity products and services, which would remain available for purchase by all market participants.

These proposed fee increases will be immediately effective upon filing. However, going forward and until December 1, 2024, the Exchange will waive all fees set forth herein to the extent that such fees exceed the levels that would have been charged for the same products and services purchased during that time period, had such fees been calculated at the rates set forth in SR–ISE–2024–44 (*i.e.,* pricing reflective of a 5.5% increase from prior fee levels). This waiver is reasonable, equitable, and not unfairly discriminatory because it will afford all customers in excess of the 30-day prior notice period for fee changes set forth in the Exchange's service terms.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed fees will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Intramarket Competition

The Exchange believes that the proposed fees do not put any market participants at a relative disadvantage compared to other market participants. As noted above, the fee schedule would continue to apply to all purchasers of the Exchange's connectivity products and services in the same manner as it does today albeit at inflation-adjusted rates for certain fees, and customers may choose whether to purchase these products and services at all. The Exchange also believes that the level of the proposed fees neither favor nor penalize one or more categories of market participants in a manner that would impose an undue burden on competition. Likewise, the proposed fee waiver described above will apply to all purchasers of the Exchange's connectivity products and services in the same manner and therefore will not burden competition among them.

Intermarket Competition

The Exchange believes that the proposed fees do not impose a burden on competition or on other SROs that is not necessary or appropriate. In determining the proposed fees, the Exchange utilized an objective and stable metric with limited volatility. Utilizing Data PPI over a specified period of time is a reasonable means of recouping the Exchange's investment in maintaining and enhancing its connectivity products, services, and facilities. The Exchange believes utilizing Data PPI, a tailored measure of inflation, to increase certain fees for connectivity products and services to recoup the Exchange's investment in maintaining and enhancing such products, services, and its facilities would not impose a burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[16] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–ISE–2024–52 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–ISE–2024–52. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–ISE–2024–52 and should be submitted on or before December 18, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–27756 Filed 11–26–24; 8:45 am]

BILLING CODE 8011–01–P

[16] 15 U.S.C. 78s(b)(3)(A)(ii).

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101694; File No. SR–FICC–2024–005]

Self-Regulatory Organizations; Fixed Income Clearing Corporation; Order Approving a Proposed Rule Change, as Modified by Partial Amendment No. 1, To Modify the GSD Rules To Facilitate Access to Clearance and Settlement of All Eligible Secondary Market Transactions in U.S. Treasury Securities

November 21, 2024.

On March 11, 2024, Fixed Income Clearing Corporation (''FICC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change SR–FICC–2024–005 pursuant to Section 19(b) of the Securities Exchange Act of 1934 (''Exchange Act'') [1] and Rule 19b–4 [2] thereunder to modify FICC's Government Securities Division (''GSD'') Rulebook (''GSD Rules'') with respect to facilitating access to GSD's clearance and settlement services for all eligible secondary market transactions in U.S. Treasury securities.[3] On March 19, 2024, FICC filed Partial Amendment No. 1 to make clarifications and corrections [4] to the proposed rule change. The proposed rule change, as modified by Partial Amendment No. 1, is referred to herein as the ''Proposed Rule Change.'' The Proposed Rule Change was published for public comment in the **Federal Register** on March 27, 2024.[5]

On May 1, 2024, pursuant to Section 19(b)(2) of the Exchange Act,[6] the Commission designated a longer period within which to approve, disapprove, or institute proceedings to determine whether to approve or disapprove the Proposed Rule Change.[7] On June 27, 2024, the Commission instituted proceedings to determine whether to approve or disapprove the Proposed Rule Change.[8] On September 24, 2024, pursuant to Section 19(b)(2) of the Exchange Act,[9] the Commission extended the period for the conclusion of proceedings to determine whether to approve or disapprove the Proposed Rule Change.[10]

The Commission received several comment letters on the Proposed Rule Change.[11] In addition, the Commission received a letter from FICC responding to the public comments.[12] For the reasons discussed below, the Commission is approving the Proposed Rule Change.

I. Description of the Proposed Rule Change

A. Background and Current Access Models

FICC, through GSD, serves as a central counterparty (''CCP'') and provides real-time trade matching, clearing, risk management and netting for cash purchases and sales of U.S. Treasury securities as well as repurchase and reverse repurchase transactions (''repos'') involving U.S. Treasury securities. Currently, FICC is the sole provider of clearance and settlement services for U.S. Treasury securities.

On December 13, 2023, the Commission adopted amendments to the standards applicable to covered clearing agencies, such as FICC,[13] requiring each such clearing agency for U.S. Treasury securities to have written policies and procedures reasonably designed to, among other things, ensure that it has appropriate means to facilitate access to clearance and settlement services of all eligible secondary market transactions in U.S. Treasury securities, including those of the clearing agency's indirect participants.[14]

1. Direct Participation at FICC

GSD's CCP services are currently available directly to entities that are approved under the GSD Rules [15] to be Netting Members.[16] Currently, there are different categories of Netting Member based upon the type of legal entity (*i.e.,* Bank Netting Member, Dealer Netting Member, Inter-Dealer Broker Netting Member, *etc.*) and whether an entity is incorporated in the United States or not (*i.e.,* a Foreign Netting Member). Netting Member applicants must meet both financial and operational minimum eligibility requirements [17] and, once admitted, Netting Members must adhere to ongoing minimum membership standards.[18] Furthermore, both the minimum eligibility requirements and ongoing standards vary depending on the relevant Netting Membership category. However, in general, all Netting Member categories may access the services available through GSD's Comparison System [19] and Netting System.[20]

2. Indirect Participation at FICC

Market participants may also access GSD's clearing services indirectly through a Netting Member. There are currently two indirect participation models to facilitate indirect participant access to GSD—the Sponsored Service [21] and the correspondent clearing/prime broker services.[22] Each of these indirect participation models gives market participants different options to consider in accessing GSD's

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Notice of Filing, *infra* note 5, at 89 FR 21363.

[4] Partial Amendment No. 1 makes clarifications and corrections to the description of the proposed rule change and Exhibit 5. Specifically, as originally filed, the description of the proposed rule change made a reference to an incorrect section of the GSD Rulebook. Partial Amendment No. 1 corrects that reference. Additionally, as originally filed, the description of the proposed rule change and Exhibit 5 contained inconsistent references regarding whether FICC or its Board would be responsible for approving membership applications and related membership matters. Partial Amendment No. 1 clarifies and corrects those references.

[5] Securities Exchange Act Release No. 99817 (March 21, 2024), 89 FR 21362 (March 27, 2024) (File No. SR–FICC–2024–005) (''Notice of Filing'').

[6] 15 U.S.C. 78s(b)(2).

[7] Securities Exchange Act Release No. 100031 (Apr. 25, 2024), 89 FR 35269 (May 1, 2024) (File No. SR–FICC–2023–005).

[8] Securities Exchange Act Release No. 100399 (June 21, 2024), 89 FR 53681 (June 27, 2024) (SR–FICC–2024–005).

[9] 15 U.S.C. 78s(b)(2)(B)(ii)(II).

[10] Securities Exchange Act Release No. 101081 (Sept. 18, 2024), 89 FR 77949 (Sept. 24, 2024) (SR–FICC–2024–005).

[11] Comments on the Proposed Rule Change are available at *https://www.sec.gov/comments/sr-ficc-2024-005/srficc2024005.htm.*

[12] *See* Letter from Laura Klimpel, Head of Fixed Income Financing Solutions, Depository Trust & Clearing Corporation, (Aug. 1, 2024) (''FICC Letter'').

[13] A ''covered clearing agency'' is, among other things, a registered clearing agency that provides the services of a CCP, and a CCP is a clearing agency that interposes itself between the counterparties to securities transactions, acting functionally as the buyer to every seller and the seller to every buyer. 17 CFR 240.17ad–22(a); *see also* 15 U.S.C. 78c(a)(23) (defining a clearing agency). FICC is a clearing agency registered with the Commission under Section 17A of the Exchange Act (15 U.S.C. 78q–1), and it acts as a CCP.

[14] 17 CFR 240.17ad–22(e)(18)(iv)(C). *See* Securities Exchange Act Release No. 99149 (Dec. 13, 2023), 89 FR 2714 (Jan. 16, 2024) (''Adopting Release,'' and the rules adopted therein referred to herein as ''Treasury Clearing Rules'').

[15] The GSD Rules are *available at https://www.dtcc.com/~/media/Files/Downloads/legal/rules/ficc_gov_rules.pdf.* Terms not otherwise defined herein are defined in the GSD Rules.

[16] *See* GSD Rule 2, *supra* note 15.

[17] *See* GSD Rule 2A, *supra* note 15.

[18] *See* GSD Rule 3, *supra* note 15.

[19] *See* GSD Rule 5, *supra* note 15. The Comparison System includes the system of GSD services and operations in connection with the reporting, validating, and in some cases, matching of the long and short sides of a securities trade. GSD also has a limited membership that permits Comparison-Only Members to participate only in its Comparison System. FICC does not act as a CCP for activity processed through its Comparison System and the services offered through its Comparison System are not guaranteed by FICC.

[20] *See* GSD Rule 11, *supra* note 15. The Netting System includes the system of GSD services and operations in connection with aggregating and matching offsetting obligations resulting from securities trades submitted by or on behalf of Netting Members.

[21] *See* GSD Rule 3A, *supra* note 15.

[22] *See* GSD Rule 8, *supra* note 15.

clearance and settlement services. The primary difference between the two models is that an indirect participant who becomes a Sponsored Member must establish an indirect, limited purpose GSD membership, whereas the correspondent clearing/prime broker services do not require an indirect member to establish any relationship with GSD.

The Sponsored Service permits Netting Members, approved under the GSD Rules as ''Sponsoring Members,'' to sponsor certain institutional firms, referred to as ''Sponsored Members,'' into GSD membership. The Sponsoring Member is permitted to submit to FICC for comparison, novation, and netting certain types of eligible transactions either between itself and its Sponsored Members (*i.e.,* ''done-with''), or between the Sponsored Members and other third-party Netting Members (*i.e.,* ''done-away''). For operational and administrative purposes, a Sponsored Member appoints its Sponsoring Member to act as processing agent with respect to the Sponsored Member's satisfaction of its securities and funds-only settlement obligations.[23]

A Sponsored Member is a GSD Member and the legal counterparty to FICC for any submitted transactions.[24] However, the Sponsoring Member unconditionally guarantees to FICC the Sponsored Member's performance under a Sponsoring Member Guaranty, which guarantees to FICC the payment and performance of a Sponsored Member's obligations to FICC.[25] Therefore, FICC relies on the financial resources of the Sponsoring Member in relying upon the Sponsoring Member Guaranty. If a Sponsoring Member fails to perform under the Sponsoring Member Guaranty, FICC may cease to act for the Sponsoring Member both as a Sponsoring Member as well as a Netting Member.[26]

Netting Members may also submit to FICC eligible activity on behalf of their customers through the correspondent clearing/prime broker services.[27] Under the current GSD Rules, the Netting Member is referred to as the ''Submitting Member'' and the customer is referred to as the ''Executing Firm.'' [28] Unlike the Sponsored Service, FICC has no relationship with the Executing Firm,[29] and all obligations (*i.e.,* margin and settlement) under the GSD Rules remain with the Submitting Member.[30] Additionally, Submitting Members have the option of either netting Executing Firm activity with other activity they submit to FICC (*i.e.,* Submitting Member proprietary activity) or segregating Executing Firm activity in separate accounts.[31] In all cases, however, the Submitting Member must identify the relevant Executing Firm(s) on the FICC transaction submission file.[32] The current GSD Rule does not address the qualifications of a Submitting Member (or how a Netting Member becomes a Submitting Member); does not specify the information that each Submitting Member must provide to FICC regarding the Executing Firms on whose behalf it submits transactions; does not require acknowledgments from Executing Firms; and does not set forth any rules regarding the processing of transactions through the correspondent clearing/prime broker service or how such transactions are treated in the event of a default.

B. Proposed Changes [33]

1. Re-Naming the Correspondent Clearing/Prime Broker Services as the Agent Clearing Service and Providing Additional Specificity on the Agent Clearing Service

FICC proposes to re-name, consolidate, and adopt additional provisions governing GSD's existing correspondent clearing/prime broker services. Moving forward, the correspondent clearing/prime broker services would be referred to as the ''Agent Clearing Service,'' Submitting Members would be referred to as ''Agent Clearing Members,'' and Executing Firms would be referred to as ''Executing Firm Customers.'' The Agent Clearing Service would continue to allow Netting Members to submit, on behalf of their customers, transactions to FICC for novation. These proposed changes would primarily amend GSD Rule 8,[34] which currently describes the correspondent clearing/prime broker services, to describe the Agent Clearing Service with greater specificity.

FICC designed the proposed changes to the Agent Clearing Service to highlight the similarities between the Agent Clearing Service and other agent clearing models, such as those through which market participants in the cleared derivatives markets can execute commodity derivatives with third parties and then give them up to a futures commission merchant (''FCM'') for clearing.[35] FICC states that these proposed changes would enhance the ability of indirect participants to identify the Agent Clearing Service as a workable ''done-away'' model that allows indirect participants to access clearing through multiple direct participants.[36]

While the proposed changes would re-name certain terms in the GSD Rules and otherwise expand upon the description of how the correspondent clearing/prime broker access models operate, most of the proposed changes would not alter how Netting Members and their customers use this model to access GSD's services.[37] Like the correspondent clearing/prime broker models, the Agent Clearing Service would continue to facilitate agent-style trading by allowing an Agent Clearing Member to act as processing agent and credit intermediary for its Executing Firm Customers.

Specifically, the Proposed Rule Change would address various specific topics. First, the Proposed Rule Change would address Agent Clearing Member qualifications and the application process to become an Agent Clearing Member. A Netting Member, other than an Inter-Dealer Broker Netting Member, shall be eligible to become an Agent Clearing Member. An applicant to be an Agent Clearing Member would have to submit an application and provide additional information that FICC may request, and this application would include information about the applicant's customers, past and/or projected volumes of applicant customer activity, and the applicant's

[23] *See* GSD Rule 3A, *supra* note 15. An entity that chooses to become a Sponsoring Member retains its status as a Netting Member and can continue to submit any non-Sponsored Member activity to FICC as such.

[24] *See* GSD Rule 3A, section 7 (describing novation of Sponsored Member Trades) and 2 (identifying membership types), *supra* note 15.

[25] *See* GSD Rule 3A (describing the operation of the Sponsoring Member Guaranty) and 1 (defining the Sponsoring Member Guaranty), *supra* note 15.

[26] *See* Notice of Filing, *supra* note 5, at 89 FR 21365; *see also* GSD Rule 3A, Section 14; and GSD Rule 21, Sections 1(a), 1(b), 4(a) *supra* note 15.

[27] *See* GSD Rule 8, *supra* note 15.

[28] *See id.* There are no operational differences between the current correspondent clearing service and the prime broker service. The primary difference between the two services is that FICC provides a report to prime brokers that identifies margin calculation for their customers' transactions and does not provide such report to Members using the correspondent clearing service.

[29] *See* GSD Rule 1 (defining the term Executing Firm), *supra* note 15.

[30] *See* GSD Rule 8, Section 4, and GSD Rule 15, Section 1, *supra* note 15.

[31] *See id.*

[32] *See* GSD Rule 8, Section 2, *supra* note 15.

[33] For a detailed description of each proposed change, please refer generally to the Notice of Filing, *supra* note 5.

[34] *See* GSD Rule 8, *supra* note 15.

[35] *See* Notice of Filing, *supra* note 5, at 89 FR 21365–66.

[36] *See id.* FICC also states that these proposed changes would improve the transparency of the GSD Rules regarding the availability and operations of this service to both Netting Members and, indirectly, their customers. *See id.*

[37] *See* Notice of Filing, *supra* note 5, at 89 FR 21366.

controls for monitoring and mitigating risks, including any risks posed by its customers.

Second, the Proposed Rule Change would require certain information regarding an Agent Clearing Member's Executing Firm Customer Relationships to be provided to FICC. The required information would include a Legal Entity Identifier (''LEI'') for each Executing Firm Customer,[38] and each Agent Clearing Member would be required to indemnify FICC for any losses, liabilities, expenses and legal actions that could arise related to the LEI requirement. Thus, an Agent Clearing Member would establish a relationship with one or more Executing Firm Customers and provide FICC with notice confirming the Executing Firm relationship with each such customer. FICC states that this information sharing would better enable FICC to identify and manage the risks posed by such indirect participants and would support FICC's compliance with the requirements of Rule 17ad–22(e)(18)(iii) under the Exchange Act to monitor compliance with its participation requirements on an ongoing basis.[39]

In addition, the Proposed Rule Change would require that an agreement between the Agent Clearing Member and the Executing Firm Customer bind the customer to the applicable provisions of the GSD Rules. However, beyond this specific requirement the Proposed Rule Change would also acknowledge such an agreement may otherwise be on any terms and conditions mutually agreed to by the parties and confirm that the GSD Rules do not prohibit any reimbursement or other payments sharing arrangements that may be established between those parties, away from FICC.

Third, the Proposed Rule Change would define what transactions are eligible to be submitted through the Agent Clearing Service, which would remain the same as the transactions eligible for the correspondent/prime broker services and would continue to exclude Netting Eligible Auction Purchases, Brokered Transactions, GCF Repo Transactions, and CCIT Transactions.[40]

Fourth, the Proposed Rule Change would identify the rights and obligations of Agent Clearing Members. For example, it would define the role of the Agent Clearing Members as processing agents of Executing Firm Customers and establish that Agent Clearing Members are liable to FICC for all obligations arising in connection with their Agent Clearing Transactions in the same manner as if the Agent Clearing Member had executed those trades. It would also state that FICC has no liability or obligation to any Executing Firm Customer. It would also provide that FICC may request information or reports regarding Agent Clearing Transactions, which would allow FICC to continue to identify, monitor and manage the risks its Agent Clearing Members may present to it and the broader GSD membership.[41]

Fifth, the Proposed Rule Change would include specific Executing Firm Customer acknowledgements with respect to their participation in the Agent Clearing Service.[42] Because Executing Firm Customers would continue to have no relationship to FICC, the Proposed Rule Change would provide that Agent Clearing Members are responsible for affirming that their Executing Firm Customers understand, acknowledge and agree to the provisions in the relevant section of the GSD Rules.

Finally, the Proposed Rule Change would set forth rules regarding the processing of Agent Clearing Transactions. FICC would require Agent Clearing Members to process and record their customers' activity in separate ''Agent Clearing Member Omnibus Accounts,'' as opposed to the optional segregated submission approach provided for in the current GSD Rules, to facilitate FICC's ability to monitor and, ultimately, risk manage that activity appropriately.[43] It would also require that all Agent Clearing Transactions include an executing firm symbol that identifies the Executing Firm Customer. It would describe that Agent Clearing Transactions would continue to be processed in the same way that FICC processes other transactions through the GSD netting, clearing and settlement systems and would describe how Agent Clearing Transactions are processed when the optional field identifying the contra-party is either omitted or does not match on the transaction file. It would also address how a loss would be allocated within the Agent Clearing Service, that is, that the Agent Clearing Member, as principal, would be responsible for satisfying the loss allocation obligations that are calculated for its Executing Firm Customers.[44]

2. Changes to the Sponsored Service

Eliminate Separate Categories of Sponsoring Members

Under the current GSD Rules, there are two categories of Sponsoring Members—Category 1 Sponsoring Members are Bank Netting Members that meet the eligibility criteria described in Section 2(a) of Rule 3A, and Category 2 Sponsoring Members are all other eligible Netting Members.[45] While Bank Netting Members are currently subject to certain capitalization requirements as

[38] In addition to the LEI, this information would include: the name and executing firm symbol of the Executing Firm Customer; written authorization from the Executing Firm Customer to act on its behalf; confirmation that the Executing Firm Customer and the Agent Clearing Member have entered into an agreement that binds the Executing Firm Customer to the applicable provisions of the GSD Rules, as would be required by Section 3, described below; and confirmation that the Executing Firm Customer understands, acknowledges and agrees to each of the Executing Firm Customer Acknowledgments set forth in, and as would be required by the GSD Rules.

[39] *See* Notice of Filing, *supra* note 5, at 89 FR 21365; 17 CFR 240.17ad–22(e)(18)(iii).

[40] FICC states that GCF Repo Transactions and CCIT Transactions are currently excluded due to system limitations, and Brokered Transactions are necessarily excluded because Inter-Dealer Broker Netting Members are not permitted to act as Agent Clearing Members, as discussed above. The exclusion of Netting Eligible Auction Purchases is driven by the specific processing rules applicable to auctions that are external to FICC and established by the U.S. Department of the Treasury. *See* Notice of Filing, *supra* note 5, at 89 FR 21368.

[41] *See* Notice of Filing, *supra* note 5, at 89 FR 21368.

[42] These acknowledgments would include that the Agent Clearing Service is governed by the GSD Rules, including Novation of Agent Clearing Transactions; that FICC is not obligated to deal directly with the Executing Firm Customer and may deal exclusively with the Agent Clearing Member; that FICC shall have no obligations to the Executing Firm Customer with respect to any Agent Clearing Transactions submitted by an Agent Clearing Member on behalf of the Executing Firm Customer, including with respect to any payment or delivery obligations; and that the Executing Firm Customer shall have no right to receive from FICC, or any right to assert a claim against FICC with respect to, nor shall FICC be liable to the Executing Firm Customer for, any payment or delivery obligation in connection with any Agent Clearing Transactions submitted by an Agent Clearing Member on behalf of the Executing Firm Customer, and FICC shall make any such payments or redeliveries solely to the Agent Clearing Member.

[43] *See* Notice of Filing, *supra* note 5, 89 FR at 21368.

[44] The Proposed Rule Change would also provide that the Clearing Fund obligations applicable to an Agent Clearing Members' Agent Clearing Transactions would be calculated separately from the obligations calculated with respect to other activity of the Agent Clearing Member. However, FICC would have the right to apply any Clearing Fund deposits of an Agent Clearing Member to any obligations of that Member (including in their capacity as a Netting Member). As a substantive matter, the above two changes do not vary from how FICC calculates and applies loss allocation or Clearing Fund requirements under the correspondent clearing and prime broker services today. *See* Notice of Filing, *supra* note 5, 89 FR at 21369.

[45] *See* Securities Exchange Act Release No. 85470 (Mar. 29, 2019) 84 FR 13328 (Apr. 4, 2019) (SR–FICC–2018–013) (creating two categories of Netting Members to be eligible to be Sponsoring Members, expanding the eligibility of the service to other types of Netting Members in addition to Bank Netting Members). *See also* GSD Rule 3A, Section 2, *supra* note 15.

Sponsoring Member applicants,[46] Category 2 Sponsoring Member applicants are subject to financial requirements that are greater than the financial requirements applicable in their capacity as Netting Members.[47] Thus, the current tiered category structure creates differing applicant criteria based on the type of entity seeking Sponsoring Member status.

Additionally, the ongoing Sponsoring Member requirements in the GSD Rules also apply a differentiated approach for Category 1 and Category 2 Sponsoring Members. For example, a Category 1 Sponsoring Member may be subject to an increase in its Required Fund Deposit if it fails to meet the applicable capitalization requirements.[48] Alternatively, a Category 2 Sponsoring Member may be subject to a limit on the activity it can submit through the Sponsoring Service if the Sponsoring Member's VaR Charges exceed its Netting Member Capital.[49]

FICC proposes to eliminate the two categories of Sponsoring Members and make all Sponsoring Members subject to the same eligibility and ongoing requirements that are currently applicable to Category 2 Sponsoring Members. FICC states that these proposed changes would encourage additional Netting Members to become Sponsoring Members thus facilitating broader access to clearance and settlement services for eligible secondary market transactions in U.S. Treasury securities, including those of indirect participants who may seek to use the Sponsored Service as Sponsored Members.[50] The proposed changes would affect Bank Netting Members that are—or will apply to be—Sponsoring Members by removing the above-mentioned capitalization requirements and instead applying the activity limits and financial condition factors used under the current GSD Rules for Category 2 Sponsoring Members. The proposed changes would create parity among all Sponsoring Members (and applicants), which FICC states would encourage additional market participants to become Sponsoring Members, which in turn should give indirect participants a wider range of Sponsoring Members to consider should they choose to access GSD's central clearing services via the Sponsored Service.[51] FICC states that the activity limits and financial condition monitoring will allow FICC to continue to manage the risks that could be presented by any activity cleared through the Sponsored Service.[52] FICC does not believe the proposed changes would increase the risks presented to it by Bank Netting Members' participation in the Sponsored Service as Sponsoring Members because other existing risk management tools (*e.g.,* FICC's ability to impose greater and additional financial requirements,[53] the Excess Capital Premium,[54] and activity limits [55]) would be available for FICC to continue to manage those risks.[56]

Remove the ''Qualified Institutional Buyer'' Requirements for Sponsored Members

FICC proposes to remove the requirement that Sponsored Members either be ''qualified institutional buyers,'' as such term is defined by Rule 144A under the Securities Act of 1933,[57] or satisfy the financial requirements of such definition (''QIB Requirement''). This proposed change would make the Sponsored Service available to additional market participants, thereby providing such firms with access to GSD's clearing services. FICC states that expanding eligibility to become a Sponsored Member supports the goals of the Treasury Clearing Rules to facilitate increased central clearing of transactions involving U.S. Treasury securities.[58]

FICC states that this change would not increase the relevant risks because FICC risk manages the Sponsored Service primarily at the Sponsoring Member level, not the Sponsored Member level.[59] For example, a Sponsoring Member is responsible for posting to FICC the Required Fund Deposit for its sponsored activity and, while Sponsored Members are principally liable to FICC for their settlement obligations, the Sponsoring Member is also required to provide a guaranty to FICC for such obligations.[60] In the event a Sponsored Member does not satisfy its settlement obligations, FICC is able to invoke the Sponsoring Member Guaranty.[61] Additionally, Sponsoring Members may be required to provide FICC with reports or other information that FICC may require, including, for example, responses to annual or ad hoc due diligence requests.[62] FICC utilizes such due diligence requests to identify, monitor and manage the risks Sponsoring Members and their Sponsored Members may present to it. As discussed above, where FICC identifies risks (whether via the due diligence process or otherwise), FICC can impose supplemental financial requirements on a Sponsoring Member, an Excess Capital Premium charge (where applicable), and activity limits.[63] Therefore, FICC states that that its existing risk management practices with respect to the Sponsored Service, which do not rely on the QIB Requirement, are sufficiently effective.[64]

3. Clarify Eligibility Criteria for Non-U.S. and Other Applicants

Changes Regarding Non-U.S. Applicants

Currently, a Foreign Person applying to be a Netting Member must meet the eligibility criteria for the distinct

[46] Under Section 2(a) of GSD Rule 3A, Bank Netting Members applying to be a Sponsoring Member must (i) have equity capital of at least $5 billion, (ii) be ''Well-Capitalized,'' as such term is defined in the GSD Rules, and (iii) have a bank holding company that is registered under the Bank Holding Company Act of 1954, as amended and that such bank holding company also be ''Well Capitalized.'' ''Well Capitalized'' is defined in GSD Rule 1 to have the meaning given that term in the capital adequacy rules and regulations of the Federal Deposit Insurance Corporation. *Supra* note 15.

[47] These increased financial requirements do not solely relate to an applicant's capitalization, but instead are based on the applicant's anticipated use of the Sponsoring Service in relation to their financial condition. *See* Section 2(b)(ii) of GSD Rule 3A, *supra* note 15.

[48] *See* Section 2(h) of GSD Rule 3A, *supra* note 15.

[49] The ''VaR Charge'' is a component of the Required Fund Deposit and defined in GSD Rule 1; ''Netting Member Capital'' is defined in GSD Rule 1 to mean ''Net Capital, net assets or equity capital as applicable, to a Netting Member based on its type of regulation.'' *Supra* note 15.

[50] *See* Notice of Filing, *supra* note 5, at 89 FR 21370.

[51] *See id.*

[52] *See id.*

[53] *See* GSD Rule 3A, Section 2(b)(ii) (describing the factors that FICC may consider when determining whether to impose additional financial requirements on a Sponsoring Member), *supra* note 5. For the purposes of illustration only, such financial requirements could include, without limitation, additional reporting requirements, including reporting of parent company financials, or a higher minimum deposit to the Clearing Fund.

[54] *See* GSD Rule 3, Section 14 (the Excess Capital Premium is an additional Clearing Fund deposit that may be required if a Netting Member's capital levels drop below a threshold relative to its other margin requirements), *supra* note 5.

[55] The activity limit, which currently only applies to Category 2 Sponsoring Members, restricts a Sponsoring Member from submitting additional activity into its Sponsoring Member Omnibus Account(s) if its capital levels exceed the sum of its VaR Charge component of the Clearing Fund. *See* GSD Rule 3A, Section 2(h), *supra* note 5.

[56] *See* Notice of Filing, *supra* note 5, at 89 FR 21370.

[57] 17 CFR 230.144A.

[58] *See* Notice of Filing, *supra* note 5, at 89 FR 21371; Adopting Release *supra* note 14, at 2716–17 (referring to the revisions to Rule 17ad–22(e)(18) as being designed to ''bring the benefits of central clearing to more transactions involving U.S. Treasury securities, thereby reducing the overall systemic risk in the market'').

[59] *See* Notice of Filing, *supra* note 5, at 89 FR 21371.

[60] *See* GSD Rule 3A, *supra* note 15.

[61] *See id.*

[62] *See id.*

[63] *See supra* notes 53, 54, and 55.

[64] *See* Notice of Filing, *supra* note 5, 89 FR 21371.

Netting Member category of ''Foreign Netting Members.'' [65] In contrast with the eligibility criteria for other Netting Member categories, the eligibility criteria for Foreign Netting Members in Section 3(a)(v) of GSD Rule 2A do not specify or reference eligible types of legal entities.[66] Instead, Section 4(b)(ii)(E) of GSD Rule 2A provides FICC the authority to set minimum financial requirements for Foreign Netting Member applicants.[67] Additionally, Section 3(b) of GSD Rule 2A currently states that an entity can only be one category of Netting Member at a time.[68] Thus, a Foreign Person that is the foreign equivalent of, for example a Registered Investment Company, which is a legal entity recognized in the GSD Rules for U.S. entities, would apply to be a Foreign Netting Member, and would be subject to the eligibility criteria, other membership qualifications, and ongoing minimum membership standards applicable to Foreign Netting Members.[69] However, the GSD Rules also contain specific eligibility criteria, other membership qualifications, and ongoing minimum membership standards applicable to, in this example, Registered Investment Company Netting Members.[70] Therefore, in this example, the current GSD Rules are unclear as to whether the applicant entity would only be subject to the Foreign Netting Member standards or would also be subject to the Registered Investment Company Netting Member standards.[71]

To avoid this ambiguity, FICC proposes to eliminate the category of ''Foreign Netting Member'' and expand the qualifications for each category of Netting Member to include the foreign equivalent of the same legal entity types.[72] Foreign Persons that are eligible to apply to be a Netting Member would be subject to both the minimum membership standards of the applicable Netting Member category as well as the eligibility criteria currently applicable to Foreign Netting Members, currently set forth in Section 3(a)(v) of GSD Rule 2A.[73] In making the determination of whether a Foreign Person is an equivalent legal entity to the domestic legal entities that qualify for a category of Netting Member, FICC would consider, for example, the applicant's business model and its regulatory framework and designated examining authority. Therefore, the Proposed Rule Change would provide that a Foreign Person shall be eligible to become a Netting Member if either (1) it qualifies for one of the existing categories of Netting Member, or (2) FICC determines that the applicant may apply in the same way as an applicant that does not qualify under an existing category of Netting Member, as discussed with respect to ''Changes Regarding Other Applicants'' below.

Foreign Persons that are eligible to apply to be a Netting Member would be subject to both the minimum membership standards of the applicable Netting Member category and the eligibility criteria currently applicable to Foreign Netting Members, currently set forth in Section 3(a)(v) of Rule 2A. Where an applicable Netting Member category is subject to membership qualifications that are inconsistent with the qualifications applicable to a Foreign Person, then the standards applicable to a Foreign Person would apply. Although this could lead to an approach where a Foreign Person applicant remains subject to home jurisdiction requirements that are different than the requirements applicable to other Netting Members, FICC states that that this is acceptable because, as discussed further below, the GSD Rules would still provide that FICC will continue to apply the membership standards that were designed specifically to address the risks that may not be present when an applicant is not domiciled in the U.S. and whose primary regulator is not U.S.-based.[74]

Changes Regarding Other Applicants

Additionally, FICC proposes to clarify the eligibility criteria for applicants that do not fit into one of the existing Netting Member categories. In light of the adoption of the Treasury Clearing Rules, additional market participants will need to access FICC's clearance and settlement services, either as direct Netting Members or as indirect participants. However, under the current GSD Rules, FICC does not have the authority to consider a Netting Member applicant that does not meet the eligibility criteria of one of the Netting Member categories enumerated in the GSD Rules. Therefore, FICC proposes amendments to the GSD Rules that would provide a framework for FICC to consider an applicant, including a Foreign Person, to be a Netting Member if that applicant does not meet the eligibility criteria of one of the existing Netting Member categories.

Specifically, the Proposed Rule Change would first require that an applicant submit an application questionnaire and other initial application materials that demonstrate to FICC that the applicant's business and capabilities are such that it could reasonably expect material benefit from direct access to FICC's services. FICC proposes to establish minimum membership standards, including financial and other qualifications for membership, as it may determine are reasonable and appropriate based on information provided by or concerning such an applicant. FICC's determination of the minimum membership standards to apply to that applicant would be based on the risk profile of the applicant, as determined by FICC, and information related to (i) the applicant's business model, (ii) its regulatory framework and designated examining authority, (iii) its organizational structure and risk management framework, and (iv) its anticipated use of the Corporation's services.

FICC states that it cannot reliably predict which types of legal entities will apply for direct membership or predict the risk profiles of those entities.[75] The proposed changes would provide FICC with the necessary flexibility to consider any potential applicants, including legal entities that do not fit into its current Netting Member

[65] *See* GSD Rule 2A, *supra* note 15.

[66] *See id.*

[67] *See id.*

[68] *See id.*

[69] *See* Notice of Filing, *supra* note 5, 89 FR at 21372.

[70] *See* Notice of Filing, *supra* note 5, 89 FR at 21372.

[71] *See id.* FICC states that such ambiguity can have meaningful implications; for example, a Registered Investment Company Netting Member is excluded from certain requirements under the GSD Rules, and, therefore, if a Registered Investment Company that is a Foreign Person applied, and was approved, to be a Foreign Netting Member, it would not be clear if the applicable exclusions should apply to this Foreign Netting Member Applicant. *See id.*

[72] In making the determination of whether a Foreign Person is an equivalent legal entity to one of the domestic legal entities that qualify for a category of Netting Member, FICC would consider, for example, the applicant's business model and its regulatory framework and designated examining authority. *See* Notice of Filing, *supra* note 5, at 89 FR 21372.

[73] *See* GSD Rule 2A, Section 3(a)(v) (providing that a person may be eligible to apply to be a Foreign Netting Member if it ''(i) has a home country regulator that has entered into a memorandum of understanding with the SEC regarding the sharing or exchange of information, and (ii) maintains a presence in the United States, either directly or through a suitable agent, that both has available individuals fluent in English who are knowledgeable in the Foreign Person's business and can assist the Corporation's representatives as necessary, and ensures that the Foreign Person will be able to meet its data submission, settlement, and other obligations to the Corporation as a Member in a timely manner.'') and Section 4(b)(ii)(E) (specifying the minimum financial requirements for an applicant to be a Foreign Netting Member), *supra* note 15.

[74] *See* Notice of Filing, *supra* note 5, 89 FR at 21372.

[75] *See* Notice of Filing, *supra* note 5, at 89 FR 21373.

categories.[76] FICC states that these proposed changes would facilitate access to GSD's clearing services to a broader range of market participants.[77]

4. Other Proposed Changes

FICC proposes changes to the GSD Rules generally designed to describe the criteria and related requirements regarding direct and indirect access to GSD's clearance and settlement services. FICC states that these proposed changes should enhance the ability of market participants, and in particular indirect participants, to understand and evaluate the comparative tradeoffs of using GSD's central clearing services depending on the relevant access model.[78]

Specifically, FICC proposes to include a ''road map'' in the GSD Rules describing the various GSD access models that allow for both direct and indirect access to GSD's clearance and settlement services. In addition, to simplify the description of eligibility requirements in GSD Rule 2A, FICC proposes to move the definitions of the Netting Member Categories from GSD Rule 2A to the defined terms in GSD Rule 1. FICC further proposes to remove definitions which are only used once in the GSD Rules and replace those uses with the defined terms, meaning that it would remove stand-alone definitions that are used only once and instead fold the one-time definition into broader context within the GSD Rules.[79] FICC proposes to clarify eligibility criteria for FCM Netting Members to require membership in the National Futures Association. Additionally, FICC proposes to make several grammatical and other non-substantive changes to the GSD Rules to streamline, clarify, and simplify the GSD access models, related definitions, and other relevant provisions.[80]

II. Discussion and Commission Findings

Section 19(b)(2)(C) of the Exchange Act[81] directs the Commission to approve a proposed rule change of a self-regulatory organization if it finds that such proposed rule change is consistent with the requirements of the Exchange Act and rules and regulations thereunder applicable to such organization. After carefully considering the Proposed Rule Change,[82] the Commission finds that the Proposed Rule Change is consistent with the requirements of the Exchange Act and the rules and regulations thereunder applicable to FICC. In particular, the Commission finds that the Proposed Rule Change is consistent with Sections 17A(b)(3)(F)[83] and (b)(3)(I)[84] of the Exchange Act and Rules 17ad–22(e)(18)(iii), (e)(18)(iv)(C), (e)(19), and (e)(23)(ii) thereunder.[85]

A. Consistency With Section 17A(b)(3)(F) of the Exchange Act

Section 17A(b)(3)(F) of the Exchange Act[86] requires that the rules of a clearing agency, such as FICC, be designed to, among other things, promote the prompt and accurate clearance and settlement of securities transactions, and protect investors and the public interest.

As described above in Section I.B., FICC proposes changes to the GSD Rules that are designed to encourage and facilitate a greater number of market participants to utilize GSD's clearance and settlement services for transactions in U.S. Treasury securities, including for done-with and done-away transactions. Specifically, as described in Section I.B.1, FICC's consolidation of the correspondent clearing/prime broker services into the Agent Clearing Service and the substantially increased level of detail about how this service operates should allow for a better understanding of the availability of this model at FICC.[87] By updating and expanding the Agent Clearing Service to more closely resemble the nomenclature and functioning of an FCM-style model, the Proposed Rule Change should better present the Agent Clearing Service as a viable method for market participants to consider for clearing transactions in U.S. Treasury securities. The new terminology should help to show that the Agent Clearing Service operates similarly to agent clearing models in cleared derivatives markets, where market participants execute transactions with third parties and then give them up to their futures commission merchant for clearing.

Further, the increased specificity regarding the functioning of the Agent Clearing Service should help market participants better evaluate its fitness for their individual needs. The current GSD Rules do not describe a Submitting Member as an agent for an Executing Firm or as submitting given up transactions to FICC for clearing, and the current GSD Rules present only limited information about how the service functions. By contrast, the expanded rules regarding the Agent Clearing Service makes clear how the Agent Clearing Service would function. It addresses various topics, including the qualifications of Agent Clearing Members and the application process, what an Executing Firm Customer is and what information an Agent Clearing Member must provide to FICC regarding its Executing Firm Customers (including confirmation that there is an agreement binding the Executing Firm Customer to the applicable GSD Rules and that the Executing Firm Customer agrees to the specified Executing Firm Customer Acknowledgments, what transactions may be submitted through the service, the rights and obligations of the Agent Clearing Member, and how transactions are addressed in the event of a default or non-default loss event. These changes substantially expand the description of how this service functions beyond the limited and high-level information currently in the GSD Rules. The Commission understands that, based on a survey conducted by FICC, a significant number (28 percent) of Netting Member survey respondents have already indicated that they expect to facilitate clearing transactions in U.S. Treasury securities using their existing prime brokerage, agency clearing, or

[76] *See id.*

[77] *See id.*

[78] *See id.*

[79] For example, the GSD Rules currently contain a definition for Inter-Dealer Broker which is used only, in turn, to define an Inter-Dealer Broker Netting Member. The revisions would collapse the definition of an Inter-Dealer Broker into the description of an Inter-Dealer Broker Netting Member.

[80] *See* Notice of Filing, *supra* note 5, 89 FR at 21374–75.

[81] 15 U.S.C. 78s(b)(2)(C).

[82] 17 CFR 240.17ad–22(e)(18)(iii), (e)(18)(iv)(C), (e)(19), and (e)(23)(ii).

[83] 15 U.S.C. 78q–1(b)(3)(F).

[84] 15 U.S.C. 78q–1(b)(3)(I).

[85] As part of the Commission's process of analyzing the Proposed Rule Change for consistency with the Exchange Act and rules and regulations thereunder, the Commission carefully considered the public comment letters. Many of the comment letters were submitted in response to both the Proposed Rule Change and a related set of proposed rule changes (*see* Securities Exchange Act Release No. 99845 (Mar. 22, 2024), 89 FR 21603 (Mar. 28, 2024) (File No. SR–FICC–2024–802) and Securities Exchange Act Release No. 99844 (March 22, 2024), 89 FR 21586 (Mar. 28, 2024) (File No. SR–FICC–2024–007)). On October 25, 2024, FICC filed Partial Amendment No. 1 to the related set of proposed rule changes (*see* Securities Exchange Act Release No. 101455 (Oct. 28, 2024), 89 FR 87449 (Nov. 1, 2024) (File No. SR–FICC–2024–802) and Securities Exchange Act Release No. 101454 (Oct. 28, 2024), 89 FR 87441 (Nov. 1, 2024) (File No. SR–FICC–2024–007) (together, the ''Account Segregation Proposals'')). The comment letters generally did not specify which individual comments relate to the Proposed Rule Change as opposed to the Account Segregation Proposals. In the instant Order, the Commission addresses the comments related to the Proposed Rule Change. In a separate Order, the Commission addresses the comments related to the Account Segregation Proposals.

[86] 15 U.S.C. 78q–1(b)(3)(F).

[87] *See* DTCC White Paper, Looking to the Horizon: Assessing a Potential Expansion of U.S. Treasury Central Clearing (Sept. 2023) (''2023 DTCC White Paper'') at 9, *available at https://www.dtcc.com/-/media/Files/Downloads/WhitePapers/Accessing-Potential-Expansion-US-Treasury-Clearing-White-Paper.pdf.*

FCM business units currently used for clearing listed and over-the-counter derivatives.[88]

The changes regarding the Agent Clearing Service should help facilitate market participants' ability to access central clearing by providing more detail about how the service functions and, potentially, allowing market participants to leverage existing policies and practices used for other agent clearing models to clear other types of products. In addition, the changes would provide FICC with increased ability to risk manage and monitor the Agent Clearing Transactions because it would require additional information on Executing Firm Customers and the use of an Agent Clearing Omnibus Account. These changes should therefore help promote prompt and accurate clearance and settlement and protect investors and the public interest.

Additionally, FICC's proposals to streamline and clarify certain aspects of its membership standards would remove entry barriers and make it easier for market participants to utilize the Sponsored Service. First, as described above in Section I.B.2., the Proposed Rule Change would enable additional market participants to become Sponsoring Members by removing capital requirements and eliminating other distinctions between the two existing categories of Sponsoring Members. Second, the Proposed Rule Change would enable additional market participants to become Sponsored Members by removing the QIB Requirement. These changes should allow FICC to streamline the Sponsored Service and improve its accessibility to potential Sponsoring and Sponsored Members, while still allowing FICC to appropriately risk manage transactions cleared through the Sponsored Service. Therefore, this aspect of the Proposed Rule Change should facilitate greater participation in the Sponsored Service and, therefore, in central clearing more generally, subject to appropriate risk management at FICC, which is consistent with both promoting prompt and accurate clearance and settlement and the protection of investors and the public interest.

The Proposed Rule Change, as described in Section I.B.3, would also facilitate broader market participation in GSD by streamlining and clarifying the Netting Member eligibility criteria applicable to Foreign Persons and applicants that do not otherwise fit into one of the existing categories of Netting Member and would establish an application process for such entities that allows FICC to consider any applicant and the potential risk that it could bring to FICC. FICC's membership requirements are part of its overall risk management because membership requirements help to guard against defaults of any FICC member, as well as to protect FICC and the financial system as a whole from the risk that one member's default could cause others to default, potentially including FICC itself.

Additionally, FICC's proposals to add new provisions to the GSD Rules that more clearly describe the various direct and indirect GSD access models, and otherwise clarify the GSD Rule provisions regarding the GSD access models, would provide greater transparency on those subjects to market participants, and thereby enable market participants to more accurately and efficiently evaluate which model best fits their business needs.

Finally, as described above in Section I.B.4., FICC proposes to make several grammatical and other non-substantive changes to the GSD Rules to streamline, clarify, and simplify the GSD access models, related definitions, and other relevant provisions.

The Proposed Rule Change would encourage and facilitate greater participation in central clearing, while still providing sound risk management which would promote the prompt and accurate clearance and settlement of securities transactions, and would protect investors and the public interest. As the Commission explained when adopting the Treasury Clearing Rules, U.S. Treasury securities play a critical and unique role in the U.S. and global economy, serving as a significant investment instrument and hedging vehicle for investors, a risk-free benchmark for other financial instruments, and an important mechanism for the Federal Reserve's implementation of monetary policy.[89] Consequently, confidence in the U.S. Treasury market, and in its ability to function efficiently is critical to the stability of the global financial system. In central clearing, through novating transactions (*i.e.,* becoming the counterparty to both sides of a transaction), a CCP addresses concerns about counterparty risk by substituting its own creditworthiness and liquidity for the creditworthiness and liquidity of the counterparties.[90] A CCP thereby enables market participants to effectively reduce costs, increase operational efficiency, and manage risks.[91] Moreover, a CCP provides a centralized system of default management that can mitigate the potential for a single market participant's failure to destabilize other market participants or the financial system more broadly.[92] The Commission adopted the Treasury Clearing Rules, in part, to help reduce contagion risk to the CCP and bring the benefits of central clearing to more transactions involving U.S. Treasury securities, thereby lowering overall systemic risk in the market.[93]

CCP rules that are clear and comprehensible, increase operational efficiency, and more effectively manage risks, like the Proposed Rule Change, should encourage a broader scope of market participants to utilize the CCP's services, thereby promoting the prompt and accurate clearance and settlement of securities transactions, and protecting investors and the public interest, consistent with Section 17A(b)(3)(F) of the Exchange Act. The Proposed Rule Change is consistent with those objectives because it encourages and supports greater participation in GSD's central clearing services for different types of market participants and transactions. Accordingly, the Proposed Rule Change would promote the prompt and accurate clearance and settlement of securities transactions, and protect investors and the public interest, because by encouraging greater participation in central clearing, the proposals would extend the benefits of operational efficiency and risk management to a greater segment of the U.S. Treasury securities market.

For these reasons, the Proposed Rule Change is consistent with the

[88] *See* FICC Letter at 5–6, 11 (citing DTCC White Paper, The U.S. Treasury Clearing Mandate: An Industry Pulse Check (July 2024) (''2024 DTCC White Paper'') at 6, *available at https://www.dtcc.com/-/media/WhitePapers/Treasury-Clearing-Mandate.pdf*).

[89] *See* Adopting Release, *supra* note 14, 89 FR at 2715–17.

[90] *See* Adopting Release, supra note 14, 89 FR at 2716.

[91] *See id.* (citing Covered Clearing Agency Standards Proposing Release, Exchange Act Release No. 71699 (Mar. 12, 2014), 79 FR 29507, 29587 (May 27, 2014) (''CCA Standards Proposing Release'')).

[92] *See* Adopting Release, *supra* note 14, 89 FR at 2716 (citing Order Granting Temporary Exemptions Under the Securities Exchange Act of 1934 in Connection with Request of Liffe Administration and Management and Lch.Clearnet Ltd. Related to Central Clearing of Credit Default Swaps, and Request for Comments, Exchange Act Release No. 59164 (Dec. 24, 2008), 74 FR 139, 140 (Jan. 2, 2009) (''Liffe Order'')).

[93] *See* Adopting Release, *supra* note 14, 89 FR at 2716 (citing Proposing Release, Standards for Covered Clearing Agencies for U.S. Treasury Securities and Application of the Broker-Dealer Customer Protection Rule With Respect to U.S. Treasury Securities, Exchange Act Release No. 95763 (Sept. 14, 2022), 87 FR 64610, 64614 (Oct. 25, 2022) (''Proposing Release'')).

requirements of Section 17A(b)(3)(F) of the Exchange Act.[94]

B. Consistency With Section 17A(b)(3)(I) of the Exchange Act

Section 17A(b)(3)(I) of the Exchange Act requires that the rules of a clearing agency, such as FICC, do not impose any burden on competition not necessary or appropriate in furtherance of the Exchange Act.[95] Section 17A(b)(3)(I) does not require the Commission to make a finding that FICC chose the option that imposes the least possible burden on competition. Rather, the Exchange Act requires that the Commission find that the Proposed Rule Change does not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Exchange Act, which involves balancing the competitive effects of the Proposed Rule Change against all other relevant considerations under the Exchange Act.[96]

Several commenters suggest that the Proposed Rule Change's failure to include a requirement that FICC's direct participants offer done-away clearing services would not sufficiently provide for a workable done-away model.[97] For example, one commenter states that it does not expect Netting Members to offer done-away trading via the Agent Clearing Model (which would effectively result in clearing members surrendering potentially lucrative commissions from trade execution to other brokers).[98] This commenter further states that the Proposed Rule Change does not address this or otherwise provide any other mechanism to properly align Netting Members' incentives with the goal of facilitating done-away trading.[99] Another commenter states that the Proposed Rule Change ''ignores the current reality'' in which the commenter is not aware of any clearing member currently offering done-away clearing to its customers for either cash or repo transactions and the Proposed Rule Change fails to explain why done-with and done-away transactions continue to be treated differently given that a clearing member should be agnostic about with whom a trade is executed, as the counterparty of a cleared trade is FICC (*i.e.,* not the executing counterparty).[100] This commenter states that FICC has not explained the justification for treating done-with and done-away transactions differently and why it has elected to continue to permit its clearing members to require *all* customers to bundle execution and clearing in these models.[101] Another commenter states that there remain serious questions whether Netting Members view offering done-away services as practicable from a regulatory net capital perspective and whether a sufficient number of Netting Members will provide clearing services on a standalone basis, as opposed to bundling execution and clearing.[102]

As a solution to the foregoing concerns, the commenters state that FICC should require Netting Member intermediaries (*i.e.,* Sponsoring Members and Agent Clearing Members) to offer done-away clearing to their customers.[103]

In contrast to these commenters, one commenter states that a mandate from FICC is not a necessary condition for a viable done-away access model.[104] Instead, the commenter states that a Netting Member's decision to provide done-away services—or any services—to market participants is, and should remain, a commercial and risk decision of each member, and that such commercial arrangements should not be mandated by rule or otherwise.[105] The commenter further states that mandating the provision of done-away services could compromise the goals of the Treasury Clearing Rules by making the access models less attractive from a business perspective to Netting Members and cause Netting Members to limit the offerings they do make to customers if doing so would mandate other commercial arrangements or transactions that they may not wish to engage in.[106]

In response, FICC states that requiring Netting Member intermediaries to offer done-away clearing services to customers could expose FICC and its participants to additional risks and other challenges that could limit the commercial and risk management choices an intermediary could consider in offering clearing services, which in turn could reduce the number of market participants willing to provide such services.[107] FICC further states that such a contraction in the availability of direct participants providing clearing services would result in concentration of risk, increased costs, and reduced liquidity in the Treasury market.[108] Additionally, FICC states that unlike done-with clearing, done-away clearing presents unique liquidity risks to both FICC and Netting Member intermediaries.[109] For FICC, if a customer's Netting Member intermediary defaults, FICC would be obligated to perform the one-sided obligations of the done-away transactions of the customer and would need liquidity to do so.[110] For Netting Member intermediaries, done-away transactions would increase the maximum liquidity a Netting Member may be required to provide to FICC under the Capped Contingency

[94] 15 U.S.C. 78q–1(b)(3)(F).

[95] 15 U.S.C. 78q–1(b)(3)(I).

[96] *See* Bradford National Clearing Corp., 590 F.2d 1085, 1105 (D.C. Cir. 1978).

[97] *See* Letter from William C. Thum, Managing Director and Assistant General Counsel, Securities Industry and Financial Markets Association, Asset Management Group (May 24, 2024) (''SIFMA–AMG Letter'') at 5; Letter from Joanna Mallers, Secretary, Futures Industry of America, Principal Traders Group (April 17, 2024) (''FIA–PTG Letter I'') at 2–3, 6–7; Letter from Sarah A. Bessin, Deputy General Counsel and Nhan Nguyen, Associate General Counsel, Investment Company Institute (June 20, 2024) (''ICI Letter'') at 2, 4–5; Letter from Jennifer W. Han, Executive Vice President, Chief Counsel and Head of Global Regulatory Affairs, Managed Funds Association (April 17, 2024) (''MFA Letter I'') at 4–5, 7–8; Letter from Jennifer W. Han, Executive Vice President, Chief Counsel and Head of Global Regulatory Affairs, Managed Funds Association (Nov. 12, 2024) (''MFA Letter II'') at 3–4; *see also* Letter from Jiri Krol, Deputy Chief Executive Officer, Global Head of Government Affairs, Alternative Investment Management Association (April 23, 2024) (''AIMA Letter'') at 4–5 (stating that not addressing the done-away problem leaves a critical gap in access to clearing and settlement service and places significant competitive burdens on indirect participants).

[98] *See* SIFMA–AMG Letter at 5.

[99] *See id.*

[100] *See* FIA–PTG Letter I at 3.

[101] *See id.; see also* MFA Letter II at 3–4.

[102] *See* ICI Letter at 4–5.

[103] *See* FIA–PTG Letter I at 3–4; MFA Letter I at 4–5, 7–8; AIMA Letter at 4–5; SIFMA–AMG Letter at 2; ICI Letter at 2, 4–5. Commenters also state that by not including a requirement on Netting Member intermediaries to offer done-away clearing to their customers, the Proposed Rule Change does not adequately facilitate access for such customers to FICC's clearance and settlement services, consistent with Rule 17ad–22(e)(18)(iv)(C). *See* 17 CFR 240.17ad–22(e)(18)(iv)(C). The Commission addresses those comments below in Section II.D.

[104] *See* Letter from Robert Toomey, Head of Capital Markets, Managing Director/Associate General Counsel, SIFMA, at 3–4 (July 31, 2024) (''SIFMA Letter II'').

[105] *See* SIFMA Letter II at 2.

[106] *See id.*

[107] *See* FICC Letter at 11.

[108] *See id.*

[109] *See* FICC Letter at 11–14.

[110] *See* FICC Letter at 11–12. FICC also states that, by contrast, in a done-with transaction, the customer enters into the transaction with its clearing member, and that, if the clearing member then defaults, the clearing agency has the option to close out both the obligations to the clearing member and those to the customer (*i.e.,* ''both sides of the trade''), with the sole resulting payment obligation being the mark-to-market value of the positions. *See id.* at 12. One commenter states that it is ''inaccurate'' that done-away transactions have greater liquidity risks, but the commenter does not disagree with FICC's description of these liquidity concerns, and instead states that this distinction highlights a deficiency of FICC's current default management framework. *See* Letter from Stephen Berger, Managing Director, Global Head of Government & Regulatory Policy, Citadel and Citadel Securities, (Oct. 21, 2024) (''Citadel Letter'') at 5; *see also* MFA Letter II at 3–4. The concerns regarding the default management framework are discussed in Section II.D.6 *infra.*

Liquidity Facility (''CCLF''), increasing the cost of clearing done-away transactions.[111]

FICC also states that since done-away transactions are negotiated between a customer and its counterparty, the Netting Member intermediary must rely on external parties and/or processes to confirm that a transaction is consistent with the Netting Member's risk limits and regulatory requirements.[112] Therefore, FICC states that imposing a done-away mandate on Netting Members that lack the infrastructure to perform such confirmations could discourage market participants from providing clearing services to customers.[113] FICC also states that done-away clearing might subject Netting Member intermediaries to certain regulatory challenges (*e.g.,* regarding trade reporting and confirmations) and/or increased capital requirements (since it may be difficult to conclude that they have a well-founded basis on which they can exercise close-out netting rights upon a customer default).[114] FICC states that in light of the foregoing risks and challenges, a done-away mandate could have the unintended consequence of discouraging Netting Member intermediaries from providing clearing services to customers, which would concentrate risk, increase costs, and reduce liquidity in the Treasury market.[115] Instead of a done-away mandate, FICC states that Netting Member intermediaries should be allowed to decide whether and how to provide clearing services to customers after evaluating the relevant risks.[116]

As proposed, the GSD access models, including the ability to bundle execution and clearing, do not constitute a burden on competition that is not necessary or appropriate in furtherance of the Exchange Act, because the models continue to offer optionality for different types of market participants to access central clearing in different ways. After proposing the Treasury Clearing Rules,[117] the Commission received similar comments regarding the impact that the absence of a done-away mandate would have on competition for GSD's indirect participants.[118] At that time, the Commission disagreed with those comments and declined to impose a done-away mandate and did not agree that FICC's current access models constituted a burden on competition that is not necessary or appropriate in furtherance of the Exchange Act.[119] Notably, the client clearing models that FICC has proposed allow for Netting Members to offer done-away services. Although the models have not been widely used for done-away services to date, market participants have indicated that they will provide such services going forward.[120] In addition, as the Commission stated in the Treasury Clearing Adopting Release, in order to encourage Netting Member intermediaries to provide services that enable customers to access central clearing, it is best not to remove the ability of such intermediaries to determine which risks to take with respect to guaranteeing transactions to a CCP.[121] As FICC and one commenter highlighted, providing done-away clearing services brings certain risks to the Netting Member, which the Netting Member must evaluate and manage. Finally, approving the Proposed Rule Change does not preclude further action by FICC to incentivize or facilitate done-away clearing services going forward.

In addition, commenters state that the Proposed Rule Change should prohibit bundling of clearing and execution services. One commenter states that this prohibition need not include a done-away mandate, as it would simply prohibit Netting Members from requiring forced bundling, and the commenter also disagrees with FICC's legal arguments regarding whether FICC may impose such a prohibition.[122] An additional commenter states that there are economic incentives for direct participants to bundle their execution and clearing services by favoring done-with transactions.[123] This commenter cites certain prohibitions adopted by the Commodity Futures Trading Commission (''CFTC'') and states that FICC should adopt the same protections for the U.S. Treasury market, as necessary to ensure a robust done-away clearing market.[124]

In response to such comments, FICC states that such a prohibition would effectively mean that a Netting Member could not charge lower fees for done-with clearing because that would amount to tying executing to clearing, and, as a result, could be viewed as the clearing agency dictating pricing terms.[125] FICC further states that such setting of prices is not clearly consistent with Section 17A(b)(3)(E) of the Exchange Act, which provides that the rules of a clearing agency may not impose any schedule of prices, or fix rates or other fees, for services rendered by its participants.[126]

The Commission considered similar comments regarding a prohibition of bundling and clearing when it adopted the Treasury Clearing Rules.[127] Specifically, several commenters stated that the Commission should require

[111] *See* FICC Letter at 12, 14. The CCLF is a member-funded, rules-based, committed liquidity resource, designed to enable FICC to meet its cash settlement obligations in the event of a default of the member (including affiliates) to which FICC has the largest exposure in extreme but plausible market conditions. FICC allocates $15 billion of the total size of the CCLF among all members. FICC allocates the remainder of the total size of the CCLF among members depending on the amount and frequency with which they generate liquidity needs above $15 billion. *See* GSD Rule 22A, Section 2a, *supra* note 15.

[112] *See* FICC Letter at 12–13.

[113] *See id.*

[114] *See* FICC Letter at 14.

[115] *See* FICC Letter at 11.

[116] *See* FICC Letter at 5–6, 11. FICC states that for Netting Members (both current and prospective) with business units already engaged in FCM-style derivatives clearing, the ability to leverage their existing systems should enable them to offer done-away clearing for transactions in U.S. Treasury securities. *See also* FICC Letter at 7, 9 (citing 2024 DTCC White Paper *supra* note 88 at 6 (noting a significant number (28 percent) of Netting Members indicated that they expect to facilitate clearing transactions in U.S. Treasury securities through business units already engaged in done-away clearing of other product types and citing statements from Netting Members and other market participants indicating an intent to utilize their existing FCM-style systems to offer done-away clearing for U.S. Treasury securities and citing statements from Netting Members and other market participants indicating an intent to utilize their existing FCM-style systems to offer done-away clearing for U.S. Treasury securities)).

[117] *See* Covered Clearing Agency Standards Proposing Release, Securities Exchange Act Release No. 71699 (Mar. 12, 2014), 79 FR 29507 (May 27, 2014) (''Proposing Release''); Adopting Release at 2756–57, *supra* note 14 (regarding comments arguing that the Commission should require FICC obligate its members to accept done-away transactions to avoid an undue burden on competition).

[118] *See* Adopting Release at 2756–57, *supra* note 14.

[119] *See id.*

[120] *See* FICC Letter at 8 (reporting survey results that 43 percent of Netting Members would likely clear indirect participant transactions through the Agent Clearing Service). *See also, e.g.,* Bernard Goyder, ''BNY to Launch 'Done Away' UST and Repo Clearing Service,'' *available at https://www.risk.net/markets/7960175/bny-to-launch-done-away-ust-and-repo-clearing-service* (Oct. 21, 2024); Bernard Goyder, ''RJ O'Brien Plots Expansion Into US Treasury Clearing,'' *available at https://www.risk.net/markets/7959638/rj-obrien-plots-expansion-into-us-treasury-clearing* (July 1, 2024).

[121] *See* Adopting Release at 2756–57, *supra* note 14.

[122] *See* Citadel Letter at 8.

[123] *See* MFA Letter I at 5.

[124] *See id.*

[125] *See* FICC Letter at 15.

[126] *See* FICC Letter at 15–16. One commenter states that FICC also relied upon Section 17A(b)(6) regarding a prohibition on bundling and execution. *See* Citadel Letter at 8. However, FICC's reference to that statutory provision relates to a comment that would require done-away clearing services to any customer that posts margin and not to the bundling of execution and clearing services.

[127] *See* Treasury Clearing Adopting Release, *supra* note 14, 89 FR at 2756–77 (including n. 415 identifying such comments). More generally, the statutory authority for the CFTC provisions cited by one commenter differs significantly from the statutory authority applicable to the Commission for the U.S. Treasury market.

U.S. Treasury securities central clearing agencies to obligate their members to accept done-away transactions and prohibit their members from requiring clients to bundle execution and clearing.[128] In response, the Commission stated that it disagrees that the failure to require the submission of done-away transactions necessarily constitutes ''unfair discrimination,'' as discussed in Section 17A(b)(3)(F).[129] In order to encourage market participants to provide services to enable indirect access to central clearing, the Commission stated that it believes it is best not to remove the ability of FICC's direct participants to determine what risks to take with respect to guaranteeing customer transactions. In addition, the Commission also did not agree that, at that time, the current access models offered by FICC constitute a burden on competition that is not necessary or appropriate, as discussed in Section 17A(b)(3)(I).[130] The Commission's analysis remains applicable to the commenters seeking such a prohibition from FICC.

For these reasons, after considering the public comments and FICC's response, the access models in the Proposed Rule Change, which would not prevent a Netting Member from bundling execution and clearing and do not require a Netting Member to provide done-away clearing services would not impose a burden on competition not necessary or appropriate in furtherance of the Exchange Act.[131]

C. Consistency With Rule 17ad–22(e)(18)(iii)

Rule 17ad–22(e)(18)(iii) under the Exchange Act requires that a covered clearing agency, such as FICC, establish objective, risk-based, and publicly disclosed criteria for participation, which monitor compliance with such participation requirements on an ongoing basis.[132]

As described above in Section I.B.1., FICC proposes changes that would enable it to monitor activity submitted through the Agent Clearing Service. Specifically, FICC would require a Netting Member to submit an application to become an Agent Clearing Member and provide additional information regarding each Executing Firm Customer beyond that which is required for Executing Firms under the current GSD Rules, such as a Legal Entity Identifier (''LEI''). FICC would also require an Agent Clearing Member to submit activity on behalf of its Executing Firm Customer(s) through one or more separate Agent Clearing Member Omnibus Accounts, as opposed to the optional segregated submission approach provided for in the current GSD Rules. Finally, for both initial and ongoing membership purposes, FICC would require an Agent Clearing Member to provide FICC with information related to its use of the Agent Clearing Service. Adding these provisions to the GSD Rules should help FICC monitor the trading activity generated withing the Agent Clearing Service because they should allow FICC to better understand which transactions are attributable to which Executing Firm Customers submitting through an Agent Clearing Member, which should, in turn, provide better overall understanding of market participants' activity at FICC even across multiple Agent Clearing Members.

One commenter states that FICC should change its proposal regarding the requirement on Agent Clearing Members to indemnify FICC for any harm arising out of the Agent Clearing Member's failure to have the current LEIs of its Executing Firm Customers on file with FICC.[133] Specifically, the commenter states that FICC's proposal is overly broad insofar as it would ostensibly require an Agent Clearing Member to halt a customer's trading activity for minor lapses in LEI renewals and require the Agent Clearing Member to verify current LEIs on any number of LEI service provider websites.[134] The commenter states that FICC should not need to maintain such strict rules governing LEIs when other identifying information accompanies each trade.[135] Therefore, the commenter states that FICC should more narrowly tailor the indemnification provision to cover only relevant harms arising out of an Agent Clearing Member's gross negligence, willful misconduct, or fraudulent conduct.[136]

In response, FICC states that, although the Agent Clearing Member has a contractual relationship with its customers, FICC does not.[137] Therefore, the Agent Clearing Member is able to include contract provisions that obligate its customers to maintain current LEI information and notify the Agent Clearing Member of any LEI renewals or changes.[138] FICC further states that although it does not generally expect the LEI indemnification provision to give rise to significant liability, neither FICC nor its other members should bear the costs of any such liability.[139]

The Commission agrees with FICC on this point. The LEI portion of the Proposed Rule Change is consistent with FICC's existing rule regarding a Sponsoring Member's obligation to provide an LEI for its Sponsored Members.[140] Therefore, Sponsoring Members are already subject to such a requirement. An Agent Clearing Member, like a Sponsoring Member, should be able to contract with its Executing Firm Customers to ensure that it receives updated LEI information to provide to FICC. Neither FICC nor its other members should bear any liability arising out of an Agent Clearing Member's failure to have the current LEIs of its Executing Firm Customers on file with FICC.

Accordingly, the Proposed Rule Change would assist FICC in monitoring its participants' ongoing compliance with the Agent Clearing Service participation requirements, consistent with Rule 17ad–22(e)(18)(iii).[141]

D. Consistency With Rule 17ad–22(e)(18)(iv)(C)

Rule 17ad–22(e)(18)(iv)(C) under the Exchange Act requires that a covered clearing agency, such as FICC, when providing CCP services for transactions in U.S Treasury securities, establish objective, risk-based, and publicly disclosed criteria for participation, which ensure that it has appropriate means to facilitate access to clearance and settlement services of all eligible secondary market transactions in U.S. Treasury securities, including those of indirect participants.[142]

FICC states that the Proposed Rule Change is primarily designed to ensure that the access models in the GSD Rules comply with Rule 17ad–22(e)(18)(iv)(C) by constituting criteria for participation

[128] *See* Treasury Clearing Adopting Release, supra note 14, 89 FR at 2756.

[129] *See* Treasury Clearing Adopting Release, supra note 14, 89 FR at 2757.

[130] *See* Treasury Clearing Adopting Release, supra note 14, 89 FR at 2756–77.

[131] 15 U.S.C. 78q–1(b)(3)(I).

[132] 17 CFR 240.17ad–22(e)(4)(18)(iii).

[133] *See* Letter from Katherine Darras, General Counsel, International Swaps and Derivatives Association (April 17, 2024) (''ISDA Letter I'') at 5–6; Letter from Katherine Darras, General Counsel, International Swaps and Derivatives Association (July 18, 2024) (''ISDA Letter II'') at 5.

[134] *See* ISDA Letter II at 5.

[135] *See id.*

[136] *See id.*

[137] *See* FICC Letter at 41.

[138] *See id.*

[139] *See id.*

[140] *See* GSD Rules, Rule 3A, Section 2(d) (''Each Sponsoring Member shall submit the Legal Entity Identifier for each of its Sponsored Member applicants as part of the application of such Sponsored Member applicant. Each Sponsoring Member shall provide the Corporation with a Legal Entity Identifier for each of its Sponsored Members such that the Corporation shall have a current Legal Entity Identifier for each Sponsored Member at all times.'').

[141] 17 CFR 240.17ad–22(e)(18)(iii).

[142] 17 CFR 240.17ad–22(e)(18)(iv)(C).

that facilitate access to GSD's clearance and settlement services, including for indirect participants.[143] Specifically, FICC developed the Proposed Rule Change following FICC's review of GSD's existing direct and indirect access models.[144] That review examined whether those models provide market participants with access to GSD's clearance and settlement services in as flexible a means as possible, consistent with FICC's responsibility to provide sound risk management and comply with its regulatory risk management obligations under Rule 17ad–22(e) and other parts of the Exchange Act.[145]

1. Changes to the Agent Clearing Service

As described above in Section I.B.1., FICC proposes to re-name GSD's existing correspondent clearing/prime broker services as the Agent Clearing Service. FICC also proposes to consolidate and adopt additional provisions governing the re-named Agent Clearing Service. The proposed changes to re-name, consolidate, and provide additional specificity regarding the operation of the Agent Clearing Service should improve transparency of the GSD Rules regarding the Agent Clearing Service and allow market participants to better evaluate and consider how the Agent Clearing Service operates, including how it compares to existing cleared derivatives systems and infrastructure. The refinement of the proposed Agent Clearing Service should help ensure that market participants are able to evaluate and, if they choose, use this service to access FICC, including for done-away transactions, as discussed above in Section I.A. Therefore, these proposed changes are consistent with Rule 17ad–22(e)(18)(iv)(C).

Several commenters request that FICC clarify that an Agent Clearing Member would be permitted to treat its customer transactions as off-balance sheet for accounting purposes, otherwise the Agent Clearing Service may be so capital intensive as to disincentivize use of the access model.[146] In response, FICC states that it is actively working with industry groups to determine the balance sheet impact of done-away transactions.[147]

It is ultimately the responsibility of each Netting Member to determine the accounting treatment of its own transactions. FICC need not opine on the balance sheet treatment for transactions within the Agent Clearing Service in order for the Commission to evaluate the Proposed Rule Change's consistency with Rule 17ad–22(e)(18)(iv)(C).[148]

Another commenter is concerned that the rights of Executing Firm Customers are too limited vis-à-vis FICC within the Agent Clearing Service.[149] For example, the commenter states that under the Proposed Rule Change, FICC would have no obligations to Executing Firm Customers; rather, FICC's obligations would be solely to the Agent Clearing Member.[150]

In the Notice of Filing, FICC states that within the current correspondent clearing/prime broker services, an indirect participant does not establish any relationship with FICC.[151] FICC's proposed changes regarding the Agent Clearing Service would not change that aspect of the access model. In contrast, within the Sponsored Service, a Sponsored Member must establish an indirect, limited purpose membership with FICC. FICC states that one of the factors that an indirect participant may wish to consider in choosing between GSD access models is whether the participant prefers to be in a direct contractual relationship with FICC.[152]

In the Treasury Clearing Rules Adopting Release, the Commission also recognized that certain access models offered by FICC may not result in a contractual relationship or direct obligation between FICC and an indirect participant.[153] This generally would be the case in any agent clearing relationship in which an indirect participant relies upon a direct participant to submit transactions for clearing on its behalf.[154] The commenter's concern that within the Agent Clearing Service, indirect participants would not have a contractual relationship with FICC, does not render the Proposed Rule Change inconsistent with Rule 17ad–22(e)(18)(iv)(C).

2. Comments Regarding Done-Away Clearing

As discussed in more detail in Section II.B above, several commenters suggest that by not including a requirement on Netting Member intermediaries to provide done-away clearing services to customers, the Proposed Rule Change would fail to implement criteria for participation that facilitate access to GSD's clearance and settlement services for indirect participants.[155] Specifically, commenters state that if a customer is limited to done-with transactions, it would need to establish separate clearing relationships with each done-with counterparty with whom it wishes to transact, which would increase cost, complexity, operational risk, and limit the number of counterparties with whom to transact.[156] In addition, several commenters state that alternatively, these market participants may limit their cash and/or repo U.S. Treasury transactions, thereby negatively impacting market liquidity.[157] Commenters also state that FICC should prohibit the bundling of clearing and execution services to comply with Rule 17ad–22(e)(18)(iv)(C). As discussed further in Section II.B *infra,* these commenters state that such a prohibition is necessary to ensure that market participants will provide done-away clearing services.[158]

Generally, these commenters state that FICC should impose a mandate on Netting Member intermediaries to provide done-away clearing services to customers and should prohibit the

[143] *See* Notice of Filing, *supra* note 5, at 89 FR 21363.

[144] *See id.*

[145] *See* 17 CFR 240.17ad–22(e); Notice of Filing, *supra* note 5, at 89 FR 21363.

[146] *See* FIA Letter at 5, 10–11; Letter from Robert Toomey, Head of Capital Markets, Managing Director/Associate General Counsel, SIFMA, at 3–4 (May 22, 2024) (''SIFMA Letter I'') at 2, 5; SIFMA Letter II at 3. One commenter further states that if FICC can provide clarity on this matter, it would negate the need for a done-away clearing mandate in the GSD Rules. *See* SIFMA Letter I at 5.

[147] *See* FICC Letter at 14.

[148] *See* 17 CFR 240.17ad–22(e)(18)(iv)(C).

[149] *See* ICI Letter at 4.

[150] *See id.*

[151] *See* Notice of Filing, *supra* note 5, 89 FR at 21364.

[152] *See* FICC Letter at 50–51.

[153] *See* Adopting Release, supra note 14, 89 FR at 2758.

[154] *See id.*

[155] *See* FIA–PTG Letter I at 3 (stating that the Proposed Rule Change ''raises serious questions regarding whether [it] appropriately facilitate[s] access to clearing for indirect participants as required by'' Rule 17ad–22(e)(18)(iv)(C)); MFA Letter I at 3 (stating that the Proposed Rule change ''[does] not go far enough to satisfy'' Rule 17ad–22(e)(18)(iv)(C)); AIMA Letter at 4–5 (stating that the changes in the Proposed Rule Change ''are not sufficient to facilitate access to clearing for indirect participants''); SIFMA–AMG Letter at 4 (stating that FICC must ensure that the Proposed Rule Change facilitates done-away trading in a manner that fulfills the requirements of the Treasury Clearing Rules); ICI Letter at 4 (stating that ''it is not clear that the [Proposed Rule Change] fully implements the requirements of'' Rule 17ad–22(e)(18)(iv)(C)).

[156] *See* FIA–PTG Letter I at 3; MFA Letter I at 4–5; AIMA Letter at 4 (stating that without a done-away model, indirect participants will face new and unnecessary costs in having to bundle execution and clearing services or establish additional clearing relationships so that they can engage with multiple execution counterparties).

[157] *See* AIMA Letter at 4; *see also* SIFMA–AMG-Letter at 4–5 (arguing that without changes to the GSD access models, many market participants may be shut out of the U.S. Treasury market, with significant negative effects on liquidity).

[158] *See* Citadel Letter at 7–8; MFA Letter II at 4.

bundling of clearing and execution services to address these concerns.[159]

As discussed in more detail in Section II.B above, in response, FICC states that the Proposed Rule Change would meaningfully facilitate done-away clearing, without imposing a done-away mandate or prohibiting the bundling of clearing and execution services.[160] FICC also states that a done-away mandate could expose both FICC and its participants to unique risks.[161] First, as discussed in Section II.B above, done-away transactions present liquidity risks that done-with transactions do not.[162] Because done-away transactions are entered into between a customer and a counterparty other than the customer's Netting Member intermediary, if the intermediary defaults, FICC would need to perform the one-sided obligations of the customer.[163] Second, because done-away transactions are negotiated between the customer and its counterparty, the Netting Member intermediary must depend on outside processes or parties to confirm that the transactions do not give rise to risk or regulatory issues (*e.g.,* trade reporting and confirmation requirements, anti-money laundering and sanctions regulations, *etc.*).[164] FICC states that its direct participants should independently determine whether they can assume the risks associated with providing done-away clearing services.[165] Otherwise, according to FICC, the increased risks and costs associated with a done-away mandate could stifle the ongoing and positive market developments toward done-away clearing by discouraging Netting Member intermediaries from providing clearing services altogether.[166]

FICC further states that a done-away mandate could be inconsistent with Section 17A(b)(3)(E) and/or Section 17A(b)(6) of the Exchange Act.[167] FICC states that for a done-away mandate to be effective, it would likely need to prohibit the bundling of execution and clearing (and thereby prevent a Netting Member intermediary from forcing its customers into done-with transactions through more favorable terms).[168] FICC states that, as a result, a done-away mandate could be viewed as FICC dictating pricing terms, which could violate Section 17A(b)(3)(E).[169] Additionally, Section 17A(b)(6) provides that a clearing agency may not ''prohibit or limit access by any person to services offered by any participant therein.'' [170] FICC states that a requirement on Netting Member intermediaries to provide done-away clearing to customers that post margin could violate Section 17A(b)(6) because the service offered to customers who do not post margin could potentially be limited to done-with clearing.[171]

In addition, as stated above in Section II.B., one commenter also states that FICC should not impose a done-away clearing mandate.[172] Rather, the commenter states that any decision to offer done-away services should be a commercial/business decision left to clearing members, driven by evaluations of risk.[173] The commenter states that FICC can implement an access model, without a done-away clearing mandate, that would be reasonably designed to ensure that FICC has appropriate means to facilitate access to its clearance and settlement services consistent with Rule 17ad–22(e)(18)(iv)(C).[174]

The Proposed Rule Change does not include a requirement that FICC's participants offer done-away clearing or prohibit the bundling of clearing and execution services. The Commission shall approve a proposed rule change of a self-regulatory organization if it finds that it is consistent with the Exchange Act,[175] and the Proposed Rule Change is consistent with the Exchange Act and the rules thereunder, even in the absence of a done-away mandate or a prohibition on the bundling of clearing and execution services.

The Commission disagrees with the commenters arguing that FICC must impose a done-away clearing mandate on Netting Member intermediaries or prohibit the bundling of clearing and execution services to comply with Rule 17ad–22(e)(18)(iv)(C). As discussed in the Adopting Release, Rule 17ad–22(e)(18)(iv)(C) does not prescribe a particular access model, but it instead helps ensure that FICC, and any other covered clearing agency serving the U.S. Treasury market, review their indirect access models and ensure that they facilitate access to clearance and settlement services in a manner suited to the needs and regulatory requirements of market participants, including indirect participants.[176] Further, in the Adopting Release, the Commission stated that a requirement to accept done-away transactions would require a covered clearing agency to, in turn, require their direct participants to transact with their customers in specific ways and limit their ability to offer certain types of pricing services.[177]

More generally, and as stated above in Section II.A., both the Sponsored Service and the Agent Clearing Service (including the prime broker/correspondent clearing service in place currently) allow (and are currently used) for done-away clearing.[178] As stated in the Adopting Release, in order to encourage Netting Member intermediaries to provide services that enable customers to access central clearing, it is best not to remove the ability of such intermediaries to determine which risks to take with respect to guaranteeing transactions to a CCP such as FICC.[179] This is also true with respect to providing done-away clearing services. The Commission agrees with the rationale articulated by both FICC and one commenter arguing that a done-away clearing mandate could be counterproductive and ultimately discourage Netting Member intermediaries from providing clearing services to customers.[180] Additionally, it is appropriate to allow the U.S. Treasury market to adjust to the implementation of the Treasury Clearing Rules (*e.g.,* the Account Segregation Proposals) before determining that additional access models are needed.[181] For the foregoing reasons, FICC need not impose a done-away clearing mandate on Netting Member intermediaries in order to comply with Rule 17ad–22(e)(18)(iv)(C).[182]

Several commenters state that FICC should explain how its proposal to re-brand the Agent Clearing Service would actually facilitate done-away

[159] *See* FIA–PTG Letter I at 2–3, 6–7; MFA Letter I at 4–5, 7–8; AIMA Letter at 4–5.

[160] *See* FICC Letter at 8.

[161] *See* FICC Letter at 11–13.

[162] *See id.*

[163] *See id.*

[164] *See id.*

[165] *See id.*

[166] *See* FICC Letter at 13–15.

[167] *See* FICC Letter at 15–16; 15 U.S.C. 78q–1(b)(3)(E); 15 U.S.C. 78q–1(b)(6).

[168] *See* FICC Letter at 15–16.

[169] *See* 15 U.S.C. 78q–1(b)(3)(E).

[170] 15 U.S.C. 78q–1(b)(6).

[171] *See* FICC Letter at 16; 15 U.S.C. 78q–1(b)(6).

[172] *See* SIFMA Letter II at 3–4.

[173] *See id.*

[174] *See* SIFMA Letter II at 4.

[175] *See* 15 U.S.C. 78s(b)(2)(C)(i).

[176] *See* Treasury Clearing Adopting Release, *supra* note 14, 89 FR at 2755–56.

[177] *See* Treasury Clearing Adopting Release, *supra* note 14, 89 FR at 2757.

[178] *See* FICC Letter at 7, note 14 and accompanying text (highlighting that although the bulk of current done-away transactions are cash transactions cleared through the correspondent clearing/prime broker clearing models, nearly 10 percent of FICC's Sponsoring Members currently clear done-away repo transactions through the Sponsored Service).

[179] *See* Adopting Release at 2756–57, *supra* note 14.

[180] *See* FICC Letter at 11–15; SIFMA Letter II at 3–4.

[181] *See* Adopting Release at 2756–57, *supra* note 14.

[182] *See* 17 CFR 240.17ad–22(e)(18)(iv)(C).

clearing.[183] Two commenters state the re-branding and making conforming, technical amendments to the Agent Clearing Service are non-substantive and ''superficial'' and would not increase the availability of done-away trading.[184] One commenter states that there is not a significant amount of repo activity conducted through the current correspondent clearing/prime broker clearing services.[185] The commenter further questions why that would change after the services are re-branded as the Agent Clearing Service.[186] In response, FICC states that its survey results demonstrate that prior to publication of the Notice of Filing, 77 percent of market participants were not very familiar with the correspondent clearing/prime brokerage services, and that lack of familiarity is likely the reason for the relatively low level of use of those GSD access models.[187] FICC states that after publication of the Notice of Filing, its survey results indicate that 43 percent of Netting Members would likely clear indirect participant transactions through the Agent Clearing Service.[188] FICC attributes the shift among participants towards considering using the Agent Clearing Service is a result of the Proposed Rule Change's clarifications and consolidations regarding the Agent Clearing Service.[189]

The Proposed Rule Change sufficiently explains how the Agent Clearing Service would work and how it could facilitate done-away clearing. Further explanation is unnecessary for purposes of considering the Proposed Rule Change, and each market participant has to determine which access model to use for its own business purposes. However, the Commission observes that FICC has engaged in market outreach to assist market participants in evaluating and understanding the operations and business case for each access model.[190]

Several commenters raise the concern that even if a Netting Member intermediary offers done-away clearing services, customers would be required to disclose the identity of their execution counterparties to the intermediary.[191] One commenter states that requiring the disclosure of execution counterparties to the Netting Member intermediary divulges confidential information regarding the customer's trading activities and could lead to limitations placed on those execution counterparties, directly undermining a key benefit of central clearing.[192] Another commenter states that in a cleared market, the identity of a customer's original execution counterparty should be irrelevant to a clearing member because the clearing member is not exposed to the creditworthiness of the execution counterparty, meaning that a clearing member should not be in a position to limit a customer's execution counterparties.[193] This commenter also states that this concern is why the Commodity Futures Trading Commission specifically prohibited ''the type of trilateral execution agreement described by FICC.'' [194] Therefore, commenters state, FICC should enable customers to avoid disclosing the identity of their execution counterparties to their Netting Member intermediaries and prohibit the restriction of execution counterparties.[195]

FICC states that it is currently not practically feasible to prohibit a direct participant from knowing the execution counterparty's identity because there is no mechanism in the U.S. Treasury market available for someone other than a direct participant to submit transactions and counterparty information to FICC.[196] Regarding the concerns that disclosure of the identity of a customer's execution counterparty could result in the Netting Member intermediary placing limitations on the execution counterparty, FICC states that Netting Member intermediaries may, in certain cases, have legitimate reasons to know or limit a customer's execution counterparties.[197] For example, FICC states that a Netting Member may need to confirm that a customer's proposed execution counterparty has an execution or similar agreement in place with the Netting Member and that the execution counterparty has performed any obligations set forth in that agreement.[198] FICC also states that Netting Members may also need to know the identity of a customer's execution counterparty to assess certain risks, such as potential CCLF requirements.[199] FICC states that whether and how a Netting Member intermediary may restrict execution counterparties are matters that should be commercially negotiated between the intermediary and its customers, rather than dictated by FICC in the GSD Rules.[200]

The Commission acknowledges that a customer may not wish to disclose the identity of its execution counterparty to its Netting Member intermediary. Although the commenters state that FICC should enable anonymous execution, such anonymous execution is not yet possible considering the current market infrastructure. Therefore, FICC need not require Netting Member intermediaries to provide for anonymous execution in order for the Proposed Rule Change to be consistent with Rule 17ad–22(e)(18)(iv)(C).[201]

In addition, regarding the concern that a Netting Member intermediary could restrict the execution counterparty, FICC's response that a Netting Member intermediary might have legitimate reasons to know the identity and restrict execution counterparties supports the suggestion that such matters should be negotiated bilaterally between customers and their Netting Members intermediaries.[202] However, regarding potential liquidity risk arising from done-away transactions, the Commission understands that the existence of exposure arising from a done-away transaction, and not necessarily the execution counterparty to that exposure, could have an effect on the Netting Member's liquidity obligations to FICC in the event of a member default. The Commission would not view the

[183] *See* SIFMA–AMG Letter at 2, 4–5; ICI Letter at 2, 4–5; MFA Letter I at 3–4.

[184] *See* SIFMA–AMG Letter at 2, 4–5; ICI Letter at 2, 4–5.

[185] *See* MFA Letter I at 3–4.

[186] *See id.*

[187] *See* FICC Letter at 8.

[188] *See id.*

[189] *See id.*

[190] *See* FICC Letter at 4; *see generally* FICC's U.S. Treasury Clearing information website, *available at https://www.dtcc.com/ustclearing* (*e.g.,* the ''Access Central Clearing'' tab, which provides resources for direct and indirect participants to understand and evaluate each GSD access model, including explanations of recommended access models for specific types of market participants).

[191] *See* FIA–PTG Letter I at 7–8; MFA Letter I at 4–5; FIA–PTG II at 3; Citadel Letter at 4–5.

[192] *See* FIA–PTG Letter I at 7–8.

[193] *See* Citadel Letter at 4–5; *see also* Letter from Joanna Mallers, Secretary, Futures Industry of America, Principal Traders Group (Oct. 11, 2024) (''FIA–PTG Letter II'') at 3.

[194] *See* Citadel Letter at 5.

[195] *See* FIA–PTG Letter I at 7–8; MFA Letter I at 4–5.

[196] *See* FICC Letter at 16. FICC states that in other markets (*e.g.,* the U.S. markets for equity securities and cleared derivatives), there are execution facilities or affirmation platforms that provide post-trade settlement market infrastructure with counterparty information. However, in the U.S. Treasury market, such facilities or platforms are not predominant or do not currently offer similar services. *See id.*

[197] *See* FICC Letter at 17.

[198] *See id.*

[199] *See id.*

[200] *See id.*

[201] *See* 17 CFR 240.17ad–22(e)(18)(iv)(C).

[202] In addition, the Commission understands that, to the extent that a market participant is transacting on an inter-dealer broker or similar platform, the execution counterparty to the transaction would be the inter-dealer broker or platform, not the other market participant that was brought together on the platform and also had a transaction with the inter-dealer broker or platform.

identity of the execution counterparty as relevant to the potential liquidity risk arising from that transaction. Moreover, the Commission disagrees that FICC's statements regarding confirming that a proposed execution counterparty has an execution or similar agreement in place with the Netting Member equates to the types of trilateral agreements prohibited by the CFTC.[203]

One commenter asked why the Agent Clearing Service cannot be used for ''brokered transactions'' or GCF repo transactions.[204] The commenter also states that for Treasury cash transactions executed by inter-dealer brokers, there would appear to be no way to comply with the Treasury Clearing Rules via customer clearing, as the execution counterparty does not offer customer clearing services and therefore another clearing member must accept these trades via a done-away offering.[205] In response, FICC states that, with respect to general collateral repo transactions, FICC would not be able to clear such transactions through the proposed Agent Clearing Service, but it states that it is considering developing such capabilities based on feedback from market participants.[206] With respect to brokered transactions, FICC states that it would not be appropriate for transactions cleared through the proposed Agent Clearing Service to be treated as ''Brokered Transactions'' under the GSD Rules because Brokered Transactions are designed to capture certain transactions that present lower risk than other cleared transactions.[207] Moreover, the Account Segregation Proposals [208] would modify the GSD Rules regarding Brokered Transactions, further clarifying the unique treatment of Brokered Transactions due to the limited risk they present to FICC.[209] The current GSD Rules cap the amount of loss allocation that may be applied to Inter-Dealer Broker Netting Members and Non-IDB Repo Brokers submitting Brokered Transactions.[210] The Account Segregation Proposals would revise the definition of Brokered Transactions to only include the side of the transactions submitted to FICC for novation by an Inter-Dealer Broker Netting Member and entered into on the Inter-Dealer Broker Netting Member's own trading platform.[211] As a result, the favorable loss allocation treatment for Brokered Transactions would only apply to the transactions that present limited risk since an Inter-Dealer Broker is standing in between two counterparties in those transactions and is therefore completely flat.[212] Since the favorable loss allocation treatment is only appropriate for Inter-Dealer Broker Netting Members submitting Brokered Transactions, the Account Segregation Proposals would delete the term ''Non IDB Repo Broker'' from the GSD Rules.[213] Additionally, the concurrently approved Account Segregation Proposals would provide that transactions entered into on an Inter-Dealer Broker Netting Member's trading platform or similar platform may be cleared using the Sponsored Service or the Agent Clearing Service, which addresses the commenter's concern.[214]

In response to the comments regarding transactions executed on an inter-dealer broker or similar platform, the Commission agrees that, as FICC represented,[215] such transactions could be submitted through the Agent Clearing Service.

3. Changes to the Sponsored Service

As described above in Section I.B.2., FICC also proposes to update certain membership standards in the GSD Rules regarding the Sponsored Service. First, FICC proposes to eliminate the two categories of Sponsoring Members, and instead, make all Sponsoring Members subject to the same eligibility and ongoing requirements that are currently applicable to Category 2 Sponsoring Members. These proposed changes would remove the capitalization requirements on Bank Netting Members from the current GSD Rules, and instead apply the activity limits and financial condition factors used under the current GSD Rules for Category 2 Sponsoring Members. These proposed changes would create parity among all Sponsoring Members (and applicants), thereby encouraging additional market participants to become Sponsoring Members, which in turn should give indirect participants a wider range of Sponsoring Members to consider should they choose to access GSD's central clearing services via the Sponsored Service.[216] Second, FICC proposes to remove the QIB Requirement for Sponsored Members, which would make the Sponsored Service available to additional market participants (*i.e.,* those unable to meet the QIB Requirement).[217]

Therefore, the proposed changes to the GSD Rules to (1) consolidate the Sponsoring Member categories, and (2) eliminate the QIB Requirement for Sponsored Members, constitute criteria for participation that facilitate access to GSD's clearance and settlement services, including for indirect participants, are consistent with Rule 17ad–22(e)(18)(iv)(C), because the proposed changes would expand the availability of the Sponsored Service to a broader range of market participants.[218]

4. Changes to Eligibility Criteria for Non-U.S. and Other Applicants

As described above in Section I.B.2., FICC proposes to clarify the eligibility criteria for non-U.S. Netting Member applicants. Whereas the current GSD Rules are unclear as to whether a non-U.S. applicant entity would only be subject to the Foreign Netting Member standards or would also be subject to the legal entity standards, FICC proposes to streamline the relevant membership categories by eliminating the category of ''Foreign Netting Member'' and expanding the qualifications for each category of Netting Member to include the foreign equivalent of the same legal entity types. Additionally, FICC proposes to clarify the eligibility criteria for applicants (including non-U.S. entities) that do not fit into one of the existing Netting Member categories.

Following the adoption of the Treasury Clearing Rules, additional market participants will need to access FICC's clearance and settlement services, either as direct Netting Members or as indirect participants.

[203] Such agreements incorporated optional annexes that make the clearing member to one or both of the executing parties a party to the agreement. These trilateral agreements contain provisions that would permit a customer's FCM, in consultation with the swap dealer (''SD'') that is the customer's counterparty, to establish specific credit limits for the customer's swap transactions with the SD, and that the FCM will only accept for clearing those transactions that fall within these specific limits. The limits set for trades with the SD or MSP might be less than the overall limits set for the customer for all trades cleared through the FCM. CFTC, Customer Clearing Documentation, Timing of Acceptance for Clearing, and Clearing Member Risk Management, 77 FR 21278, 21279 (Apr. 9, 2012).

[204] *See* FIA–PTG Letter I at 7.

[205] *See* FIA–PTG Letter I at 3; FIA–PTG Letter II at 3.

[206] *See* FICC Letter at 22.

[207] *See* FICC Letter at 22–23.

[208] *See* Account Segregation Proposals, *supra* note 85.

[209] *See* Account Segregation Proposals, *supra* note 85, 89 FR at 87451.

[210] *See* GSD Rule 4, Section 6, *supra* note 15.

[211] *See* Account Segregation Proposals, *supra* note 85, 89 FR at 87451.

[212] *See* Account Segregation Proposals, *supra* note 85, 89 FR at 21598.

[213] *See id.*

[214] *See* Account Segregation Proposals, *supra* note 85, 89 FR at 87451; *see also* FICC Letter at 22–23.

[215] *See* Account Segregation Proposals, *supra* note 85; FICC Letter at 23.

[216] *See* Notice of Filing, *supra* note 5, 89 FR at 21370.

[217] One commenter expressed support for FICC's proposal to eliminate the QIB Requirement. *See* ICI Letter at 5. No other commenter addressed this particular change or any other changes to the Sponsored Service.

[218] *See* 17 CFR 240.17ad–22(e)(18)(iv)(C).

Whereas the current GSD Rules do not provide FICC with the authority to consider a Netting Member applicant that does not meet the eligibility criteria of one of the Netting Member categories enumerated in the GSD Rules, the proposed changes, as described in Section I.B.2, would provide a framework for FICC to consider such other applicants. FICC designed the proposed changes regarding non-U.S. and other applicants to facilitate access to GSD's clearing services to a broader range of market participants.[219]

The proposed changes to the GSD Rules to clarify the eligibility criteria for non-U.S. Netting Member applicants and applicants that do not fit into one of the existing Netting Member categories, are consistent with Rule 17ad–22(e)(18)(iv)(C), because the proposed changes would expand the availability of GSD's clearing services to a broader range of market participants.[220]

5. Changes To Clarify the GSD Access Models

As described above in Section I.B.3., FICC proposes to include a ''road map'' in the GSD Rules describing the various GSD access models that allow for both direct and indirect access to GSD's clearance and settlement services. FICC also proposes to simplify the GSD Rule definitions regarding the different types of membership and other related definitions.[221] FICC states that these proposed changes would enhance the ability of market participants to better understand and evaluate the comparative tradeoffs between GSD's different access models.[222]

Several commenters request that FICC provide further clarity regarding the GSD access models.[223] Specifically, commenters request that FICC explain the expected use cases for each of the GSD access models to enable market participants to better evaluate the relative benefits of each access model by understanding the substantive differences between them.[224] One commenter states that FICC should eliminate any access model that it cannot justify with a use case.[225] One commenter states that although the availability of multiple access models may provide flexibility to market participants, it could also introduce unnecessary complexity and confusion.[226]

FICC states that it developed four indirect access models (*i.e.,* the Sponsored Service and Agent Clearing Service, each with either segregated or non-segregated margin) after engagement with market participants to ensure a diverse array of models through which market participants can access central clearing.[227] In response to the comments requesting further clarity and challenging the need for each of the proposed access models, FICC describes some of the possible use cases and advantages of each of the four access models.[228] Specifically, FICC states that market participants might prefer the Agent Clearing Service due to its conceptual and operational similarity to an FCM-style cleared derivatives model, enabling market participants to leverage their existing legal analyses, structures, policies, and procedures to clear transactions in U.S. Treasury securities.[229] Additionally, due to the greater intermediation of the Agent Clearing Service, a Netting Member intermediary would be able to utilize a ''financial asset'' election to perfect its security interest in cleared transactions without having to file a Uniform Commercial Code financing statement, potentially reducing cost, risk, and publicity.[230] Moreover, in comparison to the Sponsored Service, the Agent Clearing Service would involve a simpler onboarding process, would not require privity of contract between indirect participants and FICC, and would not impose the same jurisdictional requirements on indirect participants.[231] On the other hand, FICC highlights potential advantages to the Sponsored Service, including being in a direct contractual relationship with FICC.[232] FICC also states that Netting Members have existing clearing agreements with many customers for the Sponsored Service without segregation and could continue to utilize their existing agreements.[233] Additionally, since the Sponsored Service has existed for nearly two decades, FICC states that market participants have achieved a certain level of confidence regarding the Sponsored Service's treatment for legal, regulatory, accounting, and other purposes.[234]

Publication of ''use cases'' or justifications are not required for a proposed rule change to be consistent with Rule 17ad–22(e)(18)(iv)(C), which requires only that a covered clearing agency have written policies and procedures reasonably designed to ensure appropriate access to its clearing and settlement services, including for indirect participants. Further, the decision of which access model to use is for each individual market participant to determine, as each market participant has different regulatory obligations, business strategies, ownership models, etc. Nevertheless, FICC's description of the reasons for each of its four access models is sound and clearly identifies potential advantages and disadvantages of each model for market participants to consider.[235]

In addition, several commenters questioned the decision to offer both segregated and non-segregated accounts in both the Sponsored Service and Agent Clearing Service. Specifically, one commenter requests that FICC explain the benefits of the access models insofar as they allow for omnibus (*i.e.,* non-segregated) margin submission.[236] Another commenter questioned whether both the Sponsored Service and Agent Clearing Service should offer segregated models.[237]

In response, FICC explains potential advantages regarding margin segregation options (*i.e.,* to explain why the GSD access models allow for both segregated and non-segregated, or omnibus, margin submission).[238] Specifically, within the Agent Clearing Service, if margin is not segregated, Clearing Fund requirements for customer transactions would be calculated on a net basis across all Executing Firm Customers whose transactions are recorded within the same account, resulting in aggregate margin obligations that are substantially lower than under the Sponsored

[219] *See* Notice of Filing, *supra* note 5, at 89 FR 21373.

[220] *See* 17 CFR 240.17ad–22(e)(18)(iv)(C).

[221] *See* Notice of Filing, *supra* note 5, 89 FR at 21374.

[222] *See* Notice of Filing, *supra* note 5, 89 FR at 21373–74.

[223] *See* FIA–PTG Letter I at 6–8; ISDA Letter I at 8; MFA Letter I at 6; AIMA Letter at 5–6; SIFMA–AMG Letter at 3, 11–12; ISDA Letter II at 2–3.

[224] *See id.*

[225] *See* MFA Letter I at 7.

[226] *See* MFA Letter I at 6; FIA–PTG Letter I at 4. For example, with a greater number of access models, a direct participant's service offerings and pricing might not be readily apparent to indirect participants. *See id.*

[227] *See* FICC Letter at 18, 20.

[228] *See* FICC Letter at 50–51.

[229] *See* FICC Letter at 20, 50–51.

[230] *See* FICC Letter at 19, 50–51.

[231] *See* FICC Letter at 19–20, 50–51.

[232] *See* FICC Letter at 50–51.

[233] *See id.*

[234] *See* FICC Letter at 20, 50–51.

[235] The Commission also understands that FICC has engaged in outreach and education efforts to further explain the different features of each model. *See generally* FICC's U.S. Treasury Clearing information website, *available at https://www.dtcc.com/ustclearing* (*e.g.,* the ''Access Central Clearing'' tab, which provides resources for direct and indirect participants to understand and evaluate each GSD access model, including explanations of recommended access models for specific types of market participants).

[236] *See* SIFMA–AMG Letter at 11–12.

[237] *See* FIA–PTG Letter at 4.

[238] *See* FICC Letter at 50–51.

Service.[239] If margin is segregated, Agent Clearing Members would not bear the costs of financing margin obligations for customer positions—a cost saving that could be passed on to customers without exposing customers to FICC, fellow customer, or Netting Member risk.[240] Regarding the Sponsored Service, FICC states that many customers have clearing agreements in place that already provide for non-segregated margin.[241] By continuing to allow non-segregated margin within the Sponsored Service, FICC would enable such customers to maintain their existing clearing agreements and associated processes.[242]

FICC's explanation of the potential reasons why a customer may want to be able to pursue the various options of segregation within both models is sound. Each market participant will have to evaluate the advantages and drawbacks of each option and determine what works best for its own business. The existence of both segregated and omnibus options for both the Agent Clearing and Sponsored Services is consistent with Rule 17ad–22(e)(18)(iv)(C), which requires only that a covered clearing agency have written policies and procedures reasonably designed to ensure appropriate access to its clearing and settlement services, including for indirect participants.

For these reasons, FICC's proposals to include a ''road map'' describing the various GSD access models and to simplify the definitions regarding GSD membership would, among other things, provide clarity in the GSD Rules regarding the models that direct and indirect participants may use to access GSD's clearance and settlement services. The proposed changes would enable market participants to better understand and evaluate the various GSD access models for clearing transactions in U.S. Treasury securities. Therefore, the proposed changes would constitute criteria for participation that facilitate access to GSD's clearance and settlement services, including for indirect participants, consistent with Rule 17ad–22(e)(18)(iv)(C).[243]

Additionally, one commenter states that FICC should require Netting Member intermediaries to allow their customers to choose whether to access clearing through the Sponsored Service or the Agent Clearing Service.[244] The same commenter further states that that margin segregation should be automatic for any Sponsored Member that posts its own margin.[245]

In response, FICC states that the best way to facilitate access to clearing is to enable direct and indirect participants to select the access method and associated terms that are most consistent with their commercial, regulatory, risk, operational, and legal considerations. Moreover, FICC states that mandating that Netting Members offer a particular service or clearing model could be inconsistent with Section 17A(b)(3)(E) of the Exchange Act, which prohibits a clearing agency from imposing any schedule of prices, or fix rates or other fees for its participants' services.[246] In response to the comment regarding automatic margin segregation within the Sponsored Service, FICC states that margin segregation should not be automatic for Sponsored Members that post their own margin, because there are scenarios in which market participants may prefer the flexibility of choosing non-segregated margin even when a Sponsored Member posts its own margin.[247]

The Proposed Rule Change does not include a requirement that FICC's Netting Members offer their customers a choice of what access model to use. The Commission shall approve a proposed rule change of a self-regulatory organization if it finds that it is consistent with the Act,[248] and the lack of a requirement that each Netting Member give its customers the choice of which access model to use is not inconsistent with the Act.

One commenter raises concerns as to whether FICC has the operational capability to onboard and account for the large number of new accounts that would need to be established to support the increased volume of clearing activity that would arise from FICC's implementation of its requirements pursuant to the Treasury Clearing Rules.[249] Specifically, the commenter states that that FICC would need to establish and maintain a large number of new accounts because each Agent Clearing Member would need to set up an individual account at FICC for each indirect participant for which the Agent Clearing Member would segregate margin.[250]

In response, FICC states it proposed each access model after confirming that FICC has the ability, from a legal, operational, risk, regulatory, and commercial perspective, to provide such a model.[251] Regarding individual accounts, FICC states that neither the Sponsored Service nor the Agent Clearing Service would necessitate individual accounts for each customer.[252]

The Commission agrees that neither the Proposed Rule Change nor FICC's implementation of its other requirements pursuant to the Treasury Clearing Rules would require FICC to establish and maintain accounts for each indirect participant.[253] Moreover, in its supervisory capacity regarding FICC, the Commission routinely and regularly receives data, reports, and other information regarding FICC's clearance and settlement activities, including FICC's operational capabilities. Based on the Commission's supervisory knowledge, FICC has the requisite operational capacity to offer the access models that it has proposed.[254]

One commenter raised concerns regarding the inability of FCMs to utilize the GSD access models.[255] Specifically, the commenter states that certain regulatory requirements to which FCMs are subject would conflict with FCMs participating in both the Sponsored Service and Agent Clearing Service.[256] The commenter urges FICC

[239] *See id.*

[240] *See id.*

[241] *See id.*

[242] *See id.*

[243] *See* 17 CFR 240.17ad–22(e)(18)(iv)(C).

[244] *See* MFA Letter I at 7.

[245] *See id.*

[246] *See* FICC Letter at 32–33; 15 U.S.C. 78q–1(b)(3)(E).

[247] *See* FICC Letter at 21–22.

[248] *See* 15 U.S.C. 78s(b)(2)(C)(i).

[249] *See* SIFMA–AMG Letter at 12.

[250] *See id.*

[251] *See* FICC Letter at 22.

[252] *See id.*

[253] *See https://www.dtcc.com/-/media/Files/Downloads/Microsites/Treasury-Clearing/FICC-Treasury-Clearing-Client-Impact-Roadmap.pdf.*

[254] *See* 17 CFR 240.17ad–22(e)(18)(iv)(C).

[255] *See* Letter from Walt L. Lukken, President and Chief Executive Officer, Futures Industry of America (April 18, 2024) (''FIA Letter'') at 2–12. On July 1, 2024, FICC filed a separate proposed rule change that would, among other things, require each Netting Member to submit for central clearing all eligible secondary market transactions in U.S. Treasury securities to which it is a counterparty. *See* Securities Exchange Act Release No. 100417 (June 25, 2024), 89 FR 54602 (July 1, 2024) (SR–FICC–2024–009) (''Trade Submission Proposal''). The Commission notes that the FIA Letter includes a request for relief from the clearing requirement in the Trade Submission Proposal. *See* FIA Letter at 2–3. The commenter appropriately submitted a separate comment letter in response to the Trade Submission Proposal requesting similar relief, and the Commission will address the comment when adjudicating the Trade Submission Proposal. However, the commenter's request is outside the scope of the instant Proposed Rule Change.

[256] *See* FIA Letter at 4, 7–8 (citing CFTC Regulations regarding acceptable FCM counterparties, delivery-versus-payment and payment-versus-delivery requirements, posting collateral as margin for repos entered into with customer funds, FCM bankruptcy management, FCM repos with affiliates, and FCMs holding customer assets in customer segregated accounts).

to allow Netting Members to maintain sub-accounts for futures customer funds, cleared swaps customer funds, and foreign futures customer funds that comply with CFTC requirements.[257] Additionally, the commenter states that FCMs are currently seeking relief from the CFTC to recognize FICC as an acceptable counterparty and otherwise align the GSD access models with CFTC requirements.[258] In the interim, the commenter requests that FICC apply to FCMs certain GSD Rules that would exempt a Netting Member's Covered Affiliate from submitting trades to FICC if the obligation to submit the trade would cause a violation of any applicable law, rule, or regulation.[259] The commenter further requests that FICC work with FCMs and the CFTC to develop alternative CFTC-compliant access models.[260]

FICC states that it is open to considering additional access models if necessary to address market participants' regulatory or other needs.[261] In response to the commenter's request regarding sub-accounts, FICC states that the GSD Rules would allow Netting Members to instruct FICC to establish separate accounts for certain kinds of transactions and to have such accounts constitute separate margin portfolios.[262] Thus, a Netting Member that enters into transactions using futures, cleared swaps, or foreign futures customer funds could have those transactions recorded in an account that does not net with the Netting Member's other accounts for purposes of calculating margin or funds-only settlement amounts.[263]

The commenter specifically seeks relief from the CFTC from certain CFTC regulations, which are not within the Commission's jurisdiction.[264] The commenter also requests that FICC continue to apply certain GSD Rule provisions that would exempt FCMs from the requirement to submit trades to FICC if such trade submission would cause the FCM to be in violation of any applicable rule, or regulation.[265] The Commission notes that the GSD Rule provisions cited by the commenter are currently the subject of the Trade Submission Proposal, a separate pending proposed rule change filed by FICC.[266] Because the commenter's request to be excluded from the trade submission requirement deals with GSD Rule provisions that are subject to change as part of a separate proposed rule change, the Commission is not addressing the comment in the instant Order. For the same reason, the Commission is not addressing the commenter's request to require FICC to apply those GSD Rule provisions that are subject to change as part of a separate proposed rule change.[267]

Finally, the commenter requests that FICC work with FCMs and the CFTC to develop access models that are more suitable for FCMs than the Agent Clearing Service.[268] As mentioned above, FICC states that it is open to considering additional access models if necessary to address market participants' regulatory or other needs.[269] Additionally, FICC states that it continues to actively engage with the FCM community to resolve outstanding issues regarding the GSD access models.[270]

One commenter requests that FICC confirm that a bank's branches and Netting Member's affiliates can establish a separate margin portfolio within the Netting Member's account that would be separately netted and margined, such that they would not have to establish indirect access to FICC.[271] Because the commenter's request relates directly to GSD Rule provisions that are subject to change as part of the Trade Submission Proposal, a separate pending proposed rule change filed by FICC,[272] the Commission is not addressing the comment in the instant Order.

6. Comments Regarding Default Within the Client Clearing Models

Commenters raised several issues related to how FICC should address certain aspects of default within the Agent Clearing and Sponsored Services.

One commenter states that FICC should allow indirect participants to close out their positions with a defaulting Sponsoring Member or Agent Clearing Member.[273] For example, the commenter states that under the current GSD Rules, the process for closing out indirect participants' trade positions under the Sponsored Service is driven entirely by FICC, with indirect participants having no ''say'' in whether their positions are closed out, meaning that the customer may need to continue to rely on an insolvent (or near insolvent) Netting Member to make or receive payments on its behalf.[274] This commenter also states that FICC should clearly address Executing Firm Customers close-out rights in the event of the default of their Agent Clearing Member.[275] Alternatively, the commenter states that in the event of such a default, customers should be able to elect to receive payment directly from FICC, with FICC using any customer funds held at FICC to satisfy such amounts owed.[276] Similarly, an additional commenter states that the GSD Rules should address the situation of a FICC default simultaneous with a Sponsoring Member default, suggesting that Sponsored Members should have the ability to promptly close out and manage its positions.[277]

In response, FICC states that it was not aware of any such U.S. CCP that provides either for customers to have the ability to direct the CCP to terminate trades or to make payments directly to the customer, but that, instead, CCPs interface directly with clearing members, as agents for their customers consistent with the framework of an intermediated clearing arrangement.[278] FICC further states that, from a risk perspective, it important to FICC to interface with Netting Members as agents for their customers because Netting Members are subject to comprehensive operational requirements and testing that are designed to ensure that they have the capability to perform and to receive performance from FICC and that such performance will not expose FICC to operational risks (*e.g.,* systems failures and viruses).[279] FICC states that because customers are not subject to such requirements, FICC cannot establish interoperability without exposing itself, its participants, and the broader market to significant operational risk.[280] FICC also states that imposition of operational standards to customers would be quite burdensome, if not infeasible, for many customers, and that such burdens would likely outweigh any benefits of establishing interoperability with customers, because in a Netting Member default scenario, FICC would generally

[257] *See* FIA Letter at 8.

[258] *See* FIA Letter at 2–3, 11.

[259] *See* FIA Letter at 4–5; GSD Rule 11, Section 3 and GSD Rule 18, Section 2, *supra* note 15.

[260] *See* FIA Letter at 5, 8–10.

[261] *See* FICC Letter at 23.

[262] *See id.*

[263] *See id.*

[264] *See* FIA Letter at 4–5.

[265] *See id.;* GSD Rule 11, Section 3 and GSD Rule 18, Section 2, *supra* note 15.

[266] *See* Trade Submission Proposal, *supra* note 257.

[267] *See* FIA Letter at 11.

[268] *See* FIA Letter at 4–5.

[269] *See* FICC Letter at 23.

[270] *See* FICC Letter at 23–24.

[271] *See* ISDA Letter I at 6–7; ISDA Letter II at 5.

[272] *See* Trade Submission Proposal, *supra* note 257, at 89 FR 54605.

[273] *See* SIFMA–AMG Letter at 2, 6, 11.

[274] *See* SIFMA–AMG Letter at 7.

[275] *See id.*

[276] *See* SIFMA–AMG Letter at 2, 6, 11.

[277] *See* ICI Letter at 14.

[278] FICC Letter at 27.

[279] *See id.*

[280] *See id.*

close out trades or settle through the trustee or receiver of the defaulting member and applicable insolvency law would likely prohibit FICC from engaging directly with customers.[281]

The Proposed Rule Change does not include these types of close-out provisions for indirect participants that the commenter seeks. The Commission shall approve a proposed rule change of a self-regulatory organization if it finds that it is consistent with the Act,[282] and the lack of such close-out provisions is not inconsistent with the Act.

One commenter requests that FICC clarify the differences in the GSD Rules between the Sponsored Service and Agent Clearing Service governing a default of the Sponsoring Member or Agent Clearing Member.[283] The commenter states that the Proposed Rule Change suggests that customer positions will always be closed-out under the Agent Clearing Service, whereas FICC may elect to continue to settle customer positions under the Sponsored Service in the event of a Netting Member default.[284] FICC agrees with the commenter's suggestion that FICC should have the opportunity to settle the outstanding cleared transactions that a defaulting Agent Clearing Member has cleared through the Agent Clearing Service.[285] FICC states that, as a general matter, settlement may in many instances be the most effective and customer-protective way to address a member default scenario, so long as the receiver or trustee of the defaulting member consents.[286]

The Proposed Rule Change does not include the ability for FICC to settle the transactions of a defaulting Agent Clearing Member's customers that the commenter seeks. The Commission shall approve a proposed rule change of a self-regulatory organization if it finds that it is consistent with the Act,[287] and the lack of such close-out provisions is not inconsistent with the Act.

Some commenters question why the proposed Agent Clearing Service does not include a close-out mechanism regarding a defaulted customer's open positions, which could pose unique risks to an Agent Clearing Member by forcing it to keep a defaulted customer's positions open until the default is resolved.[288] One commenter further states that FICC may have declined to provide a mechanism for liquidating customer trades because, in contrast to the Sponsored Service, Executing Firm Customers are not members of FICC and therefore a ''close out amount'' cannot be calculated as between the customer and FICC.[289] However, this commenter also states that FICC could amend its rulebook to explicitly allow Netting Members to liquidate positions with defaulting customers, with such close-out procedure then addressed in account documentation between the Agent Clearing Member and its Executing Firm Customer.[290] Several commenters also state that FICC should allow an Agent Clearing Member to liquidate the transactions of a defaulted customer by transferring the positions to its proprietary account or by transferring offsetting positions to its omnibus account.[291] In addition, one commenter states that FICC should include similar trade liquidation procedures for done-away transactions cleared through the Sponsored Service.[292]

In response, FICC states that the Agent Clearing Service was designed to closely resemble the clearing model used in the futures and cleared swap market, and that such clearing models do not, to FICC's knowledge, prescribe a close-out mechanism for a clearing member to use to close out its customers' trades.[293] FICC further states that, instead, the clearing models generally leave it to the bilateral agreement between clearing members and their customers to address how such close-out should be effected. FICC also states that it is open to considering steps FICC can take to facilitate the ability of Netting Members to address a customer default situation and to promote legal certainty for both done-away and done-with transactions under the Agent Clearing and Sponsored Services.

The Proposed Rule Change does not include these types of close-out provisions that the commenter seeks. However, the Commission shall approve a proposed rule change of a self-regulatory organization if it finds that it is consistent with the Act,[294] and the lack of such close-out provisions is not inconsistent with the Act.

Several commenters state that the GSD Rules should provide for a porting mechanism to enable a customer to transfer positions to another Netting Member intermediary for risk management or business-related reasons.[295] Some commenters highlight that porting mechanisms exist in the cleared futures market as an important risk management tool.[296] In addition, one commenter states that in the event of a clearing member default, *all* non-defaulting customers will want the option to avoid immediately having their positions closed-out by FICC (regardless of whether their original execution counterparty was the clearing member or a third party), through either continuing to settle open positions or porting them to another clearing member.[297]

In response, FICC states that it intends to propose amendments to the GSD Rules that would add porting provisions similar to those adopted by other U.S.

[281] *See id.*

[282] *See* 15 U.S.C. 78s(b)(2)(C)(i).

[283] *See* FIA–PTG Letter at 8.

[284] *See* FIA–PTG Letter at 8; FIA–PTG Letter II at 3.

[285] *See* FICC Letter at 25–26.

[286] *See* FICC Letter at 26. FICC further states that it is considering amendments to the Proposed Rule Change that would give FICC the option to effectuate such settlement, but that it would be more efficient to propose such changes after the Commission has considered the Proposed Rule Change, but at the very least before Dec. 31, 2025. *See id.*

[287] *See* 15 U.S.C. 78s(b)(2)(C)(i).

[288] *See* SIFMA Letter I at 2–3 (stating that FICC should revise the Agent Clearing Service to allow Netting Members to liquidate positions of defaulting indirect participants, consistent with what is available in the Sponsored Service); *see also* ISDA Letter I at 2–3 and ISDA Letter II at 4 (similarly discussing the need to close-out positions by transferring them to the proprietary/house account or by transferring offsetting positions to the omnibus account).

[289] *See* SIFMA Letter I at 3.

[290] *See id.*

[291] *See* ISDA Letter I at 2–3 (stating that FICC should provide in the GSD Rules that an Agent Clearing Member may liquidate an Executing Firm Customer's positions by transferring the positions to its proprietary/house account or by transferring positions into the Agent Clearing Member Omnibus Account to flatten open positions of the Executing Firm Customer); ISDA Letter II at 4 (same); FIA Letter at 5, 10 (stating that FICC should incorporate a rule that authorizes an Agent Clearing Member, in connection with liquidating an Executing Firm Customer's open positions upon its default, to cause the Executing Firm Customer's open positions to be transferred from the applicable Agent Clearing Member Omnibus Account and/or transfer to the Agent Clearing Member Omnibus Account transactions that offset or flatten the Executing Firm Customer's open positions); SIFMA Letter I at 2–3 (stating that FICC's proposed rules should permit Netting Members to transfer a defaulting customer's positions to the Netting Member's Proprietary Account or Agent Clearing Member Omnibus Account to flatten open positions of the defaulting Executing Firm Customer).

[292] *See* ISDA Letter II at 4.

[293] *See* FICC Letter at 26.

[294] *See* 15 U.S.C. 78s(b)(2)(C)(i).

[295] *See* FIA–PTG Letter I at 8; ISDA Letter I at 5; MFA Letter I at 6, 8; FIA Letter at 11; SIFMA Letter I at 2, 4; SIFMA–AMG Letter at 2–3; ISDA Letter II at 3–4; FIA–PTG Letter II at 2; MFA Letter II at 7.

[296] *See* ISDA Letter I at 5 (stating that many cleared futures clients are accustomed to their porting rights and use them as an important risk management tool); ISDA Letter II at 3–4 (stating that the commenting association's members have already come to rely on this type of guardrail in the futures clearing model as an essential risk management tool); MFA Letter I at 6 (stating that porting is an important risk management tool that provides additional certainty to indirect participants, particularly during periods of market stress); SIFMA–AMG Letter at 8 (stating that the ability to port positions is an important feature of the cleared swaps and futures market.).

[297] *See* Citadel Letter at 5.

CCPs, to make clear that porting is possible for FICC-cleared trades.[298] FICC also states its belief that it will be more efficient to wait until the Commission decides whether to approve or disapprove the Proposed Rule Change before proposing a specific porting framework, and states that it will seek to facilitate porting before December 31, 2025.[299] FICC also states that any porting framework would need to take into consideration the fact that many FICC-cleared customer transactions are overnight, and that porting may not be practical for such transactions because they will generally settle before the porting can be completed.[300] FICC further states that the ability to settle (which is currently included in the GSD Rules governing the Sponsored Service) is therefore substantially more important than the ability to port.[301]

The Proposed Rule Change does not contain any provisions related to porting customer transactions at FICC. However, the Commission shall approve a proposed rule change of a self-regulatory organization if it finds that it is consistent with the Act,[302] and the lack of porting provisions is not inconsistent with the Act.

Accordingly, for the reasons above, the Proposed Rule Change is consistent with Rule 17ad–22(e)(18)(iv)(C).[303]

E. Consistency With Rule 17ad–22(e)(23)(ii)

Rule 17ad–22(e)(23)(ii) under the Exchange Act requires a covered clearing agency, such as FICC, to establish, implement, maintain, and enforce written policies and procedures reasonably designed to provide sufficient information to enable participants to identify and evaluate the risks, fees, and other material costs they incur by participating in the covered clearing agency.[304]

Several commenters state that FICC should regularly publish statistics regarding the GSD access models, such as the volumes and proportion of transactions cleared through each access model and transactions executed on done-with and done-away bases.[305] The commenters suggest that FICC's publication of such data would enable market participants to better evaluate which access model best fits their business needs.[306] FICC responds that it intends to collect and publish information regarding the GSD access models, including the (1) number of Netting Members enabled to use each model, (2) number of Sponsoring Members enabled to offer done-away clearing, and (3) volumes of trading through each access model, including the number of transactions and total notional.[307] The Commission agrees that FICC's regular publication of the foregoing data should provide information that would better enable market participants to evaluate the GSD access models.

One commenter states that in addition to regularly publishing the data referenced in the immediately preceding paragraph, FICC should also regularly publish the number of clearing members who are in fact clearing more than *de minimis* volumes pursuant to each such model, and clearly separate out done-with and done-away activity.[308] The Proposed Rule Change does not contain any provisions related to FICC's publication of the specific data requested by the commenter. The Commission shall approve a proposed rule change of a self-regulatory organization if it finds that it is consistent with the Act,[309] and the lack of provisions regarding FICC's regular publication of the data requested by the commenter is not inconsistent with the Act.

For the reasons discussed above, the Proposed Rule Change would enable FICC to establish, implement, maintain, and enforce written policies and procedures reasonably designed to provide sufficient information to enable members to identify and evaluate the risks, fees, and other material costs they incur as FICC's members, consistent with Rule 17ad–22(e)(23)(ii).[310]

III. Conclusion

On the basis of the foregoing, the Commission finds that the Proposed Rule Change is consistent with the requirements of the Exchange Act and in particular with the requirements of Section 17A of the Exchange Act[311] and the rules and regulations promulgated thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Exchange Act[312] that proposed rule change SR–FICC–2024–005, be, and hereby is, Approved.[313]

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[314]

Sherry R. Haywood,

Assistant Secretary.

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[298] *See* FICC Letter at 25.

[299] *See id.*

[300] *See id.*

[301] *See id.*

[302] *See* 15 U.S.C. 78s(b)(2)(C)(i).

[303] *See* 17 CFR 240.17ad–22(e)(18)(iv)(C).

[304] 17 CFR 240.17ad–22(e)(23)(ii).

[305] *See* FIA–PTG Letter I at 4; MFA Letter I at 8; AIMA Letter at 6.

[306] *See id.*

[307] *See* FICC Letter at 20–21.

[308] *See* FIA–PTG Letter II at 4.

[309] *See* 15 U.S.C. 78s(b)(2)(C)(i).

[310] 17 CFR 240.17ad–22(e)(23)(ii).

[311] 15 U.S.C. 78q–1.

[312] 15 U.S.C. 78s(b)(2).

[313] In approving the proposed rule change, the Commission considered the proposals' impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[314] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101698; File No. SR–MIAX–2024–40]

Self-Regulatory Organizations; MIAX Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rule 402, Criteria for Underlying Securities, Exchange Rule 307, Position Limits, and Exchange Rule 309, Exercise Limits To Allow the Exchange To List and Trade Options on the iShares Bitcoin Trust (the "Trust")

November 21, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 18, 2024, Miami International Securities Exchange, LLC (''MIAX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Exchange Rule 402, Criteria for Underlying Securities, Exchange Rule 307, Position Limits, and Exchange Rule 309, Exercise Limits.

The text of the proposed rule change is available on the Exchange's website at *https://www.miaxglobal.com/markets/us-options/miax-options/rule-filings,* at MIAX's principal office, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Exchange Rule 402, Criteria for Underlying Securities, Exchange Rule 307, Position Limits, and Exchange Rule 309, Exercise Limits,[3] to allow the Exchange to list and trade options on the iShares Bitcoin Trust (the ''Trust''), designating the Trust as appropriate for options trading on the Exchange.[4] This is a competitive filing based on a similar proposal submitted by Nasdaq ISE, LLC (''ISE'') and approved by the Securities and Exchange Commission (''Commission'').[5]

Current Exchange Rule 402(i)(4) provides that securities deemed appropriate for options trading include shares or other securities (''Exchange Traded Fund Shares'') that are traded on a national securities exchange and are defined as ''NMS stock'' under Rule 600 of Regulation NMS, and that meet specified criteria enumerated in the rule. Sub Section 4 of Exchange Rule 402(i) provides that such shares or other securities:

> (4) are issued by the SPDR® Gold Trust or the iShares COMEX Gold Trust or the iShares Silver Trust or the ETFS Silver Trust or the ETFS Gold Trust or the ETFS Palladium Trust or the ETFS Platinum Trust or the Sprott Physical Gold Trust; or

In addition, the underlying securities and Exchange Rule 402i, including the commodity based trusts in Exchange Rule 402(i)(4), must meet the requirements of Exchange Rule 402(i), Sections (5)(i)(A) or (B).

Proposal

The Exchange proposes to amend Exchange Rule 402(i)(4) to expand the list of securities that are appropriate for options trading on the Exchange.

Description of the Trust[6]

The shares are issued by the Trust, a Delaware statutory trust. The Trust operates pursuant to a trust agreement (the ''Trust Agreement'') between the Sponsor, BlackRock Fund Advisors (the ''Trustee'') as the trustee of the Trust and Wilmington Trust, National Association, as Delaware trustee . The Trust issues shares representing fractional undivided beneficial interests in its net assets. The assets of the Trust consist only of bitcoin, held by a custodian on behalf of the Trust except under limited circumstances when transferred through the Trust's prime broker temporarily (described below), and cash. Coinbase Custody Trust Company, LLC (the ''Bitcoin Custodian'') is the custodian for the Trust's bitcoin holdings, and maintains a custody account for the Trust (''Custody Account''); Coinbase, Inc. (the ''Prime Execution Agent''), an affiliate of the Bitcoin Custodian, is the prime broker for the Trust and maintains a trading account for the Trust (''Trading Account''); and Bank of New York Mellon is the custodian for the Trust's cash holdings (the ''Cash Custodian'' and together with the Bitcoin Custodian, the ''Custodians'') and the administrator of the Trust (the ''Trust Administrator''). Under the Trust Agreement, the Trustee may delegate all or a portion of its duties to any agent, and has delegated the bulk of the day to day responsibilities to the Trust Administrator and certain other administrative and record-keeping functions to its affiliates and other agents. The Trust is not an investment company registered under the Investment Company Act of 1940, as amended.

The investment objective of the Trust is to reflect generally the performance of the price of bitcoin. The Trust seeks to reflect such performance before payment of the Trust's expenses and liabilities. The shares are intended to constitute a simple means of making an investment similar to an investment in bitcoin through the public securities market rather than by acquiring, holding and trading bitcoin directly on a peer-to-peer or other basis or via a digital asset exchange. The shares have been designed to remove the obstacles represented by the complexities and operational burdens involved in a direct investment in bitcoin, while at the same time having an intrinsic value that reflects, at any given time, the investment exposure to the bitcoin owned by the Trust at such time, less the Trust's expenses and liabilities. Although the shares are not the exact equivalent of a direct investment in bitcoin, they provide investors with an alternative method of achieving investment exposure to bitcoin through the public securities market, which may be more familiar to them.

Custody of the Trust's Bitcoin

An investment in the shares is backed by bitcoin held by the Bitcoin Custodian on behalf of the Trust. All of the Trust's bitcoin will be held in the Custody Account, other than the Trust's bitcoin which is temporarily maintained in the Trading Account under limited circumstances, *i.e.,* in connection with creation and redemption Basket[7] activity or sales of bitcoin deducted from the Trust's holdings in payment of Trust expenses or the Sponsor's fee (or, in extraordinary circumstances, upon liquidation of the Trust). The Custody Account includes all of the Trust's bitcoin held at the Bitcoin Custodian,

[3] The Exchange notes that its affiliate exchanges, MIAX Pearl and MIAX Sapphire, submitted substantively identical proposals. The Exchange notes that all the rules of Chapter III of the MIAX Options Exchange, including Rules 307 and 309, are incorporated by reference to MIAX Pearl and MIAX Sapphire. The Exchange also notes that all of the rules of Chapter III of the MIAX Options Exchange, including Rules 307 and 309, and the rules of Chapter IV of the MIAX Options Exchange, including Rule 402, are incorporated by reference to MIAX Emerald.

[4] On January 10, 2024, the Commission approved proposals by NYSE Arca, Inc., The Nasdaq Stock Market LLC, and Cboe BZX Exchange, Inc. to list and trade the shares of 11 bitcoin-based commodity-based trust shares and trust units, including the iShares Bitcoin Trust. *See* Securities Exchange Act Release No. 99306 (Jan. 10, 2024), 89 FR 3008 (Jan. 17, 2024) (order approving File Nos. SR–NYSEARCA–2021–90; SR–NYSEARCA–2023–44; SR–NYSEARCA–2023–58; SR–NASDAQ–2023–016; SR–NASDAQ–2023–019; SR–CboeBZX–2023–028; SR–CboeBZX–2023–038; SR–CboeBZX–2023–040; SR–CboeBZX–2023–042; SR–CboeBZX–2023–044; SR–CboeBZX–2023–072) (''Bitcoin ETP Order'').

[5] *See* Securities Exchange Act Release No. 101128 (September 20, 2024), 89 FR 78942 (September 26, 2024) (SR–ISE–2024–03) (Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing of Amendment Nos. 4 and 5 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment Nos. 1, 4, and 5, to Permit the Listing and Trading of Options on the iShares Bitcoin Trust).

[6] *See* Securities Exchange Act Release No. 99306 (Jan. 10, 2024), 89 FR 3008 (Jan. 17, 2024) (order approving File Nos. SR–NYSEARCA–2021–90; SR–NYSEARCA–2023–44; SR–NYSEARCA–2023–58; SR–NASDAQ–2023–016; SR–NASDAQ–2023–019; SR–CboeBZX–2023–028; SR–CboeBZX–2023–038; SR–CboeBZX–2023–040; SR–CboeBZX–2023–042; SR–CboeBZX–2023–044; SR–CboeBZX–2023–072) (Order Granting Accelerated Approval of Proposed Rule Changes, as Modified by Amendments Thereto, To List and Trade Bitcoin-Based Commodity-Based Trust Shares and Trust Units) for a complete description of the Trust.

[7] The Trust issues and redeems Shares only in blocks of 40,000 or integral multiples thereof. A block of 40,000 Shares is called a ''Basket.'' These transactions take place in exchange for Bitcoin.

but does not include the Trust's bitcoin temporarily maintained at the Prime Execution Agent in the Trading Account from time to time. The Bitcoin Custodian will keep all of the private keys associated with the Trust's bitcoin held in the Custody Account in ''cold storage''.[8] The hardware, software, systems, and procedures of the Bitcoin Custodian may not be available or cost-effective for many investors to access directly.

The Exchange believes that offering options on the Trust will benefit investors by providing them with an additional, relatively lower cost investing tool to gain exposure to spot Bitcoin as well as a hedging vehicle to meet their investment needs in connection with Bitcoin products and positions. Similar to other commodity-based trusts on which options may be listed on the Exchange (*e.g.* SPDR® Gold Trust, the iShares COMEX Gold Trust, the iShares Silver Trust, or the ETFS Gold Trust),[9] the Trust essentially offers the same objectives and benefits to investors as do other commodity-based trusts on which options may be listed on the Exchange.

Options on the Trust will trade in the same manner as options on other ETFs on the Exchange. Exchange Rules that currently apply to the listing and trading of all options on ETFs on the Exchange, including, for example, Rules that govern listing criteria, expirations, exercise prices, minimum increments, position and exercise limits (including as proposed herein), margin requirements, customer accounts and trading halt procedures, will apply to the listing and trading of options on the Trust on the Exchange. Today, these rules apply to options on the various commodities-based trusts deemed appropriate for options trading on the Exchange pursuant to Exchange Rule 402(i)(4).

The Exchange's initial listing standards for ETFs on which options may be listed and traded on the Exchange will apply to the Trust. Pursuant to Exchange Rule 402(a), a security (which includes ETFs) on which options may be listed and traded on the Exchange must be registered (with the Commission) and be an NMS stock (as defined in Rule 600 of Regulation NMS under the Act,) and be characterized by a substantial number of outstanding shares that are widely held and actively traded. Exchange Rule 402(i) requires that, in relevant part, ETFs must either (1) meet the criteria and standards set forth in Exchange Rule 402(a) or Exchange Rule 402(b), or (2) be available for creation or redemption each business day from or through the issuer in cash or in kind at a price related to net asset value, and the issuer must be obligated to issue ETFs in a specified aggregate number even if some or all of the investment assets required to be deposited have not been received by the issuer, subject to the condition that the person obligated to deposit the investments has undertaken to deliver the investment assets as soon as possible and such undertaking is secured by the delivery and maintenance of collateral consisting of cash or cash equivalents satisfactory to the issuer, as provided in the respective prospectus.

Options on the Trust will also be subject to the Exchange's continued listing standards set forth in Exchange Rule 403(g), for ETFs deemed appropriate for options trading pursuant to Exchange Rule 402(i). Specifically, Exchange Rule 403(g) provides that ETFs that were initially approved for options trading pursuant to Exchange Rule 402(i) shall be deemed not to meet the requirements for continued approval, and the Exchange shall not open for trading any additional series of option contracts of the class covering that such ETFs, if the ETFs are delisted from trading pursuant to Exchange Rule 403(b)(4), are halted or suspended from trading in their primary market. Additionally, options on ETFs may be subject to the suspension of opening transactions in any of the following circumstances: (1) in the case of options covering ETFs approved for trading under Exchange Rule 402(i)(5)(i)(A), in accordance with the terms of paragraphs (b)(1), (2), and (3) of Exchange Rule 403; (2) in the case of options covering ETFs approved for trading under Exchange Rule 402(i)(5)(i)(B), following the initial twelve-month period beginning upon the commencement of trading in the ETFs on a national securities exchange and are defined as an NMS stock, there are fewer than 50 record and/or beneficial holders of such ETFs for 30 or more consecutive trading days; (3) the value of the index or portfolio of securities, non-U.S. currency, or portfolio of commodities including commodity futures contracts, options on commodity futures contracts, swaps, forward contracts and/or options on physical commodities and/or financial instruments and money market instruments on which the ETFs are based is no longer calculated or available; or (4) such other event shall occur or condition exist that in the opinion of the Exchange makes further dealing in such options on the Exchange inadvisable.

Options on the Trust would be physically settled contracts with American-style exercise.[10] Consistent with current Exchange Rule 404, which governs the opening of options series on a specific underlying security (including ETFs), the Exchange will open at least one expiration month for options on the Trust[11] and may also list series of options on the Trust for trading on a weekly,[12] monthly,[13] or quarterly[14] basis. The Exchange may also list long-term equity option series (''LEAPS'') that expire from 12 to 39 months from the time they are listed.[15]

Pursuant to Exchange Rule 404, Interpretation and Policy .06, which governs strike prices of series of options on ETFs, the interval between strike prices of series of options on ETFs approved for options trading pursuant to Exchange Rule 402(i) shall be fixed at a price per share which is reasonably close to the price per share at which the

[8] The term ''cold storage'' refers to a safeguarding method by which the private keys corresponding to the Trust's bitcoins are generated and stored in an offline manner, subject to layers of procedures designed to enhance security. Private keys are generated by the Bitcoin Custodian in offline computers that are not connected to the internet so that they are more resistant to being hacked.

[9] *See* Exchange Rule 402(i)(4).

[10] *See* Exchange Rule 401, which provides that the rights and obligations of holders and writers are set forth in the Rules of the Options Clearing Corporation (''OCC''); *see also* OCC Rules, Chapters VIII (which governs exercise and assignment) and Chapter IX (which governs the discharge of delivery and payment obligations arising out of the exercise of physically settled stock option contracts).

[11] *See* Exchange Rule 404(b). The monthly expirations are subject to certain listing criteria for underlying securities described within Exchange Rule 404 and its Interpretations and Policies. Monthly listings expire the third Friday of the month. The term ''expiration date'' (unless separately defined elsewhere in the OCC By-Laws), when used in respect of an option contract (subject to certain exceptions), means the third Friday of the expiration month of such option contract, or if such Friday is a day on which the exchange on which such option is listed is not open for business, the preceding day on which such exchange is open for business. *See* OCC By-Laws Article I, Section 1. Pursuant to Exchange Rule 404(c), additional series of options of the same class may be opened for trading on the Exchange when the Exchange deems it necessary to maintain an orderly market, to meet customer demand or when the market price of the underlying stock moves more than five strike prices from the initial exercise price or prices. Pursuant to Exchange Rule 404(e), new series of options on an individual stock may be added until the beginning of the month in which the options contract will expire. Due to unusual market conditions, the Exchange, in its discretion, may add a new series of options on an individual stock until the close of trading on the business day prior to expiration.

[12] *See* Exchange Rule 404, Interpretations and Policies .02.

[13] *See* Exchange Rule 404, Interpretations and Policies .13.

[14] *See* Exchange Rule 404, Interpretations and Policies .03.

[15] *See* Exchange Rule 404(d).

underlying security is traded in the primary market at or about the same time such series of options is first open for trading on the Exchange, or at such intervals as may have been established on another options exchange prior to the initiation of trading on the Exchange. With respect to the Short Term Options Series or Weekly Program, during the month prior to expiration of an option class that is selected for the Short Term Option Series Program, the strike price intervals for the related non-Short Term Option (''Related non-Short Term Option'') shall be the same as the strike price intervals for the Short Term Option.[16] Specifically, the Exchange may open for trading Short Term Option Series at strike price intervals of (i) $0.50 or greater where the strike price is less than $100, and $1 or greater where the strike price is between $100 and $150 for all option classes that participate in the Short Term Options Series Program; (ii) $0.50 for option classes that trade in one dollar increments and are in the Short Term Option Series Program; or (iii) $2.50 or greater where the strike price is above $150.[17] Additionally, the Exchange may list series of options pursuant to the $1 Strike Price Interval Program,[18] the $0.50 Strike Program,[19] and the $2.50 Strike Price Program.[20] Pursuant to Exchange Rule 510, where the price of a series of options for the Trust is less than $3.00, the minimum increment will be $0.05, and where the price is $3.00 or higher, the minimum increment will be $0.10[21] consistent with the minimum increments for options on other ETFs listed on the Exchange. Any and all new series of Trust options that the Exchange lists will be consistent and comply with the expirations, strike prices, and minimum increments set forth in Rules 404 and 510, as applicable.

Position and exercise limits for options on ETFs, including options on the Trust, are determined pursuant to Exchange Rules 307 and 309, respectively. Position and exercise limits for ETF options vary according to the number of outstanding shares and the trading volumes of the underlying ETF over the past six months, where the largest in capitalization and the most frequently traded ETFs have an option position and exercise limit of 250,000 contracts (with adjustments for splits, re-capitalizations, etc.) on the same side of the market; and smaller capitalization ETFs have position and exercise limits of 200,000, 75,000, 50,000 or 25,000 contracts (with adjustments for splits, re-capitalizations, etc.) on the same side of the market. The Exchange proposes to cap the position and exercise limits for the Trust at 25,000 contracts. Capping the position and exercise limits at 25,000 contracts, the lowest limits available in options, would address concerns related to manipulation and protection of investors as this number is extremely conservative for the Trust and is more than appropriate given its liquidity.

For purposes of addressing position and exercise limits, the Exchange applies position and exercise limits for options for each underlying security and does not aggregate position and exercise limits. In considering the appropriate position and exercise limits for the Trust, the Exchange reviewed the data presented by ISE in its filing, specifically in Exhibit 3 of the filing,[22] where ISE measured the Trust's market capitalization and ADV against other industry data as explained further below. The Commission should consider the position and exercise limits for options on the Trust exclusive of other options on bitcoin.

In its filing, ISE considered the Trust's market capitalization and ADV, and prospective position limit in relation to other securities. In measuring the Trust against other securities, ISE aggregated market capitalization and volume data for securities that have defined position limits utilizing data from The Options Clearing Corporations (''OCC'').[23] This pool of data took into consideration 3,984 options on single stock securities, excluding broad based ETFs.[24] Next, ISE aggregated the data based on market capitalization and ADV and grouped option symbols by position limit utilizing statistical thresholds for ADV and market capitalization that were one standard deviation above the mean for each position limit category (*i.e.* 25,000, 50,000 to 65,000, 75,000, 100,000 to less than 250,000, 250,000 to 400,000, 450,000 to 1,000,000, and greater than or equal to 1,000,000)(sic).[25] Exchange Rule 307(d) sets out position limits for various contracts. For example, on the Exchange like on ISE, a 25,000 contract limit applies to those options having an underlying security that does not meet the requirements for a higher options contract limit. ISE performed an exercise to demonstrate the Trust's position limit relative to other options symbols in terms of market capitalization and ADV. For reference the market capitalization for the Trust was 19,789,068 billion[26] with an ADV, for the preceding three months prior to August 7, 2024, of greater than 26 million shares.[27] Today, by comparison, other options symbols with similar market capitalization and ADV have a position limit in excess of 400,000.[28] Therefore, the proposed 25,000 same side position limit for options on the Trust is extremely conservative relative to these options symbols which are a full standard deviation above the mean in comparison.

Second, ISE reviewed the Trust's data relative to the market capitalization of the entire bitcoin market in terms of exercise risk and availability of deliverables. Utilizing data as of August 3, 2024, there were 19,737,193 bitcoins in circulation.[29] ISE took a price of $57,000 that equates to a market capitalization of greater than 1.125 trillion US dollars, and applied that to a position limit of 400,000 for options on the Trust.[30] If a position limit of 400,000 options were considered (the position limit that would be typically assigned based upon data) the exercisable risk would represent only 6.6% of the outstanding shares of the Trust. The 25,000 position limit being sought only represents 0.4% of the outstanding shares of the Trust. Since the Trust has a creation and redemption process managed through the issuer, additionally it can be compared the position limit sought to the total market capitalization of the entire bitcoin market. In this case, the exercisable risk for options on the Trust would be less

[16] *See* Exchange Rule 404, Interpretations and Policies .02(e).

[17] *Id.*

[18] *See* Exchange Rule 404, Interpretation and Policy .01.

[19] *See* Exchange Rule 404, Interpretation and Policy .04.

[20] *See* Exchange Rule 404(f).

[21] *See* Exchange Rule 510.

[22] *See* Securities Exchange Act Release No. 101128 (September 20, 2024), 89 FR 78942 (September 26, 2024) (SR–ISE–2024–03) (Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment Nos. 1, 4, and 5, to Permit the Listing and Trading of Options on the iShares Bitcoin Trust) (Exhibit 3) (''IBIT Approval Order'') (letter from Angela Dunn, Nasdaq ISE, LLC, to Vanessa Countryman, Secretary, Commission, dated August 21, 2024)(''ISE Letter'').

[23] The computations are based on OCC data from August 6, 2024. Data displaying zero values in market capitalization or ADV were removed.

[24] The Trust has one asset and therefore is not comparable to a broad based ETF where there are typically multiple components.

[25] *See* ISE Letter at 10.

[26] ISE acquired this figure as of August 13, 2024. *See https://www.ishares.com/us/products/333011/ishares-bitcoin-trust.* The global supply of bitcoin grows each day bitcoin are minted.

[27] *See* ISE Letter at 10.

[28] *See, eg,.* iShares® iBoxx® $ High Yield Corporate Bond ETF (''HYG'') with a market capitalization of 13,859,235,000 billion as of November 4, 2024. *See https://www.ishares.com/us/products/239565/ishares-iboxx-high-yield-corporate-bond-etf.* The Exchange notes that HYG has a position limit of 500,000 contracts.

[29] *See* ISE Letter at 10.

[30] Id.

than 0.01% of the market capitalization of all outstanding bitcoin. Assuming a scenario where all options on the Trust's shares were exercised given the proposed 25,000 per same side position limit, this would have a virtually unnoticed impact on the entire bitcoin market. This analysis demonstrates that the proposed 25,000 per same side position limit is also extremely conservative and more than appropriate for options on the Trust.

Third, ISE reviewed the proposed position limit by comparing it to position limits for derivative products regulated by the Commodity Futures Trading Commission (''CFTC''). While the CFTC, through the relevant Designated Contract Markets, only regulates options positions based upon delta equivalents (creating a less stringent standard), ISE examined equivalent bitcoin futures position limits. In particular, ISE looked at the CME bitcoin futures contract [31] that has a position limit of 2,000 futures.[32] On August 7, 2024, CME bitcoin futures settled at $55,000.[33] Taking the position limit of 2,000 futures at a $5 multiplier [34] equates to $550 million of notional value for bitcoin futures. By way of comparison, on August 7, 2024, the Trust settled at $31.19 per share, which would equate to 17,633,857 shares of the Trust [35] if the CME notional position limit were utilized. Since substantial portions of any distributed options portfolio are likely to be out of the money on expiration, an options position limit equivalent to the CME position limit for bitcoin futures (considering that all options deltas are ≤1.00) should be a bit higher than the CME implied 176,338 limit.

Of note, unlike options contracts, CME position limits are calculated on a net futures equivalent basis by contract and include contracts that aggregate into one or more base contract according to an aggregation ratio(s).[36] Therefore, if a portfolio includes positions in options on futures, CME would aggregate those positions into the underlying futures contracts in accordance with a table published by CME on a delta equivalent value for the relevant spot month, subsequent spot month, single month and all month position limits.[37] If a position exceeds position limits because of an option assignment, CME permits market participants to liquidate the excess position within one business day without being considered in violation of its rules. Additionally, if at the close of trading, a position that includes options exceeds position limits for futures contracts, when evaluated using the delta factors as of that day's close of trading, but does not exceed the limits when evaluated using the previous day's delta factors, then the position shall not constitute a position limit violation. Considering CME's position limits on futures for bitcoin, the Exchange believes that the proposed 25,000 per same side position limit is conservative and more than appropriate for options on the Trust.

In analyzing the proposed position limit for options on the Trust, ISE also considered the supply of bitcoin. Specifically, ISE examined the number of market participants with position limits that would need to exercise in unison to put the underlying asset under stress. In the case of options on the Trust, the proposed 25,000 same side position limit effectively restricts a market participant from holding positions that could be exercised in excess of 2,500,000 shares of the Trust. Utilizing data from August 12, 2024, the Trust had 611,040,000 shares outstanding, therefore 244 market participants would have to simultaneously exercise position limits in order to create a scenario that may put the underlying asset (the Trust) under stress.[38] The Exchange notes that historically, from observation only, it appears that no more than five market participants holding position limits in any security have exercised in unison in any option. As unlikely an occurrence as all market participants exercising their position limits in unison would be, if it were to occur, it should be noted that even such an occurrence would not likely put the Trust under stress as economic incentives, would induce the creation of more shares through the ETF creation and redemption process.

By way of example, given that the current global supply of bitcoin, the underlying asset of the Trust, is 19,789,068 [39] and that each bitcoin can currently be redeemed for 1,755 shares of the Trust, another 34,729,814,340 shares of the Trust could be created. To exhaust this supply of the Trust, 13,891 market participants would have to simultaneously exercise their position limit. Comparing the Trust to the SPDR Gold Shares (''GLD'') ETF or the iShares Silver Trust (''SLV'') ETF, which have position limits of 250,000 or ten times the proposed position limit for the Trust as well as lower shares outstanding in both products,[40] it is unjustified to mandate a different level of stringency with respect to a position limit for options on the Trust.

The supply of bitcoin does have a limit, which will take years to fully mint.[41] The Exchange notes that bitcoin is a viable economic alternative to traditional assets. The price of goods denominated by bitcoin has actually declined. This dynamic not only makes a fixed supply desirable, but a necessary condition of the value added by this asset in the broader economy. Further, the Exchange notes that corporations have a limited number of outstanding shares. Corporations may authorize additional shares, repurchase shares or split their shares. Similarly, ETFs, like the Trust, may also create, redeem, or split shares to suit the demand of the marketplace.

Importantly, because the supply of bitcoin is much larger than the available supply of most securities and the proposed 25,000 contract position limit is so conservative, the Exchange believes that evaluating the available supply of bitcoin in establishing a position limit for options on the Trust would demonstrate that the proposed limit is safe for investors and the market.[42] The Trust constitutes less than 2% of the entire bitcoin supply. When comparing the market capitalization of bitcoin against the largest securities, bitcoin would rank 7th among those

[31] CME Bitcoin Futures are described in Chapter 350 of CME's Rulebook.

[32] *See* the Position Accountability and Reportable Level Table in the Interpretations & Special Notices Section of Chapter 5 of CME's Rulebook.

[33] *See https://finance.yahoo.com/quote/BTC%3DF/history/?guccounter=1&guce_referrer=aHR0cHM6Ly93d3cuZ29vZ2xlLmNvbS8&guce_referrer_sig=AQAAAM7ngaS6ZQS9c2Wzx7JW2IUe-_-_1FnLyr8T-Qw4jjkleHyCENfSMIEpPPt2hCzPDEryTVyB78NIwxkwFB5Fuw-jA-YiuSmYJHBriWbV6dYn91VQfzQNt3p0I2RkYLD3HhzXPwu4AP5as-_WzHNpEBon4sk5sUZXgkapMrZR—CS.*

[34] Each bitcoin futures contract is valued at 5 bitcoins as defined by the CME CF Bitcoin Reference Rate (''BRR''). *See* CME Rule 35001.

[35] *See* ISE Letter at 11.

[36] *See https://www.cmegroup.com/education/courses/market-regulation/position-limits/positionlimits-aggregation-of-contracts-and-table.htm.*

[37] *Id.*

[38] *See https://www.ishares.com/us/products/333011/ishares-bitcoin-trust.*

[39] This figure was acquired as of August 13, 2024. *See https://www.ishares.com/us/products/333011/ishares-bitcoin-trust.* The global supply of bitcoin grows each day bitcoin are minted.

[40] As of August 13, 2024, GLD had 294,000,000 shares outstanding and SLV had 510,200,000 shares outstanding. *See https://www.ssga.com/us/en/intermediary/etfs/funds/spdr-gold-shares-gld* and *https://www.ishares.com/us/products/239855/ishares-silver-trust-fund.*

[41] A recent article suggested that the remaining supply will take over 100 years to fully mint. *See* Sen, Vivek. ''94% of Bitcoin's Supply Has Now Been Issued.'' *Bitcoin Magazine, https://bitcoinmagazine.com/business/94-of-bitcoins-supply-has-now-been-issued.* August 19, 2024.

[42] A supply consideration would likely be valuable for an option symbol that had far less liquidity than the Trust.

securities.[43] Further, the Exchange believes that its proposal to list options on the Trust with a position limit of 25,000 on the same side is a conservative position limit that does not lend itself to manipulation in the market given the ample market capitalization and liquidity in the Trust. If we look to the liquidity statistics of similar instruments and their concomitant position limits, we are able to extrapolate a reasonable standard for arriving at a position limit for a new product. In this case we can look to GLD, SLV, and the ProShares Bitcoin Strategy ETF (''BITO''). These products have volume statistics and ''float'' statistics, which gauge liquidity, which are in line, yet slightly lower than the Trust. All three of these reference products have position limits of 250,000 contracts. These reference products are remarkably similar in nature to the Trust; they are exchange-traded products (''ETPs'') holding one asset in a trust.

The Exchange further notes that Exchange Rule 1502, which governs margin requirements applicable to trading on the Exchange, including options on ETFs, will also apply to the trading of the Trust options. Notwithstanding the position limits in Exchange Rule 307(d) and exercise limits in Exchange Rule 309, the Exchange proposes the position and exercise limits for the options on the Trust to be 25,000 contracts on the same side pursuant to proposed Supplementary Material .01 to Exchange Rule 307 and proposed Supplementary Material .01 to Exchange Rule 309.

The Exchange represents that the same surveillance procedures applicable to all other options on other ETFs currently listed and traded on the Exchange will apply to options on the Trust. Also the Exchange represents that it has the necessary systems capacity to support the new option series. The Exchange believes that its existing surveillance and reporting safeguards are designed to deter and detect possible manipulative behavior which might potentially arise from listing and trading options on ETFs, including the proposed Trust options.

Today, the Exchange has an adequate surveillance program in place for options. The Exchange intends to apply those same program procedures to options on the Trust that it applies to the Exchange's other options products.[44] The Exchange's staff will have access to the surveillance programs conducted by its affiliate exchanges, MIAX Pearl and MIAX Sapphire with respect to trading in the shares of the underlying Trust when conducting surveillances for market abuse or manipulation in the options on the Trust. Additionally, the Exchange is a member of the Intermarket Surveillance Group (''ISG'') under the Intermarket Surveillance Group Agreement. ISG members work together to coordinate surveillance and investigative information sharing in the stock, options, and futures markets. In addition to obtaining surveillance data from MIAX Pearl and MIAX Sapphire, the Exchange will be able to obtain information regarding trading in the shares of the underlying Trust from Nasdaq, LLC and other markets through ISG. In addition, the Exchange has a Regulatory Services Agreement with the Financial Industry Regulatory Authority (''FINRA''). Pursuant to a multi-party 17d–2 joint plan, all options exchanges allocate regulatory responsibilities to FINRA to conduct certain options-related market surveillance that are common to rules of all options exchanges.[45]

The underlying shares of spot bitcoin ETPs, including the Trust, are also subject to safeguards related to addressing market abuse and manipulation. As the Commission stated in Bitcoin ETP Order:

> Each Exchange has a comprehensive surveillance-sharing agreement with the CME via their common membership in the Intermarket Surveillance Group. This facilitates the sharing of information that is available to the CME through its surveillance of its markets, including its surveillance of the CME bitcoin futures market.[46]
>
> The Exchange states that, given the consistently high correlation between the CME bitcoin futures market and the spot bitcoin market, as confirmed by the Commission through robust correlation analysis, the Commission was able to conclude that such surveillance sharing agreements could reasonably be ''expected to assist in surveilling for fraudulent and manipulative acts and practices in the specific context of the [Bitcoin ETPs].''[47]

In light of surveillance measures related to both options and futures as well as the underlying Trust,[48] the Exchange believes that existing surveillance procedures are designed to deter and detect possible manipulative behavior which might potentially arise from listing and trading the proposed options on the Trust. Further, the Exchange represents that it will implement any new surveillance procedures it deems necessary to effectively monitor the trading of options on the Trust.

The Exchange has also analyzed its capacity and represents that it believes the Exchange and Options Price Reporting Authority or ''OPRA'' have the necessary systems capacity to handle the additional traffic associated with the listing of new series that may result from the introduction of options on the Trust up to the number of expirations currently permissible under the Rules. Because the proposal is limited to one class, the Exchange believes any additional traffic that may be generated from the introduction of the Trust options will be manageable. Finally, the Exchange proposes a technical amendment to Exchange Rule 402(i)(4) to amend the name ''ETFS Gold Trust'' to ''Aberdeen Standard Physical Gold Trust.'' In 2018 ETFS Gold Trust was renamed.[49] At this time, the Exchange proposes to amend the name of the ETF to reflect its current name.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[50] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[51] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and

[43] *See https://companiesmarketcap.com/usa/largest-companies-in-the-usa-by-market-cap/.*

[44] The surveillance program includes real-time patterns for price and volume movements and post-trade surveillance patterns (*e.g.,* spoofing, marking the close, pinging, phishing).

[45] Section 19(g)(1) of the Act, among other things, requires every SRO registered as a national securities exchange or national securities association to comply with the Act, the rules and regulations thereunder, and the SRO's own rules, and, absent reasonable justification or excuse, enforce compliance by its members and persons associated with its members. See 15 U.S.C. 78q(d)(1) and 17 CFR 240.17d–2. Section 17(d)(1) of the Act allows the Commission to relieve an SRO of certain responsibilities with respect to members of the SRO who are also members of another SRO (''common members''). Specifically, Section 17(d)(1) allows the Commission to relieve an SRO of its responsibilities to: (i) receive regulatory reports from such members; (ii) examine such members for compliance with the Act and the rules and regulations thereunder, and the rules of the SRO; or (iii) carry out other specified regulatory responsibilities with respect to such members.

[46] *See* Bitcoin ETP Order, 89 FR at 3010–11.

[47] *See* Bitcoin ETP Order, 89 FR at 3010–11.

[48] *See* Securities Exchange Act Release No. 99295 (January 8, 2024), 89 FR 2321, 2334–35 (January 12, 2024) (SR–NASDAQ–2023–016) (Notice of Filing of Amendment No. 1 to a Proposed Rule Change To List and Trade Shares of the iShares Bitcoin Trust Under Nasdaq Rule 5711(d)).

[49] Effective October 1, 2018 ETFS Gold Trust was renamed Aberdeen Standard Gold ETF Trust. *https://www.sec.gov/Archives/edgar/data/1450923/000138713118005292/ex10-2.htm.*

[50] 15 U.S.C. 78f(b).

[51] 15 U.S.C. 78f(b)(5).

practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section (6)(b)(5) [52] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes that the proposal to list and trade options on the Trust will remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, protect investors because offering options on the Trust will provide investors with a greater opportunity to realize the benefits of utilizing options on an ETF based on spot bitcoin, including cost efficiencies and increased hedging strategies. The Exchange believes that offering options on a competitively priced ETF based on spot bitcoin will benefit investors by providing them with an additional, relatively lower-cost risk management tool, allowing them to manage, more easily, their positions and associated risks in their portfolios in connection with exposure to spot bitcoin. Today, the Exchange lists options on other commodity ETFs structured as a trust, which essentially offer the same objectives and benefits to investors, and for which the Exchange has not identified any issues with the continued listing and trading of options on those ETFs.

The Exchange also believes the proposal to permit options on the Trust will remove impediments to and perfect the mechanism of a free and open market and a national market system, because options on the Trust will comply with current Exchange Rules. Options on the Trust must satisfy the initial listing standards and continued listing standards currently in the Exchange Rules, applicable to options on all ETFs, including options on other commodity ETFs already deemed appropriate for options trading on the Exchange pursuant to Exchange Rule 402(i)(4). Additionally, as demonstrated above, the Trust is characterized by a substantial number of shares that are widely held and actively traded. Further, Exchange Rules that currently govern the listing and trading of options on ETFs, including permissible expirations, strike prices, minimum increments, position and exercise limits (as proposed herein), and margin requirements, will govern the listing and trading of options on the Trust. The proposed position and exercise limits for options on the Trust is 25,000 contracts. These position and exercise limits are the lowest position and exercise limits available in the options industry, are extremely conservative and more than appropriate given the Trust's market capitalization, average daily volume, and high number of outstanding shares. The proposed position limit, and exercise limit, is consistent with the Act as it addresses concerns related to manipulation and protection of investors because, as demonstrated above, the position limit (and exercise limit) is extremely conservative and more than appropriate given the Trust is actively traded. In support of the proposed position and exercise limits for options on the Trust is 25,000 contracts, the Exchange is citing the in depth analysis ISE did in its filing. As noted above, in the IBIT Approval Order, ISE considered the: (i) Trust's market capitalization and ADV, and prospective position limit in relation to other securities; (ii) market capitalization of the entire bitcoin market in terms of exercise risk and availability of deliverables; (iii) proposed position limit by comparing it to position limits for derivative products regulated by the CFTC; and (iv) supply of bitcoin. Based on the Exchange's review of IBIT Approval Order, the Exchange believes that the setting position and exercise limits for options on the Trust is 25,000 contracts is more than appropriate for the Trust. The proposed position and exercise limits reasonably and appropriately balance the liquidity provisioning in the market against the prevention of manipulation. The Exchange believes these proposed limits are effectively designed to prevent an individual customer or entity from establishing options positions that could be used to manipulate the market of the underlying as well as the Bitcoin market.[53]

The Exchange represents that it has the necessary systems capacity to support options on the Trust. The Exchange believes that its existing surveillance and reporting safeguards are designed to deter and detect possible manipulative behavior which might arise from listing and trading options on ETFs, including the Trust options. Today, the Exchange has an adequate surveillance program in place for options. The Exchange intends to apply those same program procedures to options on the Trust that it applies to the Exchange's other options products.[54] The Exchange's staff will have access to the surveillance programs conducted by its affiliate exchanges, MIAX Pearl and MIAX Sapphire with respect to the underlying Trust when conducting surveillances for market abuse or manipulation in the options on the Trust. The Exchange will review activity in the underlying Trust when conducting surveillances for market abuse or manipulation in the options on the Trust. Additionally, the Exchange is a member of the ISG under the Intermarket Surveillance Group Agreement. ISG members work together to coordinate surveillance and investigative information sharing in the stock, options, and futures markets. In addition to obtaining surveillance data from MIAX Pearl and MIAX Sapphire, the Exchange will be able to obtain information from Nasdaq, LLC and other markets through ISG. In addition, the Exchange has a Regulatory Services Agreement with FINRA. Pursuant to a multi-party 17d–2 joint plan, all options exchanges allocate regulatory responsibilities to FINRA to conduct certain options-related market surveillance that are common to rules of all options exchanges.[55]

The underlying shares of spot bitcoin ETPs, including the Trust, are also subject to safeguards related to addressing market abuse and manipulation. As the Commission stated in Bitcoin ETP Order:

Each Exchange has a comprehensive surveillance-sharing agreement with the CME via their common membership in the Intermarket Surveillance Group.

[52] *Id.*

[53] *See* Securities Exchange Act Release No. 39489 (December 24, 1997), 63 FR 276 (January 5, 1998) (SR–CBOE–1997–11).

[54] The surveillance program includes real-time patterns for price and volume movements and post-trade surveillance patterns (*e.g.,* spoofing, marking the close, pinging, phishing).

[55] Section 19(g)(1) of the Act, among other things, requires every SRO registered as a national securities exchange or national securities association to comply with the Act, the rules and regulations thereunder, and the SRO's own rules, and, absent reasonable justification or excuse, enforce compliance by its members and persons associated with its members. See 15 U.S.C. 78q(d)(1) and 17 CFR 240.17d–2. Section 17(d)(1) of the Act allows the Commission to relieve an SRO of certain responsibilities with respect to members of the SRO who are also members of another SRO (''common members''). Specifically, Section 17(d)(1) allows the Commission to relieve an SRO of its responsibilities to: (i) receive regulatory reports from such members; (ii) examine such members for compliance with the Act and the rules and regulations thereunder, and the rules of the SRO; or (iii) carry out other specified regulatory responsibilities with respect to such members.

This facilitates the sharing of information that is available to the CME through its surveillance of its markets, including its surveillance of the CME bitcoin futures market.[56]

The Exchange states that, given the consistently high correlation between the CME bitcoin futures market and the spot bitcoin market, as confirmed by the Commission through robust correlation analysis, the Commission was able to conclude that such surveillance sharing agreements could reasonably be ''expected to assist in surveilling for fraudulent and manipulative acts and practices in the specific context of the [Bitcoin ETPs].'' [57]

In light of surveillance measures related to both options and futures as well as the underlying Trust,[58] the Exchange believes that existing surveillance procedures are designed to deter and detect possible manipulative behavior which might potentially arise from listing and trading the proposed options on the Trust. Further, the Exchange represents that it will implement any new surveillance procedures it deems necessary to effectively monitor the trading of options on the Trust.

Finally, the Commission has previously approved the listing and trading of options on other commodity ETFs structured as a trust, such as SPDR® Gold Trust,[59] the iShares COMEX Gold Trust [60] the iShares Silver Trust,[61] the ETFS Gold Trust,[62] and the ETFS Silver Trust.[63]

Further, the Exchange's proposal to amend the name ''ETFS Gold Trust'' to ''Aberdeen Standard Physical Gold Trust'' in Exchange Rule 402(i)(4) is consistent with the Act and the protection of investors as this amendment reflects the current name of this product.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. In this regard and as indicated above, the Exchange notes that the rule change is being proposed as a competitive response to filings submitted by ISE.[64]

The Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act as options on the Trust will be subject to initial listing standards and continued listing standards the same as other options on ETFs listed on the Exchange. Further, options on the Trust will be subject to Exchange Rules that currently govern the listing and trading of options on ETFs, including permissible expirations, strike prices, minimum increments, position and exercise limits (including as proposed to modify herein), and margin requirements. Options on the Trust will be equally available to all market participants who wish to trade such options. Also, and as stated above, the Exchange already lists options on other commodity ETFs structured as a trust.

The Exchange does not believe that the proposal to list to list and trade options on the Trust will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. To the extent that permitting options on the Trust to trade on the Exchange may make the Exchange a more attractive marketplace to market participants, such market participants are free to elect to become market participants on the Exchange. Additionally, other options exchanges are free to amend their listing rules, as applicable, to permit them to list and trade options on the Trust. The Exchange believes that the proposed rule change may relieve any burden on, or otherwise promote, competition as it is designed to increase competition for order flow on the Exchange in a manner that is beneficial to investors by providing them with a lower-cost option to hedge their investment portfolios. The Exchange notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues that offer similar products. Ultimately, the Exchange believes that offering options on the Trust for trading on the Exchange will promote competition by providing investors with an additional, relatively low-cost means to hedge their portfolios and meet their investment needs in connection with spot bitcoin prices and bitcoin related products and positions.

Finally, the Exchange's proposal to amend the name ''ETFS Gold Trust'' to ''Aberdeen Standard Physical Gold Trust'' in Exchange Rule 402(i)(4) does not impose an undue burden on competition as this amendment reflects the current name of this product.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [65] and Rule 19b–4(f)(6) thereunder.[66] Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act [67] and subparagraph (f)(6) of Rule 19b–4 thereunder.[68]

[56] *See supra* note 5.

[57] *See* Bitcoin ETP Order, 89 FR at 3010–11.

[58] *See* Securities Exchange Act Release No. 99295 (January 8, 2024), 89 FR 2321, 2334–35 (January 12, 2024) (SR–NASDAQ–2023–016) (Notice of Filing of Amendment No. 1 to a Proposed Rule Change To List and Trade Shares of the iShares Bitcoin Trust Under Nasdaq Rule 5711(d)).

[59] *See* Securities Exchange Act Release No. 57897 (May 30, 2008), 73 FR 32061 (June 5, 2008) (SR–Amex–2008–15; SR–CBOE–2005–11; SR–ISE–2008–12; SR–NYSEArca–2008–52; and SRPhlx–2008–17) (Order Granting Approval of a Proposed Rule Change, as Modified, and Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Changes, as Modified, Relating to Listing and Trading Options on the SPDR Gold Trust).

[60] *See* Securities Exchange Act Release No. 59055 (December 4, 2008), 73 FR 75148 (December 10, 2008) (SR–Amex–2008–68; SR–BSE–2008–51; SR–CBOE–2008–72; SR–ISE–2008–58; SRNYSEArca–2008–66; and SR–Phlx–2008–58) (Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Changes Relating to the Listing and Trading Options on Shares of the iShares COMEX Gold Trust and the iShares Silver Trust).

[61] *Id.*

[62] *See* Securities Exchange Act Release No. 61483 (February 3, 2010), 75 FR 6753 (February 10, 2010) (SR–CBOE–2010–007; SR–ISE–2009–106; SR–NYSEAmex–2009–86; and SR–NYSEArca–2009–110) (Order Granting Approval of Proposed Rule Changes and Notice of Filing and Order Granting Accelerated Approval of a Proposed Rule Change Relating to Listing and Trading Options on the ETFS Gold Trust and the ETFS Silver Trust).

[63] *Id.*

[64] *See supra* note 6.

[65] 15 U.S.C. 78s(b)(3)(A)(iii).

[66] 17 CFR 240.19b–4(f)(6).

[67] 15 U.S.C. 78s(b)(3)(A)(iii).

[68] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time

Continued

A proposed rule change filed under Rule 19b–4(f)(6)[69] under the Act does not normally become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[70] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Commission previously approved the listing of options on iShares Bitcoin Trust.[71] The Exchange has provided information regarding the underlying iShares Bitcoin Trust, including, among other things, information regarding trading volume, the number of beneficial holders, and the market capitalization of the iShares Bitcoin Trust. The proposal also establishes position and exercise limits for options on the iShares Bitcoin Trust and provides information regarding the surveillance procedures that will apply to iShares Bitcoin Trust options. The Commission believes that waiver of the operative delay could benefit investors by providing an additional venue for trading iShares Bitcoin Trust options. Therefore, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.[72]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

as designated by the Commission. The Exchange has satisfied this requirement.

[69] 17 CFR 240.19b–4(f)(6).

[70] 17 CFR 240.19b–4(f)(6)(iii).

[71] *See* Securities Exchange Act Release No. 101128 (September 20, 2024), 89 FR 78942 (September 26, 2024) (SR–ISE–2024–03) (Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing of Amendment Nos. 4 and 5 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment Nos. 1, 4, and 5, to Permit the Listing and Trading of Options on the iShares Bitcoin Trust).

[72] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–MIAX–2024–40 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–MIAX–2024–40. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–MIAX–2024–40 and should be submitted on or before December 18, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[73]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–27741 Filed 11–26–24; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101688; File No. SR–GEMX–2024–40]

Self-Regulatory Organizations; Nasdaq GEMX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Fees for Connectivity and Co-Location Services

November 21, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 8, 2024, Nasdaq GEMX, LLC (''GEMX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's fees for connectivity and co-location services, as described further below.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/gemx/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of

[73] 17 CFR 200.30–3(a)(12), (59).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the Exchange's fees relating to connectivity and co-location services.[3] Specifically, the Exchange proposes to raise its fees for connectivity and co-location services in General 8 as well as certain fees related to its Testing Facilities in Options 7, Section 6 by 10%, with certain exceptions.

General 8, Section 1 includes the Exchange's fees that relate to connectivity, including fees for cabinets, external telco/inter-cabinet connectivity fees, fees for connectivity to the Exchange, fees for connectivity to third party services, fees for market data connectivity, fees for cabinet power install, and fees for additional charges and services. General 8, Section 2 includes the Exchange's fees for direct connectivity services, including fees for direct circuit connection to the Exchange, fees for direct circuit connection to third party services, and fees for point of presence connectivity. With the exception of the Exchange's GPS Antenna fees and the Cabinet Proximity Option Fee for cabinets with power density >10kW,[4] the Exchange proposes to increase its fees throughout General 8 by 10%.

In addition to increasing fees in General 8, the Exchange also proposes to increase certain fees in Options 7, Section 6, which relate to the Testing Facility. Options 7, Section 6(H) provides that subscribers to the Testing Facility located in Carteret, New Jersey shall pay a fee of $1,000 per hand-off, per month for connection to the Testing Facility. The hand-off fee includes either a 1Gb or 10Gb switch port and a cross connect to the Testing Facility. In addition, Options 7, Section 6(H) provides that subscribers shall also pay a one-time installation fee of $1,000 per hand-off. The Exchange proposes to increase these aforementioned fees by 10% to require that subscribers to the Testing Facility shall pay a fee of $1,100 per hand-off, per month for connection to the Testing Facility and a one-time installation fee of $1,100 per hand-off.

The proposed increases in fees would enable the Exchange to maintain and improve its market technology and services to remain competitive with its peers. Over the years, customer demand for more sophisticated, higher-throughput, lower-latency, and higher-power connectivity solutions has increased. The Exchange continues to invest in maintaining, improving, and enhancing its connectivity and co-location products, services, and facilities—for the benefit and often at the behest of its customers. Such enhancements include refreshing hardware and expanding Nasdaq's existing co-location facility to offer customers additional space and power. Nevertheless, and with the exception of fees that were established as part of a new service in 2017 (and have remained unchanged since their adoption), the Exchange has not increased any of the fees included in the proposal since prior to 2017, and many of the fees date back to between 2010 and 2014. For each of the connectivity products and services that pre-date 2017, inflation (as measured using the ''Data PPI'' metric described below) has been between roughly 15–17%, and in no instance has such inflation been less than 10%. Nevertheless, the Exchange proposes to increase its fees only with respect to the 10% inflation that has occurred since 2017.

As discussed below, the Exchange proposes to adjust its fees by an industry- and product-specific inflationary measure. It is reasonable and consistent with the Act for the Exchange to recoup its investments, at least in part, by adjusting its fees. Continuing to operate at fees frozen at 2010–2017 levels impacts the Exchange's ability to enhance its offerings and the interests of market participants and investors.

The fee increases the Exchange proposes are based on an industry-specific Producer Price Index (''PPI''), which is a tailored measure of inflation.[5] As a general matter, the Producer Price Index is a family of indexes that measures the average change over time in selling prices received by domestic producers of goods and services. PPI measures price change from the perspective of the seller. This contrasts with other metrics, such as the Consumer Price Index (''CPI''), that measure price change from the purchaser's perspective.[6] About 10,000 PPIs for individual products and groups of products are tracked and released each month.[7] PPIs are available for the output of nearly all industries in the goods-producing sectors of the U.S. economy—mining, manufacturing, agriculture, fishing, and forestry—as well as natural gas, electricity, and construction, among others. The PPI program covers approximately 69 percent of the service sector's output, as measured by revenue reported in the 2017 Economic Census.

For purposes of this proposal, the relevant industry-specific PPI is the Data Processing and Related Services PPI (''Data PPI''), which is an industry net-output PPI that measures the average change in selling prices received by companies that provide data processing services.

The Data PPI was introduced in January 2002 by the Bureau of Labor Statistics (''BLS'') as part of an ongoing effort to expand Producer Price Index coverage of the services sector of the U.S. economy and is identified as NAICS–518210 in the North American Industry Classification System.[8] According to the BLS ''[t]he primary output of NAICS 518210 is the provision of electronic data processing services. In the broadest sense, computer services companies help their customers efficiently use technology. The processing services market consists of vendors who use their own computer systems—often utilizing proprietary softwar—to process customers' transactions and data. Companies that offer processing services collect, organize, and store a customer's transactions and other data for record-keeping purposes. Price movements for the NAICS 518210 index are based on changes in the revenue received by companies that provide data processing

[3] The Exchange initially filed the proposed pricing change on March 1, 2024 (SR–GEMX–2024–05). On April 29, 2024, the Exchange withdrew that filing and submitted SR–GEMX–2024–09. On June 27, 2024, the Exchange withdrew SR–GEMX–2024–09 and submitted SR–GEMX–2024–15. The Exchange withdrew SR–GEMX–2024–15 and replaced it with SR–GEMX–2024–33 on September 10, 2024. On October 11, 2024, the Exchange replaced SR–GEMX–2024–33 with SR–GEMX–2024–38. The instant filing replaces SR–GEMX–2024–38.

[4] The Exchange proposes to exclude the GPS Antenna fees from the proposed fee increase because, unlike the other fees in General 8, the Exchange recently increased its GPS Antenna fees. *See* Securities Exchange Act Release No. 34–99129 (December 11, 2023), 88 FR 87017 (December 15, 2023) (SR–GEMX–2023–17). The Exchange also proposes to exclude the Cabinet Proximity Option Fee for cabinets with power density >10kW from the proposed fee increase because the Exchange recently established such fee. *See* Securities Exchange Act Release No. 34–100210 (May 22, 2024), 89 FR 46476 (May 29, 2024) (SR–GEMX–2024–11). Similarly, the Exchange proposes to exclude from the proposed fee increase those fees that the Exchange recently established for services in its new NY11–4 expansion facility. *See* Securities Exchange Act Release No. 34–101262 (October 7, 2024), 89 FR 82649 (October 11, 2024) (SR–GEMX–2024–36).

[5] *See https://fred.stlouisfed.org/series/PCU51825182#0.*

[6] *See https://www.bls.gov/ppi/overview.htm.*

[7] *See Id.*

[8] *NAICS appears in table 5 of the PPI Detailed Report and is available at https://data.bls.gov/timeseries/PCU518210518210.*

services. Each month, companies provide net transaction prices for a specified service. The transaction is an actual contract selected by probability, where the price-determining characteristics are held constant while the service is repriced. The prices used in index calculation are the actual prices billed for the selected service contract.'' [9]

The Exchange believes the Data PPI is an appropriate measure to be considered in the context of the proposed rule change to modify the fee for its connectivity products because the Exchange uses its ''own computer systems'' and ''proprietary software,'' *i.e.,* its own data center and proprietary matching engine software, respectively, to collect, organize, store and report customers' transactions in U.S. equity securities on the Exchange's proprietary trading platform. In other words, the Exchange is in the business of data processing and related services.

For purposes of this proposed rule change, the Exchange examined the Data PPI value for the period from January 2017 to August 2024. The Data PPI had a starting value of 105.6 in January 2017 and an ending value of 116.022 in August 2024, a 10.422% increase. This indicates that companies who are also in the data storage and processing business have generally increased prices for a specified service covered under NAICS 518210 by an average of 10.422% during this period. Based on that percentage change, the Exchange proposes to make a one-time fee increase of only 10%, which reflects an increase covering roughly the entire period since the last price adjustments to these fees were made.

The Exchange further believes the Data PPI is an appropriate measure for purposes of the proposed rule change on the basis that it is a stable metric with limited volatility, unlike other consumer-side inflation metrics. In fact, the Data PPI has not experienced a greater than 2.16% increase for any one calendar year period since Data PPI was introduced into the PPI in January 2002. The average calendar year change from January 2002 to December 2023 was .62%, with a cumulative increase of 15.67% over this 21-year period. The Exchange believes the Data PPI is considerably less volatile than other inflation metrics such as CPI, which has had individual calendar-year increases of more than 6.5%, and a cumulative increase of over 73% over the same period.[10]

The Exchange believes the Data PPI, and significant investments into, and enhanced performance of, the Exchange support the reasonableness of the proposed fee increases.[11]

These proposed fee increases will be immediately effective upon filing. However, going forward and until December 1, 2024, the Exchange will waive all fees set forth herein to the extent that such fees exceed the levels that would have been charged for the same products and services purchased during that time period, had such fees been calculated at the rates set forth in SR–GEMX–2024–33 (*i.e.,* pricing reflective of a 5.5% increase from prior fee levels). This waiver is reasonable, equitable, and not unfairly discriminatory because it will afford all customers in excess of the 30-day prior notice period for fee changes set forth in the Exchange's service terms.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[12] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[13] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

This belief is based on two factors. First, the current fees do not properly reflect the quality of the services and products, as fees for the services and products in question have been static in nominal terms, and therefore falling in real terms due to inflation. Second, the Exchange believes that investments made in enhancing the capacity and speed of Exchange systems increase the performance of the services and products.

The Proposed Rule Change Is Reasonable

As noted above, the Exchange has not increased any of the fees included in the proposal since 2017 or earlier. However, in the years following the last fee increases, the Exchange has made significant investments in upgrades to its connectivity products, services, and facilities, enhancing the quality of its services. In other words, Exchange customers have greatly benefitted, while the Exchange's ability to recoup its investments has been hampered. Between 2017 and 2024, the inflation rate is 3.64% per year, on average, producing a cumulative inflation rate of 28.43%.[14] Using the more targeted inflation number of Data PPI, the cumulative inflation rate was 10.422%. The exchange believes the Data PPI is a reasonable metric to base this fee increase on because it is targeted to producer-side increases in the data processing industry.

Notwithstanding inflation, as noted above, the Exchange has not increased its fees at all for over seven years for the subject services. The proposed fee changes represent a modest increase from the current fees. The Exchange believes the proposed fee increase is reasonable in light of the Exchange's continued expenditure in maintaining a robust technology ecosystem. Furthermore, the Exchange continues to invest in maintaining and enhancing its connectivity products—for the benefit and often at the behest of its customers and global investors. Such enhancements include refreshing all aspects of the technology ecosystem including software, hardware, and network while introducing new and innovative products and expanded and modernized facilities.[15] The goal of the enhancements discussed above, among other things, is to provide faster, higher-capacity, and more modern connectivity products and services. Accordingly, the Exchange continues to expend resources to innovate and modernize technology so that it may benefit its members in offering its connectivity products and services.

The Proposed Fees Are Equitably Allocated and Not Unfairly Discriminatory

The Exchange believes that the proposed fee increases are equitably

[9] *See https://www.bls.gov/ppi/factsheets/producer-price-index-for-the-data-processing-and-related-servicesindustry-naics-518210.htm.*

[10] *See https://www.usinflationcalculator.com/inflation/consumer-price-index-and-annual-percent-changesfrom-1913-to-2008/.*

[11] *See supra* discussion of connectivity product and facility improvements. Additionally, other exchanges have filed for increases in certain fees, based in part on comparisons to inflation. See, *e.g.,* Securities Exchange Act Release Nos. 34–100004 (April 22, 2024), 89 FR 32465 (April 26, 2024) (SR–CboeBYX–2024–012); and 34–100398 (June 21, 2024), 89 FR 53676 (June 27, 2024) (SR–BOX–2024–16)l; Securities Exchange Act Release No. 34–100994 (September 10, 2024), 89 FR 75612 (September 16, 2024) (SR–NYSEARCA–2024–79).

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(4) and (5).

[14] *See https://www.officialdata.org/us/inflation/2017?amount=1.*

[15] *See, e.g.,* Securities Exchange Act Release No.34–101074 (September 18, 2024), 89 FR 77920 (September 24, 2024) (SR–GEMX–2024–34 (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Expand [the Exchange's] Co-Location Services).

allocated and not unfairly discriminatory because they would apply to all market participants that choose to purchase connectivity products and services from the Exchange. Any participant that chooses to purchase the Exchange's connectivity products and services would be subject to the same Fee Schedule, regardless of what type of business they operate or the use they plan to make use of the products and services. Additionally, the fee increase would be applied uniformly to market participants without regard to Exchange membership status or the extent of any other business with the Exchange or affiliated entities. The Exchange also believes that the proposal represents an equitable allocation of reasonable dues, fees and other charges because Exchange fees have fallen in real terms during the relevant period. Finally, the Exchange believes that the proposed fee changes are not unfairly discriminatory because the fees would be assessed uniformly across all market participants, in the same manner they are today, that voluntarily purchase the Exchange's connectivity products and services, which would remain available for purchase by all market participants.

These proposed fee increases will be immediately effective upon filing. However, going forward and until December 1, 2024, the Exchange will waive all fees set forth herein to the extent that such fees exceed the levels that would have been charged for the same products and services purchased during that time period, had such fees been calculated at the rates set forth in SR–GEMX–2024–33 (*i.e.,* pricing reflective of a 5.5% increase from prior fee levels). This waiver is reasonable, equitable, and not unfairly discriminatory because it will afford all customers in excess of the 30-day prior notice period for fee changes set forth in the Exchange's service terms.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed fees will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Intramarket Competition

The Exchange believes that the proposed fees do not put any market participants at a relative disadvantage compared to other market participants. As noted above, the fee schedule would continue to apply to all purchasers of the Exchange's connectivity products and services in the same manner as it does today albeit at inflation-adjusted rates for certain fees, and customers may choose whether to purchase these products and services at all. The Exchange also believes that the level of the proposed fees neither favor nor penalize one or more categories of market participants in a manner that would impose an undue burden on competition. Likewise, the proposed fee waiver described above will apply to all purchasers of the Exchange's connectivity products and services in the same manner and therefore will not burden competition among them.

Intermarket Competition

The Exchange believes that the proposed fees do not impose a burden on competition or on other SROs that is not necessary or appropriate. In determining the proposed fees, the Exchange utilized an objective and stable metric with limited volatility. Utilizing Data PPI over a specified period of time is a reasonable means of recouping the Exchange's investment in maintaining and enhancing its connectivity products, services, and facilities. The Exchange believes utilizing Data PPI, a tailored measure of inflation, to increase certain fees for connectivity products and services to recoup the Exchange's investment in maintaining and enhancing such products, services, and its facilities would not impose a burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[16] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include file number SR–GEMX–2024–40 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–GEMX–2024–40. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–GEMX–2024–40 and should be submitted on or before December 18, 2024.

[16] 15 U.S.C. 78s(b)(3)(A)(ii).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–27757 Filed 11–26–24; 8:45 am]

BILLING CODE 8011–01–P

SOCIAL SECURITY ADMINISTRATION

[Docket No: SSA–2024–0050]

Agency Information Collection Activities: Proposed Request and Comment Request

The Social Security Administration (SSA) publishes a list of information collection packages requiring clearance by the Office of Management and Budget (OMB) in compliance with Public Law 104–13, the Paperwork Reduction Act of 1995, effective October 1, 1995. This notice includes a revision of an OMB-approved information collection.

SSA is soliciting comments on the accuracy of the agency's burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and ways to minimize burden on respondents, including the use of automated collection techniques or other forms of information technology. Mail, email, or fax your comments and recommendations on the information collection(s) to the OMB Desk Officer and SSA Reports Clearance Officer at the following addresses or fax numbers.

(OMB), Office of Management and Budget, Attn: Desk Officer for SSA

(SSA), Social Security Administration, OLCA, Attn: Reports Clearance Director, Mail Stop 3253 Altmeyer, 6401 Security Blvd., Baltimore, MD 21235, Fax: 833–410–1631, Email address: *OR.Reports.Clearance@ssa.gov*

Or you may submit your comments online through *https://www.reginfo.gov/public/do/PRAmain* by clicking on Currently under Review—Open for Public Comments and choosing to click on one of SSA's published items. Please reference Docket ID Number [SSA–2024–0050] in your submitted response.

The information collection below is pending at SSA. SSA will submit it to OMB within 60 days from the date of this notice. To be sure we consider your comments, we must receive them no later than January 27, 2025. Individuals can obtain copies of the collection instruments by writing to the above email address.

Rules of Conduct and Standards of Responsibility for Appointed Representatives—20 CFR 404.1740(b)(5), 404.1740(b)(6), 404.1740(b)(9), 416.1540(b)(5), 416.1540(b)(6), and 416.1540(b)(9)—0960–0804. Section 205(a) of the Social Security Act (the Act) authorizes SSA's Commissioner to make rules and regulations and to establish procedures, not inconsistent with the provisions of this title, which are necessary or appropriate to carry out such provisions. Section 1631(d)(1) of the Act incorporates section 205(a) and applies it to Title XVI of the Act. Additionally, sections 206(a) and 1631(d)(2) of the Act provide that the Commissioner has the authority to establish rules and regulations governing the recognition of individuals who represent claimants before the Commissioner. Individuals appointed to represent claimants before SSA must report to SSA in writing whenever one of the following situations in our revised regulations occurs:

- *20 CFR 404.1740(b)(5) and 416.1540(b)(5)*—This regulatory section requires representatives to disclose to SSA in writing, at the time a medical or vocational opinion is submitted to SSA, or as soon as the representative is aware of the submission to us, if the representative's employee or any individual contracting with the representative drafted, prepared, or issued a medical or vocational opinion about a claimant's disability, or if the representative referred or suggested that the claimant seek an examination from, treatment by, or the assistance of the individual providing opinion evidence;
- *20 CFR 404.1740(b)(6) and 416.1540(b)(6)*—This regulatory section requires representatives to disclose to SSA immediately if the representative discovers that his or her services are or were used by the claimant to commit fraud against SSA;

A representative's obligation to report these events is ongoing, and SSA requires representatives to report any time one or more of these events occurs. We consider this information essential to ensure the integrity of our administrative process and to safeguard the rights of all claimants. SSA requires representatives to notify SSA in writing, but there is no prescribed format for these reports. The respondents are individuals appointed to represent claimants before SSA.

Type of Request: Revision of an OMB-approved information collection.

Regulation citations	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
404.1740(b)(5)&(6)/416.1540(b)(5)&(6)	43,600	1	5	3,633	$58.40	$212,149

* We based this figure on average hourly wages for paralegals/legal assistants and lawyers *https://www.bls.gov/oes/current/oes231011.htm* as posted by the U.S. Bureau of Labor Statistics (*https://www.bls.gov/oes/current/oes_nat.htm*).

** These figures do not represent actual costs that SSA is imposing on representatives to complete the required disclosures; rather, these are theoretical opportunity costs for the additional time representatives or their employees and associates will spend to complete the required disclosures. There is no actual charge to representatives to complete the required disclosures.

[17] 17 CFR 200.30–3(a)(12).

Dated: November 22, 2024.

Naomi Sipple,

Reports Clearance Officer, Social Security Administration.

[FR Doc. 2024–27811 Filed 11–26–24; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF STATE

[Public Notice: 12596]

Notice of Public Meeting in Preparation for International Maritime Organization Eleventh Session of the Sub-Committee on Ship Design and Construction (SDC) Meeting

The Department of State will conduct a public meeting at 11 a.m. on Wednesday, January 8, 2025, both in-person at Coast Guard Headquarters in Washington, DC, and via teleconference. The primary purpose of the meeting is to prepare for the 11th session of the International Maritime Organization's (IMO) Sub-committee on Ship Design and Construction (SDC) to be held at IMO Headquarters in London, United Kingdom from Monday, January 13 to Friday, January 17, 2025.

Members of the public may participate up to the capacity of the teleconference phone line, which can handle 500 participants or up to the seating capacity of the room if attending in person. The meeting location will be the United States Coast Guard Headquarters, and the teleconference line will be provided to those who RSVP. To RSVP, participants should contact the meeting coordinator, LCDR Bryan Andrews, by email at *bryan.j.andrews@uscg.mil.* LCDR Andrews will provide access information for in-person and virtual attendance.

The agenda items to be considered at SDC 11 include:

—Adoption of the agenda
—Decisions of other IMO bodies
—Development of Guidelines for emergency towing arrangements for ships other than tankers (2.20)
—Further development of the IP Code and associated guidance (2.4)
—Revision of the Interim explanatory notes for the assessment of passenger ship systems' capabilities after a fire or flooding casualty (MSC.1/Circ.1369) and related circulars (7.42)
—Amendments to the 2011 ESP Code (7.21)
—Amendments to the Guidelines for construction, installation, maintenance and inspection/survey of means of embarkation and disembarkation (MSC.1/Circ.1331) concerning the rigging of safety netting on accommodation ladders and gangways (7.35)
—Revision of SOLAS chapters II–1 (part C) and V, and related instruments regarding steering and propulsion requirements, to address both traditional and non-traditional propulsion and steering systems. (2.9)
—Amendment to regulation 25 of the 1988 Load Line Protocol regarding the requirement for setting of guard rails on the deck structure (7.25) Unified interpretation of provisions of IMO safety, security, environment, facilitation, liability and compensation-related conventions (7.1)
—Guidelines for use of Fibre-Reinforced Plastics (FRP) within ship structures (2.6)
—Review of the 2009 Code on Alerts and Indicators (7.47)
—Biennial status report and provisional agenda for SDC 12
—Election of Chair and Vice-Chair for 2026
—Experience-building phase for the reduction of underwater radiated noise from shipping (1.16)
—Any other business
—Report to the Maritime Safety Committee

Please note: The IMO may, on short notice, adjust the SDC 11 agenda to accommodate the constraints associated with the meeting format. Any changes to the agenda will be reported to those who RSVP.

Those who plan to participate should contact the meeting coordinator, LCDR Bryan Andrews, by email at *bryan.j.andrews@uscg.mil,* or in writing at 2703 Martin Luther King Jr. Ave. SE, Stop 7509, Washington, DC 20593–7509, by December 20, 2024. Please note that, due to security considerations, two valid, government issued photo identifications must be presented to gain entrance to the Douglas A. Munro Coast Guard Headquarters Building at St. Elizabeth's. This building is accessible by taxi, public transportation, and privately owned conveyance (upon request). Additionally, members of the public needing reasonable accommodation should advise the meeting coordinator not later than December 20, 2024. Requests made after that date will be considered but might not be possible to fulfill.

Additional information regarding this and other IMO public meetings may be found at: *https://www.dco.uscg.mil/IMO.*

(Authority: 22 U.S.C. 2656 and 5 U.S.C. 552)

Leslie W. Hunt,

Coast Guard Liaison Officer, Office of Ocean and Polar Affairs, Department of State.

[FR Doc. 2024–27795 Filed 11–26–24; 8:45 am]

BILLING CODE 4710–09–P

DEPARTMENT OF STATE

[Public Notice 12595]

30-Day Notice of Proposed Information Collection: Foreign Service Officer Test Registration Form

ACTION: Notice of request for public comment and submission to OMB of proposed collection of information.

SUMMARY: The Department of State has submitted the information collection described below to the Office of Management and Budget (OMB) for approval. In accordance with the Paperwork Reduction Act of 1995 we are requesting comments on this collection from all interested individuals and organizations. The purpose of this Notice is to allow 30 days for public comment.

DATES: Submit comments up to December 18, 2024.

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

FOR FURTHER INFORMATION CONTACT: Gailyn McClung, 771–205–1565. Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents to Board of Examiners for the Foreign Service, Department of State SA–1, H–518. 2401 E Street NW, Washington, DC 20522.

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Registration for the Foreign Service Officer Test.
- *OMB Control Number:* 1405–0008.
- *Type of Request:* Extension of a Currently Approved Collection.
- *Originating Office:* Bureau of Human Resources, Board of Examiners.
- *Form Number:* DS–1998E.
- *Respondents:* Registrants for the Foreign Service Officer Test.
- *Estimated Number of Respondents:* 7,000.
- *Estimated Number of Responses:* 7,000.

• *Average Time Per Response:* 2 hours.

• *Total Estimated Burden Time:* 14,000 hours.

• *Frequency:* Annually.

• *Obligation to Respond:* Required to Obtain or Retain a Benefit.

We are soliciting public comments to permit the Department to:

• Evaluate whether the proposed information collection is necessary for the proper functions of the Department.

• Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.

• Enhance the quality, utility, and clarity of the information to be collected.

• Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

Individuals registering for the Foreign Service Officer Test will complete a Registration Form, asking for their name, contact information, ethnicity, education and work history, and military experience. The information will be used to prepare and issue admission to the Foreign Service Officer Test, to provide data useful for improving future tests, and to conduct research studies based on the test results.

Methodology

The registration process, which includes concurrent application submission and seat selection, opens approximately four (4) weeks prior to each testing window. To register, individuals go to *pearsonvue.com/fsot/* during the four-week period prior to a specific testing window to create an account, submit completed eligibility verification and application forms, and select a location and seat for the specific test date.

David J. Burger,

Director, GTM/TAC/BEX, Department of State.

[FR Doc. 2024–27735 Filed 11–26–24; 8:45 am]

BILLING CODE 4710–15–P

DEPARTMENT OF STATE

[Public Notice: 12590]

Request for Information for the 2025 Trafficking in Persons Report

SUMMARY: The Department of State (''the Department'') requests written information to assist in reporting on the degree to which the United States and foreign governments meet the minimum standards for the elimination of trafficking in persons (''minimum standards'') that are prescribed by the Trafficking Victims Protection Act of 2000.

DATES: Submissions must be made in writing to the Office to Monitor and Combat Trafficking in Persons at the Department of State by 5 p.m. EST on February 3, 2025.

SUPPLEMENTARY INFORMATION: This written information will assist in the preparation of the Trafficking in Persons Report (''TIP Report'') which the Department submits annually to the U.S. Congress on governments' concrete actions to meet the minimum standards for the elimination of trafficking in persons (''minimum standards'') that are prescribed by the Trafficking Victims Protection Act of 2000 (Div. A, Pub. L. 106–386), as amended (''TVPA''). Foreign governments that do not meet the minimum standards and are not making significant efforts to do so may be subject to restrictions on nonhumanitarian, nontrade-related foreign assistance from the United States, as defined by the TVPA. Please refer to the Information Sought Relevant to the Minimum Standards of this Notice for the questionnaire and to the Addresses, Scope of Interest, and Information Sought sections for additional instructions on submission requirements. Written submissions and supporting documentation may be submitted by the following method:

• *Email: tipreport@state.gov* for submissions related to foreign governments and *tipreportUS@state.gov* for submissions related to the United States.

Scope of Interest: The Department requests information relevant to assessing the United States' and foreign governments' concrete actions to meet the minimum standards for the elimination of trafficking in persons during the reporting period (April 1, 2024–March 31, 2025). The minimum standards are listed in the *Background* section. Submissions must include information relevant to efforts to meet the minimum standards and should include, but need not be limited to, answering the questions in the *Information Sought* section. Submissions need not include answers to all the questions; only those questions for which the submitter has direct professional experience should be answered, and that experience should be noted. For any critique or deficiency described, please provide a recommendation to remedy it. Note the country or countries that are the focus of the submission. Submissions may include written narratives answering the questions presented in this Notice, research, studies, statistics, fieldwork, training materials, evaluations, assessments, and other relevant evidence of local, state/provincial, and federal/central government efforts. To the extent possible, precise dates and numbers of officials or individuals affected should be included. Questions below seek to gather information and updates from the details provided and assessment on government efforts made in the 2024 TIP Report. Furthermore, we request information on the government's treatment of vulnerable populations and underserved communities, including how the government may have systemically denied opportunities to a community to participate in aspects of economic, social, and civic life that has led to heighted risk to human trafficking or how the government's anti-trafficking response may have treated certain groups differently. Written narratives providing factual information should provide citations of sources, and copies of and links to the source material should be provided. Please send electronic copies of the entire submission, including source material. If primary sources are used, such as research studies, interviews, direct observations, or other sources of quantitative or qualitative data, provide details on the research or data-gathering methodology and any supporting documentation. The Department only includes in the TIP Report information related to trafficking in persons as defined by the TVPA; it does not include, and is therefore not seeking, information on commercial sex, migrant smuggling, visa fraud, or child abuse, unless such crimes also involve the elements of sex trafficking or forced labor.

Confidentiality: Please provide the name, phone number, and email address of a single point of contact for any submission. It is Department practice not to identify in the TIP Report information concerning sources to safeguard those sources. Note, however, that any information submitted to the Department may be releasable pursuant to the provisions of the Freedom of

Information Act or other applicable law. Submissions related to the United States will be shared with U.S. government agencies, as will submissions relevant to efforts by other U.S. government agencies.

Response: This is a request for information only; there will be no response to submissions. Remuneration for responses will not be provided. In order to expend appropriated funds, there must be specific authority to do so. The Department of State has no authority to expend funds for this purpose.

Background

Definitions: The TVPA defines ''severe forms of trafficking in persons'' as:

- The recruitment, harboring, transportation, provision, obtaining, patronizing, or soliciting of a person for the purpose of a commercial sex act that is induced by force, fraud, or coercion, or in which the person induced to perform such act has not attained 18 years of age.
  - Persons under age 18 in commercial sex are trafficking in persons victims regardless of whether force, fraud, or coercion were involved.
- The recruitment, harboring, transportation, provision, or obtaining of a person for labor or services, through the use of force, fraud, or coercion, for the purpose of subjection to involuntary servitude, peonage, debt bondage, or slavery.
  - Forced labor may take the form of domestic servitude, forced begging, forced criminal activity (*e.g.,* drug smuggling), and prison labor that is not a consequence of a conviction in a court of law.
- Children recruited or used as soldiers or for labor or services can be a severe form of human trafficking when the activity involves force, fraud, or coercion. Children may be victims regardless of gender.

The TIP Report: The TIP Report is the most comprehensive worldwide report assessing governments' efforts to combat trafficking in persons. It represents an annually updated global assessment of the nature and scope of trafficking in persons and the broad range of government actions to confront and eliminate it. The U.S. government uses the TIP Report to inform diplomacy, encourage partnership in creating and implementing laws and policies to combat trafficking, and target resources on prevention, protection, and prosecution programs. Worldwide, international organizations (IOs), foreign governments, and nongovernmental organizations (NGOs) use the TIP Report as a tool to examine where resources are most needed. Prosecuting traffickers, protecting victims, and preventing trafficking are the ultimate goals of the TIP Report and of the U.S government's anti-trafficking policy.

The Department prepares the TIP Report with information from across the U.S. government, foreign government officials, nongovernmental and international organizations, survivors of trafficking in persons, published reports, and research related to every region. The TIP Report focuses on concrete actions made by governments to fight trafficking in persons, including prosecutions, convictions, and sentences for traffickers, as well as victim identification and protection measures and prevention efforts. Note that rankings only consider government actions to combat human trafficking, not NGOs' or IOs' activities. Each TIP Report narrative also includes prioritized recommendations for each country. These recommendations are used to assist the Department in measuring governments' progress from one year to the next and determining whether governments meet the minimum standards for the elimination of trafficking in persons or are making significant efforts to do so.

The TVPA creates a four-tier ranking system. Tier placement is based principally on the extent of concrete government action to combat trafficking. The Department first evaluates whether the government fully meets the TVPA's minimum standards for the elimination of trafficking, as set forth in Sec. 108 of the Trafficking Victims Protection Act, as amended (22 U.S.C. 7106). Governments that do so are placed on Tier 1. For other governments, the Department considers the extent of such efforts. Governments that are making significant efforts to meet the minimum standards are placed on Tier 2. Governments that do not fully meet the minimum standards and are not making significant efforts to do so are placed on Tier 3. Finally, the Department considers Watch List criteria and, when applicable, places countries on the Tier 2 Watch List. For more information, the 2024 TIP Report can be found at *www.state.gov/reports/2024-trafficking-in-persons-report.*

Since the inception of the TIP Report in 2001, the number of countries included and ranked has more than doubled; the 2024 TIP Report included 188 countries and territories. Around the world, the TIP Report and the promising practices reflected therein have inspired legislation, national action plans, policy implementation, program funding, protection mechanisms to complement prosecution efforts, and a stronger global understanding of this crime.

Since 2003, the primary reporting on the United States' anti-trafficking activities has been through the annual Attorney General's Report to Congress and Assessment of U.S. Government Activities to Combat Human Trafficking mandated by section 105 of the TVPA (22 U.S.C. 7103(d)(7)). Since 2010, the TIP Report, through a collaborative interagency process, has included an assessment of U.S. government anti-trafficking efforts in light of the minimum standards to eliminate trafficking in persons set forth by the TVPA.

Information Sought Relevant to the Minimum Standards

Submissions should include, but need not be limited to, answers to relevant questions below for which the submitter has direct professional experience within the reporting period (April 1, 2024–March 31, 2025). Citations to source material should also be provided. Note the country or countries that are the focus of the submission. Please see the *Scope of Interest* section above for detailed information regarding submission requirements.

Overview

1. What were the government's major accomplishments in addressing human trafficking since April 1, 2024? In what significant ways have the government's efforts to combat trafficking in persons changed in the past year? How have new laws, regulations, policies, or implementation strategies (*e.g.,* substantive criminal laws and procedures, mechanisms for civil remedies, and victim-witness programs, generally and in relation to court proceedings) affected its anti-trafficking response?

2. Over the past year, what were the greatest deficiencies in the government's anti-trafficking efforts? What were the limitations on the government's ability to address human trafficking problems in practice?

3. Provide additional information and/or recommendations to improve the government's anti-trafficking efforts overall.

4. Highlight effective strategies and practices that other governments could consider adopting.

Prosecution

5. Provide observations regarding the implementation of existing laws, policies, and procedures. Are there gaps in anti-trafficking legislation that could be amended to improve the

government's response? Are there any government policies that have undermined or otherwise negatively affected anti-trafficking efforts within that country?

6. Do government officials understand the nature of all forms of trafficking? If not, provide examples of misconceptions or misunderstandings. Did the government effectively provide or support anti-trafficking trainings for officials including on enforcement of policies, and laws; and/or on victim identification measures or procedures? If not, how could it be improved?

7. Provide observations on overall anti-trafficking law enforcement efforts and the efforts of police and prosecutors to investigate, prosecute, and convict traffickers. Is the government equally vigorous in pursuing forced labor and sex trafficking, domestic and transnational trafficking, and crimes that involve its own nationals or foreign citizens? Were anti-trafficking laws equitably enforced, or were certain communities disproportionately affected?

8. Does law enforcement pursue trafficking cases seeking to hold criminally accountable private employers or corporations for forced labor in supply chains?

9. Do judges appear appropriately knowledgeable and sensitized to trafficking cases? Do they implement and encourage trauma-informed practices in their courts?

10. Describe any allegations of official complicity in trafficking crimes, including of state-sponsored forced labor. What measures did the government take to end such practices? What proactive measures did the government take to prevent official complicity in trafficking in persons crimes? How did the government respond to reports of complicity during the reporting period, including investigations, prosecutions, convictions, and sentencing of complicit officials? Were these efforts sufficient?

11. Is there evidence nationals of the country deployed abroad as part of a diplomatic, peacekeeping, or other similar mission have engaged in or facilitated trafficking, including in domestic servitude? Has the government vigorously investigated, prosecuted, convicted, and sentenced nationals engaged in these activities?

12. If the government has entered into a bilateral, multilateral, or regional anti-trafficking information-sharing and cooperation arrangements, is the agreement effective and has it resulted in concrete and measurable outcomes?

Protection

13. Did the government make a coordinated, proactive effort to identify victims of all forms of trafficking? If there were any new (or changes to preexisting) formal/standard procedures for screening for trafficking, including of individuals in immigration detention or removal proceedings, and for victim referral to protection services, were those procedures sufficient and how did the government implement them?

14. If the government had written procedures to guide officials in referring potential trafficking victims to services (*e.g.,* national referral mechanism, or a formal framework to complement victim identification procedures a government uses to ensure trafficking victims' referral and access to protection services), were front-line officials across government sectors and other responsible stakeholders aware of the procedures and how to use them? Did officials implement the referral procedures and was implementation equitable across all affected populations? Did officials effectively coordinate among one another and with relevant NGOs to conduct screenings and refer victims to care? Did the referral procedures require victims to interact with law enforcement before being referred to social service providers?

15. Did government policy require a person to be formally identified as a trafficking victim to receive certain services or benefits? If yes, which services or benefits were limited to persons formally identified as trafficking victims? If applicable, which officials or entities did the government authorize to formally identify individuals as trafficking victims?

16. If commercial sex is legalized or decriminalized in the country, how did health officials, labor inspectors, or police identify trafficking victims among persons involved in commercial sex? If commercial sex is illegal, did the government proactively identify trafficking victims during law enforcement operations or other encounters with commercial sex establishments?

17. Were there any new (or changes to preexisting) services available for victims and survivors (legal, medical, food, shelter, interpretation, mental health care, employment, training, etc.)? If NGOs provide the services, does the government adequately support their work either financially or otherwise? Did all victims and survivors of both labor and sex trafficking—regardless of citizenship, gender identity, racial/ethnic identity, sexual orientation, religious affiliation, and physical ability—receive the same quality and level of access to services?

18. What was the overall quality of victim care? How could victim services be improved? Are services victim-centered and trauma-informed? Were services linked to whether a victim assisted law enforcement or participated in a trial, or whether a trafficker was convicted? Were there populations that lacked access to care, including shelter and other services?

19. Where were child victims placed (*e.g.,* in shelters, foster care, or juvenile justice detention centers), and what kind of specialized care did they receive?

20. If the government operates or funds any trafficking-specific hotlines (including those run by NGOs), did calls to those hotlines lead to victim identification, victim referral to care, and/or criminal investigations?

21. What is the level of cooperation, communication, and trust between service providers and law enforcement?

22. Were there means by which victims could obtain restitution from defendants in criminal cases or file civil suits against traffickers for damages, and did this happen in practice? Did prosecutors request and/or courts order restitution in all cases where it was required, and if not, why?

23. Please provide observations on trafficking victims and survivors' ability to access justice, as they define it, and the treatment of survivors throughout the criminal legal process. How did the government support victims who assisted in the investigation and prosecution of trafficking cases, and did it do so in a trauma-informed way? How did the government protect victims during the trial process and ensure victims were not re-traumatized during participation in the process? What, if any, alternatives were available to victims instead of speaking to law enforcement during investigations (for example, speaking to a victim-witness advocate, social worker, psychologist, etc.)? Did law enforcement allow a representative or advocate to accompany victims during interviews? In what ways could the government increase support for victims in prosecutions against traffickers?

24. Did the government provide, through a formal policy or otherwise, temporary or permanent residency status, or other relief from deportation, for foreign national victims of human trafficking who may face retribution or hardship in the countries to which they would be deported? Were foreign national victims given the opportunity to seek legal employment while in this

temporary or permanent residency? Were such benefits linked to whether a victim assisted law enforcement, whether a victim participated in a trial, or whether there was a successful prosecution? Does the government repatriate victims who wish to return home or assist with third-country resettlement? Are victims awaiting repatriation or third-country resettlement offered services? Are victims indeed repatriated, or are they deported?

25. Does the government effectively assist its nationals exploited abroad? Does the government work to ensure victims receive adequate assistance and support for their repatriation while in destination countries? Does the government provide adequate assistance to repatriated victims after their return to their countries of origin, and if so, what forms of assistance?

26. Were potential trafficking victims incarcerated, fined, or otherwise penalized solely for unlawful acts committed as a direct result of being trafficked (*e.g.,* subject to commercial sex, drug-related, or other criminal charges, or subject to deportation/immigration enforcement or administrative penalties)? If so, do these victims disproportionately represent a certain gender, race, ethnicity, or other group or particular type of trafficking?

Prevention

27. What efforts has the government made to prevent human trafficking? Did the government take new or ongoing steps to ensure policies did not further marginalize communities already overrepresented among trafficking victims, increasing their risk to human trafficking? If so, did it take efforts to implement those policies?

28. If the government had a national action plan to address trafficking, how was it implemented in practice? Were NGOs and other relevant civil society stakeholders consulted in the development and implementation of the plan? Who will monitor its implementation and/or measure its impact?

29. Please describe any government-funded anti-trafficking information or education campaigns or training, whether aimed at the public or at specific sectors or stakeholders/actors. What strategies did the campaigns employ to ensure messaging and images did not legitimize and/or perpetuate harmful or racialized narratives and/or stereotypes about victims, survivors, and perpetrators? Were campaign materials readily available, cost-free, and accessible in various languages, including braille? Does the government provide financial support to NGOs working to promote public awareness?

30. Did the government seek and include the input of survivors in crafting or implementing anti-trafficking laws, regulations, policies, or programs? If so, did the government take steps to ensure input was received and incorporated from a diverse group of survivors?

31. How did the government regulate, oversee, and screen for trafficking indicators in the labor recruitment process, including for both licensed and unlicensed recruitment and placement agencies, individual recruiters, and sub-brokers? Did the government prohibit (in any context) charging workers recruitment fees and prohibit the recruitment of workers through knowingly fraudulent job offers (including misrepresenting wages, working conditions, location, or nature of the job), contract switching, and confiscating or otherwise denying workers access to their identity documents? If there are laws or regulations on recruitment, did the government effectively enforce them? Did the government allow migrant workers to change employers in a timely manner without obtaining special permissions?

32. Did the government coordinate with other governments (*e.g.,* via bilateral agreements with migrant labor sending or receiving countries) on safe and responsible labor recruitment including prevention measures to target known trafficking indicators? To what extent were these implemented? Are workers (both nationals of the country and foreign nationals) in all industries (*e.g.,* domestic work, agriculture, etc.) equally and sufficiently protected under existing labor laws?

33. Did government policies, regulations, or agreements relating to migration, labor, trade, and investment facilitate vulnerabilities to, or incidence of, forced labor or sex trafficking? If so, what actions did the government take to ensure that its policies, regulations, and agreements relating to migration, labor, trade, border security measures, and investment did not facilitate trafficking?

34. Did the government take tangible action to prevent forced labor in domestic or global supply chains? Did the government make any efforts to prohibit and prevent trafficking in the supply chains of its own public procurement?

35. Did the government provide assistance to other governments in combating trafficking in persons through trainings or other assistance programs?

36. What measures has the government taken to reduce its nationals' or foreigners' participation in domestic and extraterritorial child sexual exploitation? Note: This was previously covered as ''child sex tourism.''

Territories and Semi-Autonomous Regions

37. Provide any information about trafficking trends and government anti-trafficking efforts in dependent territories and semi-autonomous regions to prosecute traffickers, identify and provide services to victims, and prevent trafficking.

Trafficking Profile

38. Describe human trafficking trends, drivers, methods, source/destination dynamics, industries and sectors, impacted demographics, recruitment methods, etc.

39. What groups, including vulnerable populations and underserved communities, are at particular risk of sex trafficking or forced labor? Vulnerable populations and underserved communities are populations sharing a particular characteristic, as well as geographic communities, that have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life. This term may include, but is not limited to, women and girls, persons with disabilities, indigenous peoples, people of African descent, racial and ethnic minorities, refugees and internally displaced people, religious minorities, LGBTQI+ persons, rural residents, migrants, as well as those who are otherwise adversely affected by persistent poverty or inequality. Please also consider: adults arrested for engaging in commercial sex acts, undocumented migrants, asylum seekers, stateless persons, persons with severe mental illness, unhoused persons, children in welfare systems or aging out of such systems, previously incarcerated people, members of marginalized racial and ethnic communities, people in early or forced marriages, people living with HIV/AIDS, or individuals or communities living in conflict, crisis, or post-disaster settings.

40. Are any Chinese, Cuban, or North Korean persons present in the country as part of government-to-government agreements and/or in foreign government-affiliated projects? If present, are these individuals subjected to or at high risk of forced labor?

41. Provide any information about trafficking trends, general numerical data on victims identified, or risk factors

stemming from climate-related change or disasters, as well as any efforts to mitigate these vulnerabilities; emerging migration crises and associated vulnerabilities to human trafficking; the ongoing trafficking risk as a result of conflict; and the use of technology to recruit and exploit victims, including cyber or online scam operations involving indicators of trafficking.

Child Soldiering

42. Using the definition of ''child soldier'' as defined by the Child Soldiers Prevention Act of 2008 (CSPA), describe instances, cases, and reports, including anecdotal reports, of:

a. Use of any person under the age of 18 in direct hostilities as a member of governmental armed forces, police, or other security forces;

b. Conscription or forced recruitment of persons under the age of 18 into governmental armed forces, police, or other security forces;

c. Voluntary recruitment of any person under 15 years of age into governmental armed forces, police, or other security forces;

d. Recruitment (forced or voluntary) or use in hostilities of persons under the age of 18 by armed groups distinct from the armed forces of a state.

e. Abuse of male and female children recruited by governmental armed forces, police, or other security forces, and government-supported armed groups (*e.g.,* sexual abuse or use for forced labor). Describe the manner and age of conscription, noting differences in treatment or conscription patterns based on gender.

43. Did the government provide support to an armed group that recruits and/or uses child soldiers? What was the extent of the support (*e.g.,* in-kind, financial, training, etc.)? Where did the provision of support occur (within the country or outside of the country)? In cases where the government was included on the CSPA list in 2024 based on its support to non-state armed groups that recruit and/or use child soldiers, describe whether the government took steps to pressure the group to cease its recruitment or use of child soldiers, publicly disavow the group's recruitment or use of child soldiers, or cease its support to that group.

44. Describe any government efforts to prevent or end child soldier recruitment or use, including efforts to disarm, demobilize, and reintegrate former child soldiers. (*i.e.,* enacting any laws or regulations, implementing a United Nations Action Plan or Roadmap, specialized training for officials, procedures for age verification, etc.)

Cynthia D. Dyer,

Ambassador-at-Large, Office to Monitor and Combat Trafficking in Persons, Department of State.

[FR Doc. 2024–27815 Filed 11–26–24; 8:45 am]

BILLING CODE 4710–17–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Availability, Notice of Public Comment Period, Notice of Public Meetings, and Request for Comment on the Revised Draft Tiered Environmental Assessment for SpaceX Starship/Super Heavy Vehicle Increased Cadence at the Boca Chica Launch Site in Cameron County, Texas

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

ACTION: Notice of availability, notice of public comment period, notice of public meetings, and request for comment.

SUMMARY: In accordance with the National Environmental Policy Act of 1969, as amended (NEPA), Council on Environmental Quality NEPA-implementing regulations, and FAA Order 1050.1F, *Environmental Impacts: Policies and Procedures,* the FAA is announcing the availability of the Revised Draft Tiered Environmental Assessment for SpaceX's proposal to increase the number of launches and landings of its Starship/Super Heavy vehicle at the Boca Chica Launch Site in Cameron County, Texas (Revised Draft EA), and its intent to hold public meetings. The Revised Draft EA analyzes SpaceX's proposal to increase launch and landing cadence up to 25 annual Starship/Super Heavy orbital launches, including: up to 25 annual landings of Starship (Second stage), and up to 25 annual landings of Super Heavy (First stage). The Revised Draft EA also addresses vehicle upgrades.

DATES: No registration is required for the four in-person public meetings that will be held at the following dates and times (Central):

- Tuesday, January 7, 2025; 1 p.m.–3 p.m. & 5:30 p.m.–7:30 p.m. CT.
- Thursday, January 9, 2025; 1 p.m.–3 p.m. & 5:30 p.m.–7:30 p.m. CT.

Registration is required for the virtual public meeting that will be held on Monday, January 13, 2025; 5:30 p.m.–7:30 p.m. CT.

The public comment period for the Revised Draft EA will close on January 17, 2025.

ADDRESSES: The locations for the meetings are as follows:

- January 7, 2025; Texas Southmost College, Jacob Brown Auditorium, 600 International Boulevard, Brownsville, TX 78520.
- January 9, 2025; Port Isabel Event & Cultural Center, Queen Isabella Room, 309 E Railroad Avenue, Port Isabel, TX 78578.
- January 13, 2025; Registration Link: *https://us02web.zoom.us/webinar/register/WN_6f5su5mtTne_vBr8MqJOLA,* Dial-in phone number: 888–788–0099 (Toll Free), Webinar ID: 879 9253 6128, Passcode: 900729.

The Revised Draft EA is available for review at *https://www.faa.gov/space/stakeholder_engagement/spacex_starship.* The FAA invites interested parties to submit comments on the Revised Draft EA. Public comments can be submitted electronically to *www.regulations.gov* under Docket No. FAA–2024–2006, by postal mail to Ms. Amy Hanson, FAA Environmental Specialist, SpaceX EA, c/o ICF 1902 Reston Metro Plaza Reston, VA 20190, or delivered in written or verbal form during a public meeting. Instructions on how to submit comments can be found on the FAA web page at the address listed above.

FOR FURTHER INFORMATION CONTACT: Amy Hanson at 847–243–7609 or *SpaceXBocaChica@icf.com.*

SUPPLEMENTARY INFORMATION: The FAA will provide a pre-recorded presentation during the first half hour of the public meetings. The public will also have an opportunity to submit comments during the meetings. English-Spanish translation services will be provided. Both English and Spanish versions of the presentation will be made available to the public on December 16, 2024, on this website listed above. More information on the public meetings can be found at: *https://www.faa.gov/space/stakeholder_engagement/spacex_starship.* If any accommodation for the public meetings is needed (such as additional translation services), please submit a request by December 16, 2024, to the project email address: *SpaceXBocaChica@icf.com.* For any media inquiries, please contact the FAA Press Office at *pressoffice@faa.gov.*

Before including your address, phone number, email address, or other personal identifying information in your comment, be advised that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask the FAA in your comment to withhold from public review your personal identifying information, the

FAA cannot guarantee that it will be able to do so. All comments received during the comment period will be given equal weight and be taken into consideration in the preparation of the Final EA.

Issued in Washington, DC, on November 20, 2024.

Stacey Molinich Zee,

Manager, Operations Support Branch.

[FR Doc. 2024–27533 Filed 11–26–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Transportation Project in Florida

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Limitation on Claims for Judicial Review of Actions by Florida Department of Transportation (FDOT), pursuant to 23 U.S.C. 327, and other Federal Agencies.

SUMMARY: The FHWA, on behalf of the FDOT, is issuing this notice to announce actions taken by FDOT and other Federal Agencies that are final agency actions. These actions relate to the proposed State Road (S.R.) 535/Vineland Road Project Development and Environment (PD&E) Study (Financial Management Number 437174–2). The proposed S.R. 535/Vineland Road project will reduce congestion and improve safety from US 192 to World Center Drive (S.R. 536), a distance of approximately 2.35 miles. Improvements consist of widening the existing roadway from four to six lanes, improvements to intersections, and the construction of stormwater management facilities. These actions grant licenses, permits, or approvals for the project.

DATES: By this notice, the FHWA, on behalf of FDOT, is advising the public of final agency actions subject to 23 U.S.C. 139(l)(1). A claim seeking judicial review of the Federal Agency actions on the listed highway project will be barred unless the claim is filed on or before April 28, 2025. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

ADDRESSES: The Type 2 Categorical Exclusion and additional project documents can be viewed and downloaded from the project website at: *https://www.cflroads.com/project/437174-2,* or by contacting FDOT Office of Environmental Management, 605 Suwannee Street, MS 37, Tallahassee, Florida 32399, during normal business hours are 8:00 a.m. to 5:00 p.m. (Eastern Standard Time), Monday through Friday, except State holidays.

FOR FURTHER INFORMATION CONTACT: Jennifer Marshall, P.E., Director, FDOT Office of Environmental Management, FDOT; telephone (850) 414–4316; email: *Jennifer.Marshall@dot.state.fl.us.*

SUPPLEMENTARY INFORMATION: Effective December 14, 2016, and as subsequently renewed on May 26, 2022, the FHWA assigned, and the FDOT assumed, environmental responsibilities for this project pursuant to 23 U.S.C. 327. Notice is hereby given that FDOT and other Federal Agencies have taken final agency actions subject to 23 U.S.C. 139 (l)(1) by issuing licenses, permits, or approvals for the proposed highway improvement project. The actions by FDOT and other Federal Agencies on the project, and the laws under which such actions were taken are described in the Type II Categorical Exclusion approved on November 15, 2024, and in other project records for the listed project. The Type II Categorical Exclusion and other documents for the listed project are available by contacting FDOT at the address provided above. The project subject to this notice is:

Project Location: The project is located in Osceola and Orange Counties, Florida. The project limits are S.R. 535/Vineland Road from US 192 to north of World Center Drive (S.R. 536), a distance of approximately 2.35 miles.

Project Actions: This notice applies to the Type II Categorical Exclusion and all other Federal Agency licenses, permits, or approvals for the listed project as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. *General:* National Environmental Policy Act (NEPA) [42 U.S.C. 4321*et seq.*]; Federal-Aid Highway Act (FAHA) [23 U.S.C. 109 and 23 U.S.C. 128]; 23 CFR part 771.

2. *Air:* Clean Air Act (CAA) [42 U.S.C. 7401–7671(q)], with the exception of project level conformity determinations [42 U.S.C. 7506].

3. *Noise:* Noise Control Act of 1972 [42 U.S.C. 4901–4918]; 23 CFR772.

4. *Land:* Section 4(f) of the Department of Transportation Act of 1966 [23 U.S.C. 138 and 49 U.S.C. 303]; 23 CFR part 774; Land and Water Conservation Fund (LWCF) [54 U.S.C. 200302–200310].

5. *Wildlife:* Endangered Species Act (ESA) [16 U.S.C. 1531–1544 and 1536]; Marine Mammal Protection Act [16 U.S.C. 1361–1423h], Anadromous Fish Conservation Act [16 U.S.C. 757(a)–757(f)]; Fish and Wildlife Coordination Act [16 U.S.C. 661–667(d)]; Migratory Bird Treaty Act (MBTA) [16 U.S.C. 703–712]; Magnuson-Stevenson Fishery Conservation and Management Act of 1976, as amended [16 U.S.C. 1801–1891d], with Essential Fish Habitat requirements [16 U.S.C. 1855(b)(2)].

6. *Historic and Cultural Resources:* Section 106 of the National Historic Preservation Act of 1966, as amended [54 U.S.C. 3006101 *et seq.*]; Archaeological Resources Protection Act of 1979 (ARPA) [16 U.S.C. 470(aa)–470(II)]; Preservation of Historical and Archaeological Data [54 U.S.C.312501–312508]; Native American Grave Protection and Repatriation Act (NAGPRA) [25 U.S.C. 3001–3013; 18 U.S.C. 1170].

7. *Social and Economic:* Civil Rights Act of 1964 [42 U.S.C. 2000 d–2000d–1]; American Indian Religious Freedom Act [42 U.S.C. 1996]; Farmland Protection Policy Act (FPPA) [7 U.S.C. 4201–4209].

8. *Wetlands and Water Resources:* Clean Water Act (Section 319, Section 401, Section 404) [33 U.S.C. 1251–1387]; Coastal Barriers Resources Act (CBRA) [16 U.S.C. 3501–3510]; Coastal Zone Management Act (CZMA) [16 U.S.C. 1451–1466];; Safe Drinking Water Act (SDWA) [42 U.S.C. 300f–300j—26]; Rivers and Harbors Act of 1899 [33 U.S.C. 401–406]; Wild and Scenic Rivers Act [16 U.S.C. 1271–1287]; Emergency Wetlands Resources Act [16 U.S.C. 3921, 3931]; Wetlands Mitigation, [23 U.S.C. 119(g) and 133(b)(3)]; Flood Disaster Protection Act [42 U.S.C. 4001–4130].

9. *Hazardous Materials:* Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) [42 U.S.C. 9601–9675]; Superfund Amendments and Reauthorization Act of 1986 (SARA); Resource Conservation and Recovery Act (RCRA) [42 U.S.C. 6901–6992(k)].

10. *Executive Orders:* E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management; E.O. 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations; E.O. 11593 Protection and Enhancement of Cultural Resources; E.O. 13007 Indian Sacred Sites; E.O. 13287 Preserve America; E.O. 11514 Protection and Enhancement of Environmental Quality; E.O. 13112 Invasive Species.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on

Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(l)(1).

Issued on: November 21, 2024.

Karen M. Brunelle

Director, Office of Project Development, Federal Highway Administration, Tallahassee, Florida.

[FR Doc. 2024–27817 Filed 11–26–24; 8:45 am]

BILLING CODE 4910–RY–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Environmental Impact Statement: Cameron, Hidalgo, And Willacy Counties, Texas

AGENCY: Texas Department of Transportation (TxDOT), Federal Highway Administration (FHWA), Department of Transportation.

ACTION: Federal notice of intent to prepare an Environmental Impact Statement (EIS).

SUMMARY: FHWA, on behalf of TxDOT, is issuing this notice to advise the public that an EIS will be prepared for a proposed transportation project to study the effects of constructing a highway improvement project from Interstate Highway (I–) 69C/United States Highway (US) 281 to I–69E/US 77 in Hidalgo, Cameron, and Willacy Counties, Texas (CSJ: 0921–02–353). The proposed project will be referred to herein as I–69 Connector, or the I–69 Connector Project. The proposed project is approximately 25 miles in length.

FOR FURTHER INFORMATION CONTACT: Francisco Chapa, P.E., TxDOT Pharr District Project Manager, 600 West I–2, Pharr, Texas, 78577, (956) 702–6344, *Francisco.chapa@txdot.gov.*

SUPPLEMENTARY INFORMATION: The environmental review, consultation, and other actions required by applicable Federal environmental laws for this project are being, or have been, carried-out by TxDOT pursuant to 23 U.S.C. 327 and a Memorandum of Understanding dated December 9, 2019, and executed by FHWA and TxDOT.

The purpose and need of the proposed I–69 Connector is to alleviate/reduce traffic congestion and improve regional mobility, to improve and increase transportation network connectivity, to address future population growth and travel demands, and to provide an east-west hurricane evacuation route.

The proposed project would evaluate a new potential connection from I–69C/US 281 to I–69E/US 77 in Hidalgo, Cameron, and Willacy Counties, Texas (CSJ: 0921–02–353). The proposed project could potentially include constructing a highway on new location for approximately 25 miles with grade separations at intersections with major crossroads.

The EIS will evaluate a range of build alternatives and a no-build alterative. Possible build alternatives include the four alternatives that were evaluated in the I–69 Connector Route Feasibility Study. Each alternative would be evaluated on the same right-of-way width and level of detail during the Alternative Analysis process.

Alternative A

Alternative A starts on the western end at the intersection of I–69C/US 281 and State Highway (SH) 107. It follows SH 107 for approximately 3.2 miles to the east, where SH 107 curves north, before continuing on new location eastward for approximately 12.3 miles. After intersection with International Boundary and Water Commission (IBWC)'s North Floodway, the alignment follows SH 107 southeast for 2.2 miles before turning north at the intersection of Farm-to-Market (FM) 1425 for approximately 1.1 miles and continuing east for approximately 6.5 miles until the eastern end of the project at I–69E/US 77. Alternative A is on partial new location and approximately 25.5 miles long.

Alternative B

Alternative B starts on new alignment at the western end at I–69C/US 281 and approximately 0.15 mile south of E. Richardson Road. This alignment continues east for approximately 3.4 miles, and curves slightly south at the intersection of SH 107 before continuing on new location for approximately 12.3 miles. After the alignment's intersection with the IBWC's North Floodway, the alignment moves slightly south until the intersection with FM 1425 for approximately 2.1 miles, then continues east for approximately 7 miles until the eastern end of the project at I–69E/US 77. Alternative B is on new location and approximately 24.8 miles long.

Alternative C

Alternative C starts on new alignment at the western end at I–69C/US 281 and approximately 0.70 mile north of E. Richardson Road. The alignment continues east for approximately 9.7 miles until curving south after the intersection with FM 88. The alignment continues east for approximately 15.3 miles until the eastern end of the project at I–69E/US 77. Alternative C is on new location and approximately 25 miles long.

Alternative D

Alternative D starts on new alignment at the western end at I–69C/US 281 and approximately 0.7 mile north of E. Richardson Road. The alignment continues east for approximately 9.3 miles until curving north 0.3 mile west of the intersection with FM 88. The alignment continues northeast for approximately 4.3 miles then continues east for approximately 9.6 miles until the intersection with I–69E/US 77. Alternative D is on new location and approximately 23 miles long.

Section 106 and Section 4(f) Historic Properties. The proposed build alternatives will be evaluated for potential adverse impacts to historic properties (*i.e.* properties that are eligible for or listed in the National Register of Historic Places) within the study area.

Environmental Justice (EJ). The proposed build alternatives will be evaluated for potential adverse impacts to EJ communities due to anticipated relocations as well as other impacts such as access, noise, and visual aesthetics. Additional analysis and public involvement will be conducted during the National Environmental Policy Act process to assess if the project would result in any disproportionately high and adverse effects on low-income and minority communities.

Wildlife and threatened and endangered species. The proposed build alternatives will be evaluated for potential adverse impacts to wildlife and threatened and endangered species within the study area.

Floodplains. The proposed build alternatives will be evaluated for potential adverse impacts to floodplains within the study area.

The EIS will evaluate the potential impacts and benefits to the resources/communities identified above as well as the following other subject areas: Limited English Proficiency communities, land use, right-of-way, social and community resources, traffic noise, air quality, water resources, hazardous materials sites, cultural resources, biological resources, protected lands 4(f) and 6(f), and visual resources.

It is anticipated that the following would be required: Texas Antiquities Code permit and concurrence, Section 106 historic/archeological resources concurrence, Section 4(f) evaluation approval, Section 7 consultation with U.S. Fish and Wildlife, IBWC Permit, and U.S. Army Corp of Engineers Section 404 Nationwide Permit(s).

A Tentative Schedule is outlined below.

The Agency Scoping Meeting was held July 29, 2024.

Public Scoping Meeting: January 21 and 23, 2025.

The FEIS/ROD is anticipated Summer 2027.

In addition to the public scoping meeting, a public hearing will be held after the Draft EIS is prepared. Public notice will provide the time and place of the hearing. After the public hearing and end of Draft EIS comment period, issuance of the Final EIS/Record of Decision is anticipated. If a build alternative is selected, all permits and authorization decisions would occur before construction.

The following entities have been invited to be cooperating agencies for this EIS: U.S. Environmental Protection Agency, U.S. Fish and Wildlife Service, U.S. Department of Agriculture, Natural Resource Conservation Service, National Park Service, U.S. Army Corp of Engineers, Federal Emergency Management Agency, Federal Transit Administration, Federal Railroad Administration, International Boundary and Water Commission, U.S. Customs and Border Protection, U.S. Department of Housing and Urban Development, Santa Ana National Wildlife Refuge, Lower Rio Grande Valley National Wildlife Refuge, Kiowa Tribe, Mescalero Apache Tribe, Tonkawa Tribe of Oklahoma, Apache Tribe of Oklahoma, and Comanche Nation of Oklahoma.

The following entities have been invited to be participating agencies for this EIS: Texas Commission on Environmental Quality, McAllen Historic Preservation Council, Texas Division of Emergency Management, The Texas General Land Office, Texas Historical Commission/State Historic Preservation Officer, Texas Parks and Wildlife Department, Cameron County Regional Mobility Authority, Hidalgo County Regional Mobility Authority, Hidalgo County Planning and Development, Cameron County Planning and Development, Hidalgo County, Cameron County, Willacy County, Texas Department of Public Safety, City of Harlingen, City of Lyford, City of McAllen, City of Donna, City of Edinburg, City of Elsa, City of La Feria, City of La Villa, City of Alamo, City of San Juan, City of Weslaco, City of Mercedes, City of Palm Valley, City of Pharr, City of Raymondville, Town of Combes, Rio Grande Valley Metropolitan Planning Organization, Cameron County Historical Commission, Hidalgo County Historical Commission, Willacy County Historical Commission, Hidalgo County Drainage District No. 1, Cameron County Irrigation District No. 2, McAllen Economic Development Corporation (EDC), Harlingen EDC, Edinburg EDC, Alamo EDC, Donna EDC, Lyford EDC, Mercedes EDC, Pharr EDC, San Juan EDC, Weslaco EDC, Elsa EDC, and Combes EDC.

TxDOT will issue a single Final Environmental Impact Statement and Record of Decision document pursuant to 23 U.S.C. 139(n)(2), unless TxDOT determines statutory criteria or practicability considerations preclude issuance of a combined document.

In accordance with 23 U.S.C. 139, cooperating agencies, participating agencies, and the public will be given an opportunity for continued input on project development. A in-person public scoping meeting is planned for Tuesday, January 21, 2025, from 5 p.m. to 7 p.m. CST at J. Economedes High School 1414 N Alamo Rd, Edinburg, Texas 78541, and January 23, 2025, from 5 p.m. to 7 p.m. CST at Elma E. Barrera Elementary School, Hwy 107, Santa Rosa, Texas 78593. The public scoping meeting will provide an opportunity for the public to review and comment on the draft coordination plan and schedule, the project purpose and need, the range of alternatives, and methodologies and level of detail for analyzing alternatives. It will also allow the public an opportunity to provide input on any expected environmental impacts, anticipated permits or other authorizations, and any significant issues that should be analyzed in depth in the EIS. In addition to the public scoping meeting, a public hearing will be held after the draft EIS is prepared. Public notice will be given of the time and place of the meeting and hearing.

The public meeting will be conducted in English. If you need an interpreter or document translator because English is not your primary language or you have difficulty communicating effectively in English, one will be provided to you. If you have a disability and need assistance, special arrangements can be made to accommodate most needs. If you need interpretation or translation services or you are a person with a disability who requires an accommodation to attend and participate in the public scoping meeting, please contact Norma Robledo, TxDOT Pharr District, at (956) 702–6161 no later than 4 p.m. CT, Thursday, January 16, 2025. Please be aware that advance notice is required as some services and accommodations may require time for the Texas Department of Transportation to arrange.

The public is requested to provide public comments on alternatives or impacts and on relevant information, studies, or analyses with respect to this proposed project. Comments may be provided in writing by mail to Francisco Chapa, TxDOT Project Manager at 600 West I–2, Pharr, Texas, 78577 or by email to *Francisco.Chapa@txdot.gov* or to *PHR_I69_Connector@txdot.gov.* Comments must be received by Friday, February 7, 2025.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction.)

Michael T. Leary,

Director, Planning and Program Development, Federal Highway Administration.

[FR Doc. 2024–27823 Filed 11–26–24; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number [FRA–2010–0029]

The National Railroad Passenger Corporation's Request To Amend Its Positive Train Control Safety Plan and Positive Train Control System

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of availability and request for comments.

SUMMARY: This document provides the public with notice that, on November 14, 2024, the National Railroad Passenger Corporation (Amtrak) submitted a request for amendment (RFA) to its FRA-approved Positive Train Control Safety Plan (PTCSP) to provide supplemental information to its initial RFA, submitted November 7, 2024, to support updates to Amtrak's Onboard Computer (OBC) Serial platform and Fusion software release. As this RFA may involve a request for FRA's approval of proposed material modifications to an FRA-certified positive train control (PTC) system, FRA is publishing this notice and inviting public comment on Amtrak's RFA to its PTCSP.

DATES: FRA will consider comments received by December 17, 2024. FRA may consider comments received after that date to the extent practicable and without delaying implementation of valuable or necessary modifications to a PTC system.

ADDRESSES:

Comments: Comments may be submitted by going to *https://www.regulations.gov* and following the online instructions for submitting comments.

Instructions: All submissions must include the agency name and the

applicable docket number. The relevant PTC docket number for this host railroad is Docket No. FRA–2010–0029. For convenience, all active PTC dockets are hyperlinked on FRA's website at *https://railroads.dot.gov/research-development/program-areas/train-control/ptc/railroads-ptc-dockets.* All comments received will be posted without change to *https://www.regulations.gov;* this includes any personal information.

FOR FURTHER INFORMATION CONTACT: Gabe Neal, Staff Director, Signal, Train Control, and Crossings Division, telephone: 816–516–7168, email: *Gabe.Neal@dot.gov.*

SUPPLEMENTARY INFORMATION: In general, Title 49 United States Code (U.S.C.) Section 20157(h) requires FRA to certify that a host railroad's PTC system complies with Title 49 Code of Federal Regulations (CFR) part 236, subpart I, before the technology may be operated in revenue service. Before making certain changes to an FRA-certified PTC system or the associated FRA-approved PTCSP, a host railroad must submit, and obtain FRA's approval of, an RFA to its PTCSP under 49 CFR 236.1021.

Under 49 CFR 236.1021(e), FRA's regulations provide that FRA will publish a notice in the **Federal Register** and invite public comment in accordance with 49 CFR part 211, if an RFA includes a request for approval of a material modification of a signal or train control system. Accordingly, this notice informs the public that, on November 14, 2024, Amtrak submitted an RFA to its PTCSP for its Advanced Civil Speed Enforcement System II (ACSES II), which seeks FRA's approval for updates to its OBC Serial platform and Fusion software release. That RFA is available in Docket No. FRA–2010–0029.

Interested parties are invited to comment on Amtrak's RFA to its PTCSP by submitting written comments or data. During FRA's review of Amtrak's RFA, FRA will consider any comments or data submitted within the timeline specified in this notice and to the extent practicable, without delaying implementation of valuable or necessary modifications to a PTC system. *See* 49 CFR 236.1021; *see also* 49 CFR 236.1011(e). Under 49 CFR 236.1021, FRA maintains the authority to approve, approve with conditions, or deny a railroad's RFA to its PTCSP at FRA's sole discretion.

Privacy Act Notice

In accordance with 49 CFR 211.3, FRA solicits comments from the public to better inform its decisions. DOT posts these comments, without edit, including any personal information the commenter provides, to *https://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *https://www.transportation.gov/privacy.* See *https://www.regulations.gov/privacy-notice* for the privacy notice of *regulations.gov.* To facilitate comment tracking, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. If you wish to provide comments containing proprietary or confidential information, please contact FRA for alternate submission instructions.

Issued in Washington, DC

Carolyn R. Hayward-Williams,

Director, Office of Railroad Systems and Technology.

[FR Doc. 2024–27818 Filed 11–26–24; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

[Docket No. FTA–2024–0015]

Notice of Availability of Proposed Circular Updates and Request for Comments

AGENCY: Federal Transit Administration (FTA), Department of Transportation (DOT).

ACTION: Notice; request for comments.

SUMMARY: The Federal Transit Administration (FTA) has placed in the docket and on its website proposed guidance in the form of an updated circular pertaining to procurements financed in whole or part with Federal assistance awarded by FTA through grants or cooperative agreements (*i.e.,* ''third party'' procurements). This updated circular would cancel and replace Circular FTA C 4220.1F, most recently revised March 18, 2013. The proposed updates reflect statutory and regulatory changes that have occurred since the last update, as well as providing additional non-binding guidance. By this notice, FTA invites public comment on its proposed circular, ''Third Party Contracting Guidance.''

DATES: Comments must be submitted by December 27, 2024. Late-filed comments will be considered to the extent practicable.

ADDRESSES: Please submit your comments by only one of the following methods, identifying your submission by docket number FTA–2024–0015. All electronic submissions must be made to the U.S. Government electronic site at *https://www.regulations.gov/.*

(1) *Federal eRulemaking Portal:* Go to *https://www.regulations.gov/* and follow the online instructions for submitting comments.

(2) *Mail:* Docket Management Facility: U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.

(3) *Hand Delivery or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, between 9 a.m. and 5 p.m. Eastern time, Monday through Friday, except Federal holidays.

(4) *Fax:* 202–366–7951.

Instructions: You must include the agency name (Federal Transit Administration) and docket number (FTA–2024–0015) at the beginning of your comments. Submit two copies of your comments if you submit them by mail. For confirmation that FTA received your comments, include a self-addressed stamped postcard. Note that all comments received will be posted without change to *https://www.regulations.gov/* including any personal information provided and will be available to internet users. For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

Docket: For access to the docket to read background documents and comments received, go to *https://www.regulations.gov/* at any time or to the U.S. Department of Transportation, 1200 New Jersey Avenue SE, Docket Operations, M–30, West Building Ground Floor, Room W12–140, Washington, DC 20590 between 9 a.m. and 5 p.m. Eastern Time, Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: For third party contracting questions, contact Tara Murphy, Division Chief, Office of Administration, Federal Transit Administration, 1200 New Jersey Ave. SE, Room E41–311, Washington, DC 20590, phone: (202) 366–5647 or email *tara.murphy@dot.gov.* For legal questions, Christopher Hall, Office of Chief Counsel, same address, Room E56–312, phone (202) 941–9595 or email *christopher.hall@dot.gov.*

SUPPLEMENTARY INFORMATION:

Overview

FTA proposes an update to its Third Party Contracting Guidance Circular, which would replace and cancel the current iteration dated March 18, 2013 (C 4220.1F). The proposed circular would update FTA's guidance for

recipient procurements financed with FTA assistance (third party contracts) to reflect current statutory and regulatory text, including the Infrastructure Investment and Jobs Act (IIJA), Public Law 117–582, signed into law on November 15, 2021; the Fixing America's Surface Transportation (FAST) Act, Public Law 114–94, signed into law on December 4, 2015; and new or updated administrative requirements from 2 CFR parts 200 and 1201.

This notice does not include the proposed circular; electronic versions of the proposed circular may be found on the docket at *https://www.regulations.gov,* docket number FTA–2024–0015, or on FTA's website at *https://www.transit.dot.gov.*

Chapter-By-Chapter Summaries

Throughout the proposed circular, revisions are proposed that would clarify or reorganize sections for improved readability, without substantively altering guidance from the current Circular 4220.1F. The proposed circular also updates citations to authority and adds citations to improve transparency about the sources of requirements. Proposed changes that would not have a substantive effect are not necessarily called out in this notice.

Chapter I

In Chapter I, FTA proposes to revise several key definitions, including ''Approval, Authorization, Concurrence, Waiver,'' ''Best Value,'' ''Change Order,'' ''Common Grant Rules,'' ''Constructive Change,'' ''Contract,'' ''Design-Build Project,'' ''Governmental Recipient,'' ''Joint Procurement,'' ''Non-Governmental Recipient,'' ''Recipient,'' ''State or Local Government Purchasing Schedule or Purchasing Contract,'' ''Third Party Contract,'' and ''Value Engineering.'' In most cases, revisions were to simplify definitions, or align definitions with existing statute or regulations. Additionally, this chapter would introduce new definitions, such as ''Alternate Contracting Method (ACM),'' ''Progressive Design-Build (PDB),'' and ''Public-Private Partnership (P3).''

FTA also proposes to update language in this chapter describing the Federal Transit Administration (FTA) and the roles of FTA's headquarters, regional, and metropolitan offices in supporting public transportation agencies.

Chapter II

FTA proposes to revise Chapter II to clarify the circular's effect and applicability, including by distinguishing between binding requirements (*e.g.,* described using ''must'' or ''shall'') and non-binding recommendations (*e.g.,* described using ''may'' or ''should''). Throughout the proposed circular, revisions would take care to distinguish between the mandatory and the advisory. The proposed revisions would specify how the circular applies to different entities, including States, Tribes, non-State recipients, and third party contractors, and would simplify the Project Types and Third Party Contracts sections under the Applicability of the Circular. Updates would consolidate or remove outdated and inapplicable sections from this Chapter, such as those on ''Other Agreement'' Assistance, Art, the Over the Road Bus Accessibility Program, and certain Operations and Preventive Maintenance contracts. These sections are redundant or otherwise no longer relevant due to program changes.

Additionally, proposed changes would expand the descriptions of available project delivery options for recipients by adding Construction Manager/General Contractor (CM/GC), Full Delivery or Program Management, and Progressive Design-Build (PDB) to the list of project delivery systems. Proposed revisions to Chapter II would also add guidance on Alternative Contracting Methods (ACMs) regarding PDB and P3. Finally, the proposed updates would revise the Federal Laws and Regulations section and the State and Local Laws and Regulations section to update the description of the relationships among Federal and State laws, regulations, and the FTA grant agreements and Master Agreement.

Chapter III

FTA proposes amendments to Chapter III that would update guidance on recipients' responsibilities, with particular emphasis on Written Standards of Conduct to address Gifts and Violations, along with new guidance on Organizational Conflicts, to reflect current Federal regulations. Similarly, the proposed changes would update guidance on Self-Certification and Third Party Contracting Capacity to clarify FTA's use of certifications and describe existing practice and procedures at FTA. Proposed revisions to Adequate Third Party Contract Provisions, Industry Contracts, Record Keeping, Procurement History, Procurement Method, Contract Type, and Contractor Selection would improve clarity, update citations, and bring them into alignment with current Federal regulations.

Proposed revisions to Chapter III would also incorporate new guidance on Constructive Changes, update guidance on Access to Records, and remove Special Notification Requirements to align with current Federal regulations. Additionally, proposed changes would update guidance regarding Use of Technology/Electronic Commerce and Electronic Bidding and Reverse Auctions.

To address the industry's growing need for control and access to data, as contracts increasingly involve data collection, new guidance would be added on Data Rights. This guidance would cover aspects such as data collection, ownership, and usage, with specific provisions on negotiating data rights to secure adequate licenses for federally funded data. It would also ensure the clear definition of data rights, negotiation of data access rights to meet Federal objectives, and inclusion of appropriate clauses.

Proposed updates would update guidance on Audits to align with updated Federal regulations.

To replace the current circular's description of protests and appeals to FTA (see below, under Chapter VII), Chapter III would include a new section describing FTA's role in the recipient's procurement disputes and FTA's interest in settlements impacting Federal funds.

Chapter IV

In Chapter IV, FTA proposes to clarify the Determining the Recipient's Needs section, including guidance on Necessity, Unnecessary Reserves and Spare Ratios, Acquisition for Assignment Purposes (''piggybacking''), Changes in the Recipient's Needs, and Joint Procurements, as well as State or Local Government Purchasing Schedules or Purchasing Contracts, in accordance with current FTA guidance and purchasing authorities and to reduce duplication of other sections of the circular. Guidance on Joint Procurements would be clarified, while Small Procurements and Lease-versus-Purchase guidance would be updated to align with existing Federal regulation. New guidance to reflect innovative procurement flexibilities introduced by the FAST Act would be introduced on Leases of Rolling Stock and Related Equipment, Leases of Removable Power Sources, reporting requirements, and lease specifications.

Additional updates would clarify Federal requirements affecting recipient acquisitions. Guidance on Responsibility Requirements and DOT Debarment and Suspension would be updated, with references to the GSA Excluded Parties List replaced by the System for Award Management (SAM). Updates to Conflicts of Interest, and Lobbying Certification and Disclosure

would improve clarity and reflect current Federal regulations and FTA policy.

The Federal Civil Rights Laws and Regulations section would be renamed Civil Rights and moved and consolidated with other civil rights-related sections for better flow. Updates within Administrative Requirements would include minor clarifications for accuracy. Under Cost Principles, unnecessary guidance on Governmental Entities, Educational Institutions, Non-Profit Entities, and For-Profit Entities would be removed because these entities all apply the same cost principles under FTA's policy.

The Payments Provision section would be updated with the latest FTA guidance on Advance Payments and Progress Payments.

Wage and Hour Requirements under Socio-Economic Requirements would be renamed the Contract Work and Hours and Safety Standards Act, to be consistent with regulation, and the information therein would be updated to reflect the most current description in Federal regulation. Fair Labor Standards guidance would be similarly updated.

Under Civil Rights, guidance would be reorganized for flow, and new guidance would address changes in the law regarding nondiscrimination on the basis of sexual orientation and gender since the last circular update.

The Targeted Contracting section would be updated. The description of U.S. DOT's Disadvantaged Business Enterprise (DBE) rule would be updated to reflect changes to that rule that took effect in 2024. The section on Small and Disadvantaged Business Enterprises and HUBZones would be expanded in accordance with existing Federal regulation.

Under Environmental Protection, guidance on the Clean Air Act, the Federal Water Pollution Control Act, and Recycled Products would be updated to reflect current Federal regulations. Energy Conservation would be updated to refer to current regulation. Preference for U.S. Property—Buy America would be updated to add reference to the Build America, Buy America Act that became law in 2021, the addition of construction materials to the list of products that must be manufactured in the United States on an FTA funded project, and reference to 2 CFR part 184, which implements the new requirement for construction materials. Guidance on Shipments by Ocean Vessel would be clarified.

Under Technical Restrictions, updates would remove unnecessary Metric Measurements guidance, because 2 CFR part 200 does not require this.

Under Rolling Stock—Special Requirements, guidance on Transit Vehicle Manufacturer Compliance with DBE Requirements would expand to include guidance on project-specific DBE participation goals. Updates on Minimum Useful Life and Spare Ratios would make clarifications and align with FTA's latest guidance. Outdated guidance on Air Pollution and Fuel Economy would be removed. Minor corrections and simplifications would be made to Preaward and Post Delivery Review, Bus Testing, In-State Dealers, and Rolling Stock Contract Options.

The Art section would be substantially removed because art no longer is an eligible expense under FTA's statute.

Guidance on Architectural and Engineering (A&E) Services would include updates on Qualifications-Based Selection, renamed from Qualifications-Based Requirements, to reorganize and clarify without substantive changes. Related updates for Construction, Service Purposes, Equivalent State Law, and Indirect Cost Rates would enhance clarity.

Under Construction—Special Requirements, guidance on Bonding, Bid Guarantees, Performance Bonds, Payment Bonds, Reduced Bonding, and Excessive Bonding would be updated to refer to current regulations and updated URLs without substantive change. Seismic Safety, Value Engineering, Equal Employment Opportunity, Davis-Bacon Wages, Anti-Kickback, Contract Work Hours and Safety Standards, and Labor Neutrality would receive non-substantive updates for clarity and regulatory alignment, and a new section on veterans' employment would be added in accordance with FTA's existing statute. The section on Preference for U.S. Property—Buy America would be consolidated earlier in the chapter. Accessibility guidance would also be relocated for clarity.

The Research, Development, Demonstration, Deployment, and Special Studies—Special Requirements section would include updates to Patent Rights, Rights in Data, Export Control, Protection of Human Subjects, and Protection of Animals to cite to current Federal regulations and FTA's Master Agreement where appropriate.

Finally, updates in Audit Services would align with current Federal regulations and dollar thresholds, with revisions to the Single Audit Act, Organizational Conflicts of Interest, Eligibility Costs, and verification processes. The section on Obtaining Indirect Cost Rates would be simplified and references to current Federal regulation would be added.

Chapter V

Chapter V would update the Force Account and Shared Use sections for clarity to refer to FTA's latest guidance on the subjects. Under Joint Procurement, guidance would be clarified. Updates to the guidance on State or Local Government Purchasing Schedules or Purchasing Contracts would be clarified, and new guidance would be provided on Interstate Purchasing of Rolling Stock and Related Equipment to account for changes to rolling stock purchasing authorities. New guidance would be added on Interstate Purchasing Schedules and guidance on Intergovernmental Agreements would be updated to reflect new authorities introduced by the FAST Act for rolling stock procurements.

New guidance on Cooperative Procurement of Rolling Stock and Related Equipment would be added to reflect new FAST Act authorities.

Guidance on Competition and Price Reasonableness would be revised to align with current Federal regulations.

The Existing Contracts (Assignments) section would be reorganized and streamlined for clarity. Information on Alternatives to Assigned Contract Rights, Joint Procurements, and Intergovernmental Procurements would be removed and consolidated with the sections elsewhere in the circular dealing with those topics. Guidance related to Impermissible Actions, Improper Contract Expansion and Improper Cardinal Changes would be updated to improve clarity. Sections on Tests, Rolling Stock, and Federal Procurement Standards would be removed from this section and consolidated with sections elsewhere in this circular dealing with those topics.

Chapter VI

For Chapter VI, the Competition Required section would incorporate changes to more closely reflect existing Federal regulations. The subsection on Unsolicited Proposals would be reorganized for flow without substantive change. Prequalification guidance would be updated to match current regulation, adding Objective Factors and refining sections on Currentness (formerly Lists), Sources, and Qualification Periods.

Solicitation Requirements and Restrictions would also be updated to align with Federal regulations, including clarifications in the subsections What to Include and Brand Name or Equal. Prohibitions would be revised, with updates on Excessive Qualifications, Unnecessary Experience, Improper Prequalification, Retainer

Contracts, Excessive Bonding, Brand Name Only, and Geographic Restrictions (formerly In-State or Local Geographic Restrictions). Regarding geographic restrictions, changes since the last circular update include authority in IIJA to apply local hiring targets to construction projects, and the removal of a former prohibition against geographic restrictions from 2 CFR part 200. A reference to Self-Dealing and Bid Rigging would be added to the list of prohibited restrictions on competition.

The section on Organizational Conflicts of Interest would be revised to include new guidance on the Recipient's Conflicts in accordance with current regulation. Updates to Contractor's Conflicts would include expanded guidance on Biased Ground Rules in accordance with existing regulation.

The Prohibited or Restricted Contract Types section would be simplified, with clarifications on Cost Plus a Percentage of Cost—Prohibited, Percentage of Construction Cost—Prohibited, and Time and Materials—Restricted. Subsections on When to Use and Firm Ceiling Price would be removed as unnecessary.

Methods of Procurement would be revised to reflect updated Federal regulations, including a new section on Self-Certified Micro-Purchase Thresholds, which were introduced by a new provision in 2 CFR part 200 that took effect in 2024. Under the new provision, a recipient may set for itself a micro-purchase threshold that is higher than the Federal micro-purchase threshold. Procedures, including Distribution (formerly Competition) and Documentation, would be clarified, and the Small Purchases subsection would be renamed Simplified Acquisitions for accuracy, regulatory alignment, and to avoid confusion with FTA's unrelated ''small purchases'' Buy America waiver. The Simplified Acquisitions section would be updated to align with the current regulations, including updates to Competition and Documentation.

Sealed Bids (Formal Advertising) would undergo updates to align with current Federal regulations and simplify guidance, with specific clarifications in When Appropriate, Fixed Price Contract, Discussions Unnecessary, and Procurement Procedures.

Competitive Proposals (Request for Proposals) would be updated for regulatory consistency, with clarification in When Appropriate and Discussion Expected. Procurement Procedures would see updates in Notice (formerly Publicity), Written Procedures (formerly Evaluation Method), Price and Other Factors, and the absorption of Best Value into Price and Other Factors.

The section on Two-Step Procurement Procedures would receive additional guidance and clarifications.

Guidance on Architectural and Engineering (A&E) Services and Other Services would be updated for clarity, and a new statement would be added to make clear that Multiple Award Indefinite-Delivery A&E Contracts are permissible.

Information on Design-Bid-Build (DBB) would be incorporated into a new section on Mixed A&E-Construction Contracts, covering both DBB and Progressive Design-Build (PDB). The Procurement Method section would be updated, with Construction Predominant, Design Services Predominant, and Selection Processes sections absorbed into Procurement Method for streamlined guidance.

The Other Than Full and Open Competition section would be revised to more closely follow Federal regulations. Guidance on Micro-Purchases, Sole Source, Unsolicited Proposals, and Restricted Data Rights would be updated for clarity. The Exigency or Emergency section would be clarified, with Unusual and Compelling Urgency absorbed under Exigency or Emergency. The significantly outdated paragraph about Associated Capital Maintenance Item Exception would be removed.

Updates would clarify guidance on Cardinal Changes, including revised guidance on when cardinal changes impair competition and how to recognize cardinal changes that impair competition.

Eligible Costs would be updated to align with the current Federal regulation and FTA policy in its Master Agreement. The section on Adjustments to Project Costs would be removed as unnecessary.

Cost Analysis and Price Analysis would receive minor revisions for clarity and organization, and the sentence on Federal cost principles would be removed as redundant with the following subsection, Guidance on Cost and Price Analysis.

Guidance on Evaluations and Contract Award would be updated with minor changes for clarity, and a new information on disqualifying offerors with recent Tax Liability or Felony Convictions.

Chapter VII

Chapter VII in Circular 4220.1F deals with protests, changes, disputes, and appeals of the recipient's procurement decisions to FTA. The proposed circular would eliminate Chapter VII and replace it with a new paragraph in proposed Chapter III on Recipient Responsibilities and FTA's Role in Procurement Disputes. That paragraph would restate the current regulation, which commits procurement decisions to the discretion of the recipient and states that FTA will not substitute its judgment for that of the recipient unless the matter is primarily a Federal concern. It also would state FTA's interest in settlements of procurement disputes that would commit Federal funds or the proceeds of procurement disputes arising from federally funded procurements.

Appendices

FTA proposes to revise the appendices of the circular to improve accuracy, accessibility, and ensure alignment with current best practices. Specifically, Appendix A, References, would be revised to reflect sources incorporated in this version. Appendix B, FTA Regional and Metropolitan Office Contact Information, and Appendix C, Third Party Contracting Checklist, would be removed to streamline the document and focus on core guidance. Additionally, Appendix D, Provisions, Certifications, Reports, Forms, and Other—Matrices, would be removed to enable more timely updates to this information on the FTA website.

Closing

After a review and consideration of the comments provided on the updates proposed, FTA will publish the updated Third Party Contracting Guidance Circular (C 4220.1G) on its website and will announce the availability of the updated circular and the response to comments in the **Federal Register**.

Veronica Vanterpool,

Deputy Administrator.

[FR Doc. 2024–27645 Filed 11–26–24; 8:45 am]

BILLING CODE 4910–57–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Information Collection Renewal; Comment Request; Computer-Security Incident Notification

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites

comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995 (PRA). In accordance with the requirements of the PRA, the OCC may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The OCC is soliciting comment concerning the renewal of its information collection titled, ''Computer-Security Incident Notification.''

DATES: Comments must be received by January 27, 2025.

ADDRESSES: Commenters are encouraged to submit comments by email, if possible. You may submit comments by any of the following methods:

- *Email: prainfo@occ.treas.gov.*
- *Mail:* Chief Counsel's Office, Attention: Comment Processing, Office of the Comptroller of the Currency, Attention: 1557–0350, 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Fax:* (571) 293–4835.

Instructions: You must include ''OCC'' as the agency name and ''1557–0350'' in your comment. In general, the OCC will publish comments on *www.reginfo.gov* without change, including any business or personal information provided, such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

Following the close of this notice's 60-day comment period, the OCC will publish a second notice with a 30-day comment period. You may review comments and other related materials that pertain to this information collection beginning on the date of publication of the second notice for this collection by the method set forth in the next bullet.

- *Viewing Comments Electronically:* Go to *www.reginfo.gov.* Hover over the ''Information Collection Review'' tab and click on ''Information Collection Review'' from the drop-down menu. From the ''Currently under Review'' drop-down menu, select ''Department of Treasury'' and then click ''submit.'' This information collection can be located by searching OMB control number ''1557–0350'' or ''Computer-Security Incident Notification.'' Upon finding the appropriate information collection, click on the related ''ICR Reference Number.'' On the next screen, select ''View Supporting Statement and Other Documents'' and then click on the link to any comment listed at the bottom of the screen.
- For assistance in navigating *www.reginfo.gov,* please contact the Regulatory Information Service Center at (202) 482–7340.

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, Clearance Officer, (202) 649–5490, Chief Counsel's Office, Office of the Comptroller of the Currency, 400 7th Street SW, Washington, DC 20219. If you are deaf, hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501 *et seq.*), Federal agencies must obtain approval from the OMB for each collection of information that they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) to include agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of title 44 generally requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, the OCC is publishing notice of the renewal of this collection.

Title: Computer-Security Incident Notification.

OMB Control No.: 1557–0350.

Type of Review: Regular.

Affected Public: Businesses or other for-profit.

Description: Pursuant to 12 CFR part 53, the OCC has established certain computer-security incident notification requirements applicable to banking organizations [1] and bank service providers.[2] Specifically, 12 CFR 53.3 requires a banking organization to notify the OCC about a ''notification incident'' as soon as possible but no later than 36 hours after the banking organization determines that a notification incident has occurred. The regulation defines a ''notification incident'' as ''a computer-security incident that has materially disrupted or degraded, or is reasonably likely to materially disrupt or degrade, a banking organization's—(i) [a]bility to carry out banking operations, activities, or processes, or deliver banking products and services to a material portion of its customer base, in the ordinary course of business; (ii) [b]usiness line(s), including associated operations, services, functions, and support, that upon failure would result in a material loss of revenue, profit, or franchise value; or (iii) [o]perations, including associated services, functions and support, as applicable, the failure or discontinuance of which would pose a threat to the financial stability of the United States.'' [3]

Additionally, a bank service provider must notify at least one bank-designated point of contact at each affected banking organization customer as soon as possible when the bank service provider determines that it has experienced a computer-security incident that has materially disrupted or degraded, or is reasonably likely to materially disrupt or degrade, covered services provided to such banking organization for four or more hours.

Estimated Burden:

Estimated Frequency of Response: On occasion; event generated.

Estimated Number of Respondents:

Reporting: 100 Respondents.

Disclosure: 832 Respondents.

Estimated Total Annual Burden: 2,795 hours.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the OCC, including whether the information has practical utility;

(b) The accuracy of the OCC's estimate of the burden of the collection of information;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection on respondents, including

[1] A banking organization as ''a national bank, Federal savings association, or Federal branch or agency of a foreign bank; provided, however, that no designated financial market utility shall be considered a banking organization.'' 12 CFR 53.2(b)(1).

[2] A bank service provider is ''a bank service company or other person that performs covered services; provided, however, that no designated financial market utility shall be considered a bank service provider.'' 12 CFR 53.2(b)(2).

[3] 12 CFR 53.2(b)(7). A ''computer-security incident'' is ''an occurrence that results in actual harm to the confidentiality, integrity, or availability of an information system or the information that the system processes, stores, or transmits.'' 12 CFR 53.2(b)(4).

through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Patrick T. Tierney,

Assistant Director, Office of the Comptroller of the Currency.

[FR Doc. 2024–27876 Filed 11–26–24; 8:45 am]

BILLING CODE 4810–33–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Action

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List (SDN List) based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: This action was issued on October 30, 2024. See **SUPPLEMENTARY INFORMATION** for relevant dates.

FOR FURTHER INFORMATION CONTACT: OFAC: Associate Director for Global Targeting, 202–622–2420; or *https://ofac.treasury.gov/contact-ofac.*

SUPPLEMENTARY INFORMATION:

Electronic Availability

The SDN List and additional information concerning OFAC sanctions programs are available on OFAC's website: *https://ofac.treasury.gov.*

Notice of OFAC Action(s)

On October 30, 2024, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authorities listed below.

BILLING CODE 4810–AL–P

Individuals

1. AYDIN, Gurhan, Konya, Turkey; DOB 20 Jan 1964; POB Konya, Turkey; nationality Turkey; Gender Male; Secondary sanctions risk: See Section 11 of Executive Order 14024.; National ID No. 30481753270 (Turkey) (individual) [RUSSIA-EO14024] (Linked To: AYTT CNC TAKIM TEZGAHLARI MAKINE SANAYI VE TICARET LIMITED SIRKETI).

   Designated pursuant to section 1(a)(iii)(C) of Executive Order 14024 of April 15, 2021, ''Blocking Property With Respect To Specified Harmful Foreign Activities of the Government of the Russian Federation,'' 86 FR 20249, 3 CFR, 2021 Comp., p. 542 (Apr. 15, 2021) (E.O. 14024) as amended by Executive Order 14114 of December 22, 2023, "Taking Additional Steps With Respect to the Russian Federation's Harmful Activities," 88 FR 89271, 3 CFR, 2023 Comp., p. 721 (Dec. 22, 2023) (E.O. 14114), for being or having been a leader, official, senior executive officer, or member of the board of directors of AYTT CNC TAKIM TEZGAHLARI MAKINE SANAYI VE TICARET LIMITED SIRKETI, a person whose property and interests in property are blocked pursuant to E.O. 14024.

2. AYDIN, Recep Cetin, Konya, Turkey; DOB 14 Nov 1996; POB Selcuklu, Turkey; nationality Turkey; Gender Male; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Passport U14618486 (Turkey) expires 05 Jun 2027; National ID No. 30442754582 (Turkey) (individual) [RUSSIA-EO14024].

   Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

3. KOKOREV, Sergei, Montenegro; DOB 04 Oct 1986; nationality Russia; Gender Male; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Passport 761579971 (Russia) (individual) [RUSSIA-EO14024].

   Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

4. DUBEN, Andrei Vladimirovich, Chile; DOB 12 Dec 1970; nationality Chile; Gender Male; Secondary sanctions risk: See Section 11 of Executive Order 14024. (individual) [RUSSIA-EO14024].

   Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the metals and mining sector of the Russian Federation economy.

5. KRAYUSHKIN, Evgeniy (a.k.a. KRAIUSHKIN, Evgenii; a.k.a. KRAIUSHKIN, Evgenii Vladimirovich; a.k.a. KRAYUSHIN, Evgeny), 19 74 Miryy Microdistrict, Uglich, Yaroslavl Region 152620, Russia; Building 41, 3 Zheleznodorozhniy Lane, Dmitrov, Moscow, Russia; 9 Melitopolskaya ul., Str. 3, Moscow, Russia; DOB 28 Mar 1990; POB Uglich, Russia; nationality Russia; Gender Male; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Passport 730727217 (Russia) expires 19 Jun 2023;

National ID No. 7812932944 (Russia) (individual) [RUSSIA-EO14024] (Linked To: TECHNOPOLE COMPANY).

Designated pursuant to section 1(a)(vii) of E.O. 14024 for having acted or purported to act for or on behalf of, directly or indirectly, TECHNOPOLE COMPANY, a person whose property and interests in property are blocked pursuant to E.O. 14024.

6. SLEPOV, Valery Mikhaylovich, Russia; DOB 21 Jul 1973; POB Moscow, Russia; nationality Russia; Gender Male; Secondary sanctions risk: See Section 11 of Executive Order 14024. (individual) [RUSSIA-EO14024] (Linked To: TECHNOPOLE COMPANY).

Designated pursuant to section 1(a)(vii) of E.O. 14024 for having acted or purported to act for or on behalf of, directly or indirectly, TECHNOPOLE COMPANY, a person whose property and interests in property are blocked pursuant to E.O. 14024.

7. STRELCHENKO, Alexey Alekseyevich (Cyrillic: СТРЕЛЬЧЕНКО, Алексей Алексеевич) (a.k.a. STRELCHENKO, Aleksei Alekseevich; a.k.a. STRELCHENKO, Aleksey), Russia; DOB 10 Aug 1955; POB Moscow, Russia; nationality Russia; Gender Male; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 770803182739 (Russia) (individual) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the marine sector of the Russian Federation economy.

8. MOLOTOV, Stanislav Igorevich, Russia; DOB 18 Oct 1985; nationality Russia; citizen Russia; Gender Male; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 772374802776 (Russia) (individual) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

9. KHOMENKO, Tatyana Valentinovna, Russia; DOB 06 Jul 1969; nationality Russia; Gender Female; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 500103405764 (Russia) (individual) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

10. KHOMENKO, Igor Vladimirovich, Russia; DOB 23 Aug 1968; nationality Russia; Gender Male; Secondary sanctions risk: See Section 11 of Executive Order 14024. (individual) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

11. USHKO, Sergei Petrovich (a.k.a. USHKO, Sergey), Russia; DOB 07 Sep 1969; POB Minsk, Belarus; nationality Russia; Gender Male; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Passport 757089471 (Russia) (individual) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

12. USHKO, Aleksandr Sergeyevich, Russia; DOB 15 Jan 1991; nationality Russia; Gender Male; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Passport 550403152 (Russia) (individual) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

13. ALBAYRAK, Ahmet Furgan, Turkey; DOB 29 Apr 1974; POB Amasya, Turkey; nationality Turkey; Gender Male; Secondary sanctions risk: See Section 11 of Executive Order 14024.; National ID No. 19906311370 (Turkey) (individual) [RUSSIA-EO14024] (Linked To: SANLITUN YATIRIM DIS TICARET LIMITED SIRKETI).

    Designated pursuant to section 1(a)(vii) of E.O. 14024 for having acted or purported to act for or on behalf of, directly or indirectly, SANLITUN YATIRIM DIS TICARET LIMITED SIRKETI, a person whose property and interests in property are blocked pursuant to E.O. 14024.

14. CONTOGURIS, Petros Nikolaos (a.k.a. CONTOGURIS, Petros Nikola; a.k.a. CONTOGURIS-TROEMEL, Petros; a.k.a. "CONTOGU, Petros Nikolao"; a.k.a. "KONTOGOURIS, Petros Nikolao"), Turkey; DOB 06 Jun 1947; POB Greece; nationality Greece; Gender Male; Secondary sanctions risk: See Section 11 of Executive Order 14024. (individual) [RUSSIA-EO14024] (Linked To: KALININ, Alexander Vladimirovich).

    Designated pursuant to section 1(a)(vi)(B) of E.O. 14024 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, Alexander Vladimirovich Kalinin, a person whose property and interests in property are blocked pursuant to E.O. 14024.

15. KALININ, Alexander Vladimirovich (a.k.a. KALININ, Aleksandr; a.k.a. KALININ, Alexander), Turkey; DOB 22 Feb 1974; POB Moscow, Russia; nationality Russia; Gender Male; Secondary sanctions risk: See Section 11 of Executive Order 14024.; National ID No. 4513147020 (Russia) (individual) [RUSSIA-EO14024] (Linked To: SANLITUN YATIRIM DIS TICARET LIMITED SIRKETI).

    Designated pursuant to section 1(a)(vii) of E.O. 14024 for having acted or purported to act for or on behalf of, directly or indirectly, SANLITUN YATIRIM DIS TICARET LIMITED SIRKETI, a person whose property and interests in property are blocked pursuant to E.O. 14024.

16. BAUMGARTNER, Andres Paul, Switzerland; DOB 02 Jan 1961; POB Zurich, Switzerland; nationality Switzerland; Gender Male; Secondary sanctions risk: See Section 11 of Executive Order 14024. (individual) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the trust and corporate formation services sector of the Russian Federation economy.

17. DELCO, Fabio Libero, Switzerland; DOB 23 Oct 1967; nationality Switzerland; Gender Male; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Passport 8489687 (Switzerland) (individual) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the trust and corporate formation services sector of the Russian Federation economy.

18. LIN, Qing (Chinese Simplified: 林青) (a.k.a. LIN, Becky), 1205, Block H, No. 1168 Sunshine Haibin Garden, Houbaibin Road, Nanshan District, Shenzhen, Guangdong, China; DOB 29 Mar 1983; POB Jiujiang, Jiangxi Province, China; nationality China; Gender Male; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Identification Number 360402198303292112 (China) (individual) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the electronics sector of the Russian Federation economy.

19. PENG, Minbo (Chinese Simplified: 彭敏波) (a.k.a. "PENG, Betty"), Unit 1507B, 15/F., Eastcore, 398 Kwun Tong Road, Kwun Tong, Kowloon, Hong Kong, China; No. 111 Changtang Group, Guandao Village, Tiaoma Town, Lianghua District, Changsha, Hunan, China; DOB 01 Oct 1982; POB Furong District, Changsha, Hunan Province, China; nationality China; Gender Female; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Passport EH4256001 (China) expires 25 Sep 2029; Identification Number 430102198210015564 (China) (individual) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the electronics sector of the Russian Federation economy.

20. CELIK, Ozgur Hasan (a.k.a. CHELIK, Yozgyur Hasan; a.k.a. HASAN, Chelik), Turkey; DOB 19 May 1976; POB Istanbul, Turkey; nationality Turkey; Gender Male; Secondary sanctions risk: See Section 11 of Executive Order 14024.; National ID No. 22694157006 (Turkey) (individual) [RUSSIA-EO14024] (Linked To: MIREX HAVACILIK VE SAVUNMA SANAYI TICARET ANONIM SERKETI).

    Designated pursuant to section 1(a)(vii) of E.O. 14024 for having acted or purported to act for or on behalf of, directly or indirectly, MIREX HAVACILIK VE SAVUNMA SANAYI TICARET ANONIM SERKETI, a person whose property and interests in property are blocked pursuant to E.O. 14024.

21. GUREYEV, Aleksey Viktorovich (Cyrillic: ГУРЕЕВ, Алексей Викторович), Turkey; DOB 26 Apr 1984; nationality Russia; Gender Male; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 772605324914 (Russia) (individual) [RUSSIA-EO14024] (Linked To: STATE CORPORATION ROSTEC).

    Designated pursuant to section 1(a)(vii) of E.O. 14024 for having acted or purported to act for or on behalf of, directly or indirectly, STATE CORPORATION ROSTEC, a person whose property and interests in property are blocked pursuant to E.O. 14024.

22. KLEMENTYEV, Mikhail Alekseyevich (a.k.a. KLEMENTEV, Mikhail), Turkey; DOB 30 Dec 1988; nationality Russia; Gender Male; Secondary sanctions risk: See Section 11 of Executive Order 14024. (individual) [RUSSIA-EO14024] (Linked To: STATE

CORPORATION ROSTEC).

Designated pursuant to section 1(a)(vii) of E.O. 14024 for having acted or purported to act for or on behalf of, directly or indirectly, STATE CORPORATION ROSTEC, a person whose property and interests in property are blocked pursuant to E.O. 14024.

23. SHACHENOK, Daria Aleksandrovna (Cyrillic: ШАЧЕНОК, ДАРЬЯ АЛЕКСАНДРОВНА), St. Petersburg, Russia; DOB 26 Apr 1982; POB St. Petersburg, Russia; nationality Russia; Gender Female; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Passport 726062731 (Russia) (individual) [RUSSIA-EO14024] (Linked To: LLC AM LOGISTICS).

Designated pursuant to section 1(a)(iii)(C) of E.O. 14024 for being or having been a leader, official, senior executive officer, or member of the board of directors of LLC AM LOGISTICS, a person whose property and interests in property are blocked pursuant to E.O. 14024.

Entities

1. AO CHIP I DIP (Cyrillic: АО ЧИП И ДИП) (a.k.a. "CHIP AND DIP"; a.k.a. "CHIP&DIP"), Ul. Gilyarovskogo D. 39, Str. 1, Moscow 129110, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Type: Retail sale of information and communications equipment in specialized stores; Tax ID No. 7729108750 (Russia); Registration Number 1027700271807 (Russia) [RUSSIA-EO14024].

   Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

2. AUTONOMOUS NON PROFIT ORGANIZATION INSTITUTE OF ENGINEERING PHYSICS (a.k.a. ANO INSTITUTE OF ENGINEERING PHYSICS), Bolshoi Udarnyi Per D 1 A, Serpukhov 142210, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 5043075306 (Russia); Registration Number 1225000027108 (Russia) [RUSSIA-EO14024].

   Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

3. BASTION EK (a.k.a. BASTION EC LIMITED LIABILITY COMPANY), Ul. Krylenko D. 26, Lit. A, Pomeshch. 5-N, Saint Petersburg 193232, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7810627000 (Russia); Registration Number 1167847441706 (Russia) [RUSSIA-EO14024].

   Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

4. ENERGON, Pr-kt Udelnyi D. 5, Lit. A, Pomeshch. 21-N Office 1, Saint Petersburg 194017, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7802608879 (Russia); Registration Number 1177847011759 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

5. ENERGOTEST LLC, Ul. Avtozavodskaya D. 14/23, Moscow 115280, Russia; Ul. Leninskaya Sloboda D. 23, Str. 2, Moscow 115280, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7725580753 (Russia); Registration Number 5067746397087 (Russia) [RUSSIA-EO14024].

   Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

6. GIGANT COMPUTER SYSTEMS LLC (a.k.a. "GCS LLC"), Ul. 2-YA Entuziastov D. 5, Korp. 41, Moscow 111024, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7720768984 (Russia); Registration Number 1127747243260 (Russia) [RUSSIA-EO14024].

   Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

7. IPC2U LLC (a.k.a. AIPISI2YU), Ul. Stavropolskaya D. 84, Str. 1, Office 212, Moscow 109380, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Type: Other information technology and computer service activities; Tax ID No. 7721557513 (Russia); Registration Number 1067746681155 (Russia) [RUSSIA-EO14024].

   Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

8. JOINT STOCK COMPANY PRIBORY SERVICE TORGOVLYA (a.k.a. JOINT STOCK COMPANY DEVICES SERVICE TRADE; a.k.a. PRIST), Ul. 2-I Donskoi Proezd D. 10 Stankonormal, Str. 4, 2-I Eta, Moscow 119071, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7721212396 (Russia); Registration Number 1037700203364 (Russia) [RUSSIA-EO14024].

   Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

9. LIMITED LIABILITY COMPANY NTC ARSENAL (Cyrillic: ОБЩЕСТВО С ОГРАНИЧЕННОЙ ОТВЕТСТВЕННОСТЬЮ НТЦ АРСЕНАЛ) (a.k.a. LTD NTC ARSENAL; a.k.a. NTTS ARSENAL), Ul. Varshavskaya D. 5A, Lit. R, Pomeshch. 8-N, Kom. 17, Saint Petersburg 196128, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7810912488 (Russia); Registration Number 1217800012055 (Russia) [RUSSIA-EO14024].

   Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

10. LLC GRANT INSTRUMENT, Ul. Tsvetochnaya D. 16, Str. 1, Pomeshch. 425, Saint Petersburg 196006, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7807042570 (Russia); Registration Number 1037819007522 (Russia)

[RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

11. LLC INTERRESURS, Ul. Marshala Govorova D. 35, Korpus 4 Lit. I, Pom.30-N, Office 717, Saint Petersburg 198095, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7839504717 (Russia); Registration Number 1147847385124 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

12. LLC SINTO, Pr-kt Moskovskii D. 12, Yaroslavl 150001, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7604079550 (Russia); Registration Number 1057600652988 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

13. MIG ELEKTRO, Ul. Shcherbakovskaya D. 53, Korp. 17, Moscow 105187, Russia; Pr-d Okruzhnoi D. 8, Str 1, Pom.4, Moscow 107553, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7719228261 (Russia); Registration Number 1027739672047 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

14. NAUCHNO PROIZVODSTVENNOE OBYEDINENIE PROGRAMMNYE KOMPLEKSY REALNOGO VREMENI (a.k.a. NPO PKRV), Per. Stolyarnyi D. 3, Korpus 1, ET/POM/KOM 4/III/5, Moscow 123022, Russia; Nab. Presnenskaya D. 8, Str. 1, Floor/Pomeshch. 44/441M, Office 7, Moscow 123112, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7105509736 (Russia); Registration Number 1107154016529 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

15. OPYTNO KONSTRUKTORSKOE BYURO PRIBOR (a.k.a. OKB PRIBOR; a.k.a. PRIBOR OPEN DESIGN BUREAU), Ul. Gerasima Kurina D. 10, K. 1, E 2 P I K 8A KAB 205A, Moscow 121108, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7703382109 (Russia); Registration Number 1157746535165 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

16. TEKHNOMAKS KRASNOYARSK, Ul. Chernyshevskogo D. 77, Kv. 7, Krasnoyarsk 660043, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 2460248300 (Russia); Registration Number 1132468044653 (Russia)

[RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

17. VOLTAG LLC, PR-D Berezovoi Roshchi D. 4, Floor 2 Office 3, Moscow 125252, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7718222676 (Russia); Registration Number 1157746520876 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

18. AYTT CNC TAKIM TEZGAHLARI MAKINE SANAYI VE TICARET LIMITED SIRKETI (a.k.a. AYTT CNC MACHINE TOOLS SAN TRADE LTD STI), Ahmet Petekci Caddesi No. 17, P, Fevzicakmak Mahallesi, Karatay, Konya 42050, Turkey; Website www.aytcnc.com; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 13 Sep 2011; Tax ID No. 1250359686 (Turkey); Trade License No. 39813 (Turkey); Central Registration System Number 0125035968600016 (Turkey) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

19. LIMITED LIABILITY COMPANY MOBULA, Pr-kt Zelenyi D. 20, Pomeshch. 29N/9, Moscow 111397, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 10 Mar 2023; Tax ID No. 7720891709 (Russia); Registration Number 1237700192861 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

20. MODULSAN MAKINA KESICI TAKIM VE DISLI SANAYI TICARET LIMITED SIRKETI, 1CA Blok, 1575. Sokak No. 1 CA/2, Akcaburgaz Mahallesi, Esenyurt 34522, Turkey; Website www.modulsan.com; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 09 Oct 2006; Tax ID No. 3340494281 (Turkey); Identification Number 0334049428100019 (Turkey); Registration Number 602993 (Turkey) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

21. TOOL COMPANY GUT LIMITED LIABILITY COMPANY (Cyrillic: ОБЩЕСТВО С ОГРАНИЧЕННОЙ ОТВЕТСТВЕННОСТЬЮ ИНСТРУМЕНТАЛЬНАЯ КОМПАНИЯ ГУТ), Pr-kt Zelenyi D. 20, Moscow 111397, Russia; Website www.guhring.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 25 Nov 2002; Tax ID No. 7716223113 (Russia); Registration Number 1027716008374 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

22. LIMITED LIABILITY COMPANY CNC VOLGA, Ul. Narskoe Lesnichestvo D. 28, Office 102, Naro-Fominsk 143302, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 05 Aug 2022; Tax ID No. 5030103242 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

23. ALIGN TRADING CO., LIMITED, Room A1-13, Blk A 3/F, Yee Lim Ind Center, 2-28, Kwai Lok Street, Kwai Chung, Hong Kong, China; Room 2901B, Bank of Communications Building, No. 3018, Shennan Middle Road, Futian District, Shenzhen, Guangdong, China; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 04 Apr 2023; Company Number 3266528 (Hong Kong); Business Registration Number 75190131 (Hong Kong) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the electronics sector of the Russian Federation economy.

24. ALLPARTS TRADING CO., LTD., Room 13, 27/F, Ho King Commercial Centre, 2-16 Fa Yuen Street, Mongkok, Kowloon, Hong Kong; Room 803, Chevalier House, 45-51 Chatham Road South, Tsim Sha Tsui, Kowloon, Hong Kong; Room 2901B, Bank of Communications, Futian District, Shenzhen, Guangdong, China; 3 Garden Road Central, Hong Kong; Unit 3, 6/F, Kam Hon Industrial Building, 8 Wang Kwun Road, Kowloon Bay, Hong Kong, China; Room 1901H, Bank of Communications Building, Futian District, Shenzhen, Guangdong, China; 4/F Building 6 Deguan Lighting Factory, No. 2 South 1st, Guangzhou, Guangdong, China; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 04 Jul 2022; Company Number 3168281 (Hong Kong) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the electronics sector of the Russian Federation economy.

25. AVTEX SEMICONDUCTOR LIMITED, 1703A, Block C, CEC Building, 2070 Shennan Middle Road, Huaqiang North, Futian District, Shenzhen, Guangdong 518031, China; Room 1003A, Fortune Harbor International Center, No. 1084 Baoyuan Road, Xixiang Street, Baoan District, Shenzhen, Guangdong 518102, China; No. 2070 Electronic Technology Building, Shennan Road, Futian District, Shenzhen, Guangdong, China; Building A, Minsheng 2nd Road, Liukeng New Village, Shiyan Street, Baoan District, Shenzhen, Guangdong, China; Room 836, 8/F Bailey Commercial Centre, 87-105 Chatham Road South, Tsim Sha Tsui, Kowloon, Hong Kong, China; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 24 Sep 2020; Company Number 2980184 (Hong Kong) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the electronics sector of the Russian Federation economy.

26. CHIPS RESOURCES LIMITED, Room 18, 27/F, Ho King Commercial Centre, 2-16 Fa Yuen Street, Mongkok, Kowloon, Hong Kong, China; Room 803, Chevalier House, 45-

51 Chatham Road South, Tsim Sha Tsui, Kowloon, Hong Kong, China; No. 1, 9/F Pat Industrial Building, Pat Tat Street, Kowloon, San Po Kong, Hong Kong, China; Room 2901B, Bank of Communications Building, No. 3018 Shennan Middle Road, Futian District, Shenzhen, Guangdong, China; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 26 Jul 2022; Company Number 3175538 (Hong Kong) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the electronics sector of the Russian Federation economy.

27. MAXTRONIC GLOBAL LIMITED, Room 2301, Dynamic World Building, Zhonghang Road, Futian District, Shenzhen, Guangdong 518031, China; Room 301, One Fuhu Street, Shenzhen, Guangdong 518000, China; Room 2411, Block A, Jiahe Building, Shennan Road, Futian District, Shenzhen, Guangdong, China; Room 2408, Dynamic World Building, Zhonghang Road, Futian District, Shenzhen, Guangdong, China; Room 3A02, Investment Bank Building, 1st Fuhua Road, Futian District, Shenzhen, China; RM02 21/F Hip Kwan Commercial Building, 38 Pitt Street, Yau Ma Tei, KL, Hong Kong, China; Room 4411, R&F Yingkai Square, 16 Huaxia Road, Zhujiang New Town, Tianhe District, Guangzhou, Guangdong, China; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 06 Nov 2018; Company Number 2762924 (Hong Kong) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the electronics sector of the Russian Federation economy.

28. MEGACHIPS LIMITED, Room 13, 27/F, Ho King Commercial Centre, 2-16 Fa Yuen Street, Mongkok, Kowloon, Hong Kong, China; Room 1206, Yishang Creative Technology Building, No. 22 Jia'an South Road, Haibin Community, Xin'an Street, Bao'an District, Shenzhen, Guangdong, China; 2901B, Bank of Communications Building, Shennan Middle Road, Huaqiang North Street, Futian District, Shenzhen, China; Website www.mega-chips.cn; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 05 Jul 2021; Company Number 3064111 (Hong Kong); Business Registration Number 73148289 (Hong Kong) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the electronics sector of the Russian Federation economy.

29. POLAR BEAR ELECTRONICS CO., LIMITED (Chinese Traditional: 北極熊電子有限公司), Unit 1406B 14/F, The Belgian Bank Bldg, Nos 721-725, Nathan Rd, KLN, Hong Kong, China; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 09 Nov 2023; Company Number 3336606 (Hong Kong); Business Registration Number 75896458 (Hong Kong) [RUSSIA-EO14024] (Linked To: CHIPS RESOURCES LIMITED).

Designated pursuant to section 1(a)(vi)(B) of E.O. 14024 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, CHIPS RESOURCES LIMITED, a person whose property and interests in property are blocked pursuant to E.O. 14024.

30. SINNO GROUP LIMITED, Room 13, 27/F, Ho King Commercial Centre, 2-16 Fa Yuen Street, Mongkok, Kowloon, Hong Kong, China; Ulitsa Leninskaya Sloboda, 19, Moskva 115280, Russia; Website https://sinnogroup.ru/; Email Address russia@sinnoelec.com; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 24 Dec 2021; Company Number 3115771 (Hong Kong); Business Registration Number 73670751 (Hong Kong) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the electronics sector of the Russian Federation economy.

31. DRUSTVO SA OGRANICENOM ODGOVORNOSCU INTERNATIONAL BUSINESS CORPORATION BAR (a.k.a. IBC MNE INTERNATIONAL BUSINESS CORPORATION DOO BAR; a.k.a. INTERNATIONAL BUSINESS CORPORATION DOO BAR), Popa Dukljanina Br. 2A, Bar, Montenegro; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Identification Number 2829908 (Montenegro); Registration Number 50601731 (Montenegro) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

32. BP DIS TICARET VE DANISMANLIK LIMITED SIRKETI, Zeytinlik Mh. Turkcu, Sk. Ferah Palas Blok No:16/2/10, Bakirkoy, Turkey; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 07 Dec 2022; Chamber of Commerce Number 1420327 (Turkey); Registration Number 426750-5 (Turkey); Central Registration System Number 0187-1584-9140-0001 (Turkey) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

33. BRK ULUSLARARASI NAKLIYAT VE TICARET LIMITED SIRKETI (a.k.a. "BRK GRUP"), Koc. Cd. Kaman Is Mer. Ino: 1 Kat:2, No:7 /8, Istanbul, Turkey; Website http://www.brklogistics.com; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 19 Aug 2015; Tax ID No. 1870681940 (Turkey); Chamber of Commerce Number 984842 (Turkey); Registration Number 987377-0 (Turkey); Central Registration System Number 0187-0681-9400-0015 (Turkey) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the transportation sector of the Russian Federation economy.

34. SINERJI ENDUSTRIYEL EKIPMAN VE INSAAT MALZEMELERI DIS TICARET LIMITED SIRKETI (a.k.a. SINERJI ENDUSTRIYEL EKIPMAN VE INSAAT MALZEMELERI DIS TICARET LIMITED), Adnan Kahveci Mah. Alemdag Cad. No: 2/1 Ic Kapi No: 48, Beylikduzu, Turkey; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 16 Dec 2022; Tax ID No. 7710665481 (Turkey); Chamber of Commerce Number 1423211 (Turkey); Registration Number 429549-5 (Turkey); Central Registration System Number 0771-0665-4810-0001 (Turkey) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

35. AVIEK LIMITED LIABILITY COMPANY, Ul. Chernyakhovskogo D. 16, Et 2 Porn. II Korn 2208, Moscow 125319, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 27 Feb 2017; Tax ID No. 7714976626 (Russia); Registration Number 1177746187190 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

36. EKVIK LIMITED LIABILITY COMPANY, Per. Dukhovskoi D. 17, Korpus 1, Floor 1 Podyezd 20 Kab 1, Moscow 115191, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 20 Mar 2015; Tax ID No. 7722320806 (Russia); Registration Number 1157746236966 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

37. ELIT LIMITED LIABILITY COMPANY, UL Marshala Chuikova D. 2A, Office 314/3, Kazan 420094, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 13 Jul 2011; Tax ID No. 1657107827 (Russia); Registration Number 1111690048414 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

38. INTELLEKT TELEKOM LIMITED LIABILITY COMPANY, Ul. Mashinostroitelei Str. 19, Pomeshch. 500/8-17, Yekaterinburg 620012, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 26 Apr 2022; Tax ID No. 6686141148 (Russia); Registration Number 1226600024034 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

39. KSIAN LIMITED LIABILITY COMPANY, UL Zhurnalistov D. 2A, Pomeshch. 404V, Kazan 420029, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 23 Mar 2023; Tax ID No. 168025061 (Russia); Registration Number 1231600011378 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

40. LIMITED LIABILITY COMPANY BAIKAL TRADING COMPANY, Ul Galiaskara Kamala D. 4A, Pomeshch. 10, Kazan 420021, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 23 Aug 2022; Tax ID No. 1655484450 (Russia); Registration Number 1221600066995 (Russia) [RUSSIA-

EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

41. SEVERNYI VETER - TB LIMITED LIABILITY COMPANY, UL Marshala Govorova D. 35, K. 4. LIT. I, Pomeshch. 16-N, Office #308A, Saint Petersburg 198095, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 16 Sep 2022; Tax ID No. 7805797462 (Russia); Registration Number 1227800122153 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

42. ACE ELECTRONIC HK CO., LIMITED, 18F, Block B, World Trade Plaza, No. 9 Fuhong Road, Futian District, Shenzhen, Guangdong, China; Unit 04 7/F Bright Way Tower, No. 33 Mong Kok Road, Kowloon, Hong Kong, China; E2 Unit, 22/F Kingsway Industrial Building Phase II, 147-175 Wo Yi Hop Road, Kwai Chung, New Territories, Hong Kong, China; 9F International Technology Building No. 3007, Shennan Avenue, Futian District, Shenzhen, Guangdong, China; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 22 Oct 2018; Company Number 2756979 (Hong Kong); Business Registration Number 69987857 (Hong Kong) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

43. MIDAS LIGHTING LIMITED (Chinese Traditional: 米達斯照明有限公司; Chinese Simplified: 米达斯照明), Rm A1 11/F Winner Bldg Hunghom, Hong Kong, China; 1402A, 14/F, The Belgian Bank Building, 721-725 Nathan Road, Kowloon, Hong Kong, China; Website https://midas-lighting.cn/; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 03 Apr 2014; Company Number 2080259 (Hong Kong); Business Registration Number 63176759 (Hong Kong) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

44. MEIN CHEIN (a.k.a. MAIN CHAIN), ul. Kantemirovskaya d. 12, lit. a, pomeshch. 20-n, kom. 25, Saint Petersburg 194100, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 25 Jan 2023; Tax ID No. 7802935570 (Russia); Legal Entity Number 253400B6LCY3RVSUCZ86; Registration Number 1237800006740 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

45. SHREYA LIFE SCIENCES PRIVATE LIMITED, Shreya House 6th floor 301/a Pereira Hill Road, Andheri East, Mumbai 400099, India; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. AADCS9890C (India); Registration Number

U51900MH1991PTC061136 (India) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

46. AFOX CORPORATION LIMITED (Chinese Simplified: 元富科技集团股份有限公司), Ft F 10/F, Hung Cheung Ind Ctr Phs1, 12 Tsing Yeung Circuit Tuen Mun, Nt, Hong Kong, China; 2/F No. 13, Lane 5, Wu Kai Sha Village, Ma On Shan, Shatin, Nt, Hong Kong, China; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 29 Oct 2009; Company Number 1385734 (Hong Kong); Business Registration Number 51366580 (Hong Kong) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

47. O-SI-ES-TSENTR, OOO (Cyrillic: ООО О-СИ-ЭС-ЦЕНТР) (a.k.a. OBSHCHESTVO S OGRANICHENNOI OTVETSTVENNOSTYU O-SI-ES-TSENTR (Cyrillic: ОБЩЕСТВО С ОГРАНИЧЕННОЙ ОТВЕТСТВЕННОСТЬЮ О-СИ-ЭС-ЦЕНТР); a.k.a. OCS-CENTER LTD), Domovladenie 6 Str. 1 Kom. 7, Km. Kievskoe Shosse 22-I (P Moskovski), Moscow 108811, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 17 Jul 2003; Tax ID No. 7701341820 (Russia); Registration Number 1037701914612 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

48. SUPERWAVE GROUP LLC (Cyrillic: ООО СУПЕРВЭЙВ ГРУПП) (a.k.a. SUPERWAVE GROUP), 15, Krasnaya Zarya twn, Vsevolozhsky District,, Leningrad Region 193149, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 25 Jan 2005; Tax ID No. 7838314569 (Russia); Registration Number 1057810023952 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

49. TORNETCOM LLC (Cyrillic: ООО ТОРНЕТКОМ) (a.k.a. TORNETKOM, OOO), D. 14 Str. 4 Etazh Mansarda Kom. 210, Ul. Novaya Basmannaya, Moscow 107078, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 9701127410 (Russia); Registration Number 1197746135730 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

50. TRADESTORY LLC (Cyrillic: ООО ТРЕЙДСТОРИ) (a.k.a. TREIDSTORI), Ul. Nametkina, 10a, Floor 4, Room I, Room 22a, Moscow 117420, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 06 Jul 2015; Tax ID No. 7727194785 (Russia); Registration Number 1157746603673

(Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

51. VEKTOR, OOO (Cyrillic: OOO BEKTOP), Ul. Bulatnikovskaya D.20, Str.3, Moscow 117403, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 06 Jul 2006; Tax ID No. 7725575432 (Russia); Registration Number 1067746783433 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

52. ATHREE COMPANY LIMITED (a.k.a. ATHREE CO LTD; a.k.a. "OOO ATRI"), Ul. Zemledelcheskaya D. 5, Saint Petersburg 197343, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 24 Dec 1998; Tax ID No. 7816135608 (Russia); Registration Number 1037835001082 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the defense and related materiel sector of the Russian Federation economy.

53. AUTONOMOUS NON PROFIT ORGANIZATION INSTITUTE FOR TESTING AND CERTIFICATION OF ARMAMENT AND MILITARY MATERIEL (a.k.a. INIS VVT), PR-D Entuziatsov, D. 11, Moscow 111024, Russia; Ul. Elektrodnaya, D. 10, Moscow 111524, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 21 Jun 1999; Tax ID No. 7705285301 (Russia); Registration Number 1037739355488 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the defense and related materiel sector of the Russian Federation economy.

54. FEDERAL STATE BUDGETARY INSTITUTION RUSSIAN ACADEMY OF ROCKET AND ARTILLERY SCIENCES (a.k.a. FEDERAL STATE BUDGETARY INSTITUTION RUSSIAN ACADEMY OF MISSILE AND ARTILLERY SCIENCES; a.k.a. FGBU RARAN; a.k.a. RUSSIAN ACADEMY OF MISSILE AND AMMUNITION SCIENCES; a.k.a. "RAMAS"), 1-YA Myasnikovskaya Ul., VL 3, Moscow 107564, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 06 May 1996; Tax ID No. 7712086681 (Russia); Registration Number 1037743041027 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the defense and related materiel sector of the Russian Federation economy.

55. JOINT STOCK COMPANY INTELLECT MASHINE (a.k.a. "JSC IM"), PR-KT Lakhtinskii, D. 85, K. 2, Lit. A, Floor 3, Office 10, PO PIB, Pomeshch #205-206, #209-210, Saint Petersburg 197229, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 15 Apr 2022; Tax ID No. 7801711200 (Russia); Registration Number 1227800047496 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the defense and related materiel sector of the Russian Federation economy.

56. JOINT STOCK COMPANY RESEARCH AND PRODUCTION ASSOCIATION VOLNA (a.k.a. AKTSIONERNOE OBSHCHESTVO NAUCHNO PROIZVODSTVENNOE OBYEDINENIE ZAVOD VOLNA; a.k.a. AO NPO ZAVOD VOLNA; a.k.a. NPO ZAVOD VOLNA JSC), Ul. Marshala Gorova D. 29, Saint Petersburg 198095, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 23 Sep 1993; Tax ID No. 7805047646 (Russia); Registration Number 1027802714158 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the defense and related materiel sector of the Russian Federation economy.

57. JOINT STOCK COMPANY SCIENTIFIC RESEARCH INSTITUTE OF COMMUNICATION SYSTEMS AND AUTOMATED CONTROL SYSTEMS (a.k.a. FEDERAL STATE UNITARY ENTERPRISE SCIENTIFIC RESEARCH INSTITUTE OF COMMUNICATION AND CONTROL SYSTEMS; a.k.a. JOINT STOCK COMPANY SCIENTIFIC RESEARCH INSTITUTE OF COMMUNICATION AND CONTROL SYSTEMS; a.k.a. JSC NIICS AND ACS; a.k.a. "AO NIISSU"), Starokaluzhskoe Shosse D. 58, Moscow 117630, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 02 Jan 1992; Tax ID No. 7728804257 (Russia); Registration Number 1127746262390 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the defense and related materiel sector of the Russian Federation economy.

58. LIMITED LIABILITY COMPANY ASTRON AERO, Ul. Parkovaya D. 1, Office 14, Lytkarino 140080, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 16 Mar 2016; Tax ID No. 5027238514 (Russia); Registration Number 1165027052431 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the defense and related materiel sector of the Russian Federation economy.

59. LIMITED LIABILITY COMPANY NAUCHNO PROIZVODSTVENNOE OBYEDINENIE KAISANT (a.k.a. NPO KAYSANT), Proezd Stroitelnyi D. 7A, K. 28, Pomeshch 224, Moscow 125632, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 07 Oct 2022; Tax ID No. 7733393203 (Russia); Registration Number 1227700641805 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the defense and related materiel sector of the Russian Federation economy.

60. MOSCOW AVIATION INSTITUTE (a.k.a. FEDERALNOE GOSUDARSTVENNOE BYUDZHETNOE OBRAZOVATELNOE UCHREZHDENIE VYSSHEGO OBRAZOVANIYA MOSKOVSKII AVIATSIONNYI INSTITUT NATSIONALNYI ISSLEDOVATELSKII UNIVERSITET; a.k.a. "MAI"), Shosse Volokolamskoe D. 4, Moscow 125993, Russia; Secondary sanctions risk: See Section 11 of Executive Order

14024.; Organization Established Date 29 Jun 1994; Tax ID No. 7712038455 (Russia); Registration Number 1037739180820 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the defense and related materiel sector of the Russian Federation economy.

61. OOO KONSTRUKTORSKOE BYURO SPEKTR INZHINIRING (a.k.a. SPEKTR ENGINEERING DESIGN BUREAU), Ul. Promyshlennaya D. 33, Berdsk 633004, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 02 Jul 2019; Tax ID No. 5445029645 (Russia); Registration Number 1195476049185 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the defense and related materiel sector of the Russian Federation economy.

62. OOO NAUCHNO PROIZVODSTVENNOE OBYEDINENIE TSVBP (a.k.a. NPO TSVBP), Pl. Kudrinskaya D. 1, Pomeshch 5A, Moscow 123242, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 19 Oct 2023; Tax ID No. 9703158566 (Russia); Registration Number 1237700707991 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the defense and related materiel sector of the Russian Federation economy.

63. STATE UNITARY ENTERPRISE CENTER FOR TECHNICAL DEVELOPMENT AND SERVICES NAMED AFTER P A SUDOPLATOV OF THE MILITARY AND CIVIL ADMINISTRATION OF THE ZAPORIZHZHIA REGION (a.k.a. STATE UNITARY ENTERPRISE VOLUNTEER BATTALION NAMED AFTER P A SUDOPLATOV OF THE MILITARY AND CIVIL ADMINISTRATION OF THE ZAPORIZHZHIA REGION; a.k.a. SUDOPLATOV BATTALION), St. Mikhail Grushevsky, Melitopol, Zaporizhzhia Oblast 272312, Ukraine; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 22 Dec 2022; Tax ID No. 9001013922 (Russia); Registration Number 1229000023603 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the defense and related materiel sector of the Russian Federation economy.

64. AKTSIONERNOE OBSHCHESTVO TAMBOVSKII ZAVOD OKTYABR (a.k.a. AO TZ OKTYABR; a.k.a. JSC TAMBOV PLANT OCTOBER; a.k.a. JSC TZ OCTOBER; a.k.a. TAMBOV PLANT OKTYABR JSC), Ul. Bastionnaya D. 1, Tambov 329028, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 6829014768 (Russia); Registration Number 1056882340173 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

65. ASF DEVELOPMENT LIMITED LIABILITY COMPANY (a.k.a. OOO ASF RAZVITIE), Ul. Lva Tolstogo D. 5, Str. 1, Pomeshch 2/1, Moscow 119021, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No.

9709074432 (Russia); Registration Number 1217700436029 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

66. AURORATOOLS LIMITED LIABILITY COMPANY (a.k.a. OOO AVRORATULS), Kolomyazhsky Ave. 27, Kab. 12, Saint Petersburg 197341, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7811677710 (Russia); Registration Number 1187847001198 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

67. AVTODOM LTD (a.k.a. OOO AVTODOM), Moskovskoe Highway, 8, Ulyanovsk 432000, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7327058837 (Russia); Registration Number 1117327001220 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

68. CENTURY OF TECHNOLOGIES HTE COMPANY LIMITED (a.k.a. CENTURY OF TECHNOLOGIES HTE CO LTD; a.k.a. OOO VEK TEKHNOLOGII PTO; a.k.a. VEK TECHNOLOGIES PTO; a.k.a. "VEK PTO"), Pl. Karla Faberzhe D. 8, Lit. A, Pomeshch 8-N, Kom. 22, Saint Petersburg 195112, Russia; Ul. Nikpolskaya 6, Building 2, Bipark Center, Office 618 (Floor 6), Moscow 117403, Russia; Sverdlovsky Tract, House 12, Office 34, Chelyabinsk 454036, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7806446153 (Russia); Registration Number 1109847047023 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

69. JOINT STOCK COMPANY BERG AB (a.k.a. AO BERG AB), Ul. Rechnikov D. 7, Str. 14, Moscow 115407, Russia; Ul. Sadovniki D. 2, Floor/Pomeshch 12/1, Moscow 115487, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7725237190 (Russia); Registration Number 1037725041683 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

70. JOINT STOCK COMPANY EXPERIMENTAL DESIGN AND TECHNOLOGICAL BUREAU VALDAY (a.k.a. AKTSIONERNOE OBSHCHESTVO OPTIKO MEKHANICHESKOE KONSTRUKTORSKOE BYURO VALDAI; a.k.a. AO OKB VALDAI; a.k.a. OKB VALDAY), Pobedy St. 107, Bldg. 2, Valday 175400, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 5302014601 (Russia); Registration Number 1175321001184 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

71. LIMITED LIABILITY COMPANY SCIENTIFIC RESEARCH INSTITUTE OF ORGANIC TECHNOLOGIES INORGANIC CHEMISTRY AND BIOTECHNOLOGY (a.k.a. NIITONKH AND BT LLC; a.k.a. OOO NIITONKH I BT; a.k.a. RESEARCH INSTITUTE OF ORGANIC INORGANIC CHEMISTRY AND BIOTECHNOLOGY; a.k.a. SCIENTIFIC RESEARCH INSTITUTE TECHNOLOGY ORGANIC NOT ORGANIC CHEMISTRY AND BIOLOGY TECHNOLOGY LIMITED LIABILITY COMPANY; a.k.a. "SARNII"), Ul. Bolshaya Sadovaya D. 239, Saratov 410005, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 6452941195 (Russia); Registration Number 1096450002373 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

72. NAUCHNO PROIZVODSTVENNOE PREDPRIYATIE TRIM SSHP IZMERITELNYE SISTEMY (a.k.a. NPP TRIM SSHP IZMERITELNYE SISTEMY; a.k.a. SCIENTIFIC PRODUCTION ENTERPRISE TRIM SSHP MEASURING SYSTEMS), PR-KT Kondratyevskii D. 40, K. 14, Lit. A, Pom. 10N, Saint Petersburg 195197, Russia; Bolshoy Sampsonievsky Prospect, D. 106, Lit. A, Saint Petersburg 194156, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7804323773 (Russia); Registration Number 1057812638839 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

73. OBORON HOLDING LLC (a.k.a. OOO OBORON KHOLDING), Vld. 85, Str. 1, Pom. 8, Lykovo 108817, Russia; Ul. Bakuninskaya, 69, Str. 1, Moscow 105082, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 9701002563 (Russia); Registration Number 1157746688879 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

74. OOO BLM SINERZHI (a.k.a. BLM SYNERGY LLC), Per. Kolodeznyi D. 3, Str. 26, Off. 212, Moscow 107076, Russia; Ul. Elektrozavodskaya D. 24, Str. 3, Kom. V 303, Moscow 107023, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7718609666 (Russia); Registration Number 1067758765733 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

75. OOO DST URAL, Ul. Geroev Tankograda D. 28P, Office 1, Chelyabinsk 454081, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7453251929 (Russia); Registration Number 1137453000992 (Russia) [RUSSIA-

EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

76. OOO KOLOVRAT (a.k.a. SIDERUS), Ul. Osennaya D. 23, Pomeshch 114A/1/9, Moscow 121609, Russia; Preobrazhenskaya Sq. 8, Moscow 107061, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 9701077015 (Russia); Registration Number 1177746518740 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

77. OOO KRASMK, Ul. Molokova D. 1, Korp. 1, Krasnoyarsk 660077, Russia; Ul. Vesny D. 32, Pomeshch 126, Krasnoyarsk 660077, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 2461208999 (Russia); Registration Number 1102468007487 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

78. OOO NAUCHNO PROIZVODSTVENNAYA FIRMA AVEK (a.k.a. NPF AVEK), Ul. Stepana Razina D. 95, Office 12, Yekaterinburg 620142, Russia; Ul. Pervomaiskaya 109-300, Yekaterinburg 620049, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 6662021290 (Russia); Registration Number 1026605414813 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

79. SOLDREAM SPB LTD (a.k.a. OOO SOLDRIM SPB), Pl. Konstitutsii D. 7, Lit. A, Pomeshch 182-N, Office 616A, Saint Petersburg 196191, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 4707020337 (Russia); Registration Number 1034701423668 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

80. TD ESKO LIMITED (a.k.a. LLC TRADING HOUSE ENERGOSPETSKOMPLEKT; a.k.a. TRADING HOUSE ESKO), Ul. Pionerskaya, Floor / Pomesch Polupodval, Lit. A., Kom. 10-12, Krasnogorsk 143402, Russia; Promyshlennaya St., House 16A, Yaroslavl 150064, Russia; Ul. Gilyarovskogo, Dom 51, Moscow 129110, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7702790095 (Russia); Registration Number 1127746401419 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

81. TECHNOBEARING LIMITED COMPANY (a.k.a. OOO TEKHNOBERING), Mitrofanyevskoe Shosse, 10-2 Floor, BTS Troitskoe, Saint Petersburg 198095, Russia; PR-KT Stachek D. 47, K. 2, Lit. Yu, Pomeshch 1, Saint Petersburg 198097, Russia; 22

Ponse St., Southern Part of the Goroleva Industrial Zone, Saint Petersburg 188508, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7839371168 (Russia); Registration Number 1079847124213 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

82. VYATKA MACHINE TOOL PLANT LLC (a.k.a. OOO VYATSKII STANKOSTROITELNYI ZAVOD; a.k.a. VSP KIROV; a.k.a. "OOO VSZ"), Ul. Tekhnicheskaya D. 22, Office 3, Kirov 610014, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 4345454570 (Russia); Registration Number 1164350074900 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

83. BENTOZER COMPANY LIMITED, 30 Soi Sukhumvit 61, Vadhana, Bangkok 10110, Thailand; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 10 Mar 2020; Registration Number 0105563043974 (Thailand) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

84. INTRACORP COMPANY LIMITED (a.k.a. INTRACORP LTD), P23 Tower, 11 Floor, 11/2 Soi Sukhumvit 23, Khlong Toei Nuea, Watthana, Bangkok 10110, Thailand; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 2018; Registration Number 0105561091211 (Thailand) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the trust and corporate formation services sector of the Russian Federation economy.

85. RBW LAB CO LTD, Watthana, Bangkok, Thailand; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 2020; Registration Number 0105563166359 (Thailand) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

86. TSEZAR GROUP COMPANY LIMITED, 30 Soi Sukhumvit 61, Sethabutr, Vadhana, Bangkok 10110, Thailand; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 16 Dec 2020; Registration Number 0105563179302 (Thailand) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

87. INEKO LLC (a.k.a. OOO INEKO (Cyrillic: ООО ИНЕКО)), Building 41, Zheleznodorozhniy Lane, Dmitrov, Moscow, Russia; 9 Melitopolskaya ul., Str. 3,

Moscow, Russia; Website www.inekocom.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 26 Apr 2018; Organization Type: Wholesale of other machinery and equipment; Tax ID No. 5007104304 (Russia); Registration Number 1185007004973 (Russia) [RUSSIA-EO14024] (Linked To: TECHNOPOLE COMPANY).

Designated pursuant to section 1(a)(vi)(B) of E.O. 14024 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, TECHNOPOLE COMPANY, a person whose property and interests in property are blocked pursuant to E.O. 14024.

88. BEREZIA MANAGEMENT LTD (a.k.a. BEREZIA MANAGEMENT LIMITED), Suite 302, 2133, Blake Building, Corner Hutson and Eyre Street, Belize City, Belize; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 25 Feb 2016; Identification Number IMO 5973619; Company Number 000004164 (Belize) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the marine sector of the Russian Federation economy.

89. CJSC PERSPECTIVE TECHNOLOGIES AGENCY (a.k.a. AKTSIONERNOE OBSHCHESTVO UPRAVLENIE PERSPEKTIVNYKH TEKHNOLOGI (Cyrillic: АКЦИОНЕРНОЕ ОБЩЕСТВО УПРАВЛЕНИЕ ПЕРСПЕКТИВНЫХ ТЕХНОЛОГИЙ); a.k.a. "UPT AO" (Cyrillic: "АО УПТ")), Ul. Samokatnaya, D. 1, Str. 2, Moscow 111033, Russia; Website upt.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 20 Dec 1994; alt. Organization Established Date 03 Sep 2002; Tax ID No. 7723022111 (Russia); Government Gazette Number 13152639 (Russia); Registration Number 1027739143717 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the marine sector of the Russian Federation economy.

90. JOINT STOCK COMPANY PERSPECTIVE TECHNOLOGIES CENTER (a.k.a. AKTSIONERNOE OBSHCHESTVO TSENTR PERSPEKTIVNYKH TEKHNOLOGI (Cyrillic: АКЦИОНЕРНОЕ ОБЩЕСТВО ЦЕНТР ПЕРСПЕКТИВНЫХ ТЕХНОЛОГИЙ); a.k.a. "JSC CPT"; a.k.a. "TSPT AO" (Cyrillic: "АО ЦПТ")), Sh. Kashirskoe, D. 44, K. 2, Moscow 115409, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 11 Jul 1996; alt. Organization Established Date 22 Oct 2002; Tax ID No. 7724185856 (Russia); Government Gazette Number 42935911 (Russia); Registration Number 1027700343626 (Russia) [RUSSIA-EO14024] (Linked To: CJSC PERSPECTIVE TECHNOLOGIES AGENCY).

Designated pursuant to section 1(a)(vi)(B) of E.O. 14024 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, CJSC PERSPECTIVE TECHNOLOGIES AGENCY, a person whose property and interests in property are blocked pursuant to E.O. 14024.

91. JSC TRANSPORT FREIGHT AGENCY (a.k.a. AKTSIONERNOE OBSHCHESTVO UPRAVLENIE TRANSPORTNYKH PEREVOZOK (Cyrillic: АКЦИОНЕРНОЕ

ОБЩЕСТВО УПРАВЛЕНИЕ ТРАНСПОРТНЫХ ПЕРЕВОЗОК); a.k.a. "UTP AO" (Cyrillic: "АО УТП")), Sh. Kashirskoe, D. 44, K. 2, Moscow 115409, Russia; Shosse Nizhnerostinskoye 28, Murmansk 183040, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 24 Jul 1997; alt. Organization Established Date 29 Oct 2002; Tax ID No. 7723134190 (Russia); Identification Number IMO 5917661; Government Gazette Number 47260547 (Russia); Registration Number 1027700371742 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the marine sector of the Russian Federation economy.

92. MOSTRELLO COMMERCIAL LTD (a.k.a. MOSTRELLO COMMERCIAL LIMITED), 20-22 Zinas Kanther, Limassol 3035, Cyprus; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 11 Mar 2011; Tax ID No. CY10283094T (Cyprus); Identification Number IMO 6241181; Business Registration Number HE283094 (Cyprus); Registration Number C283094 (Cyprus) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the marine sector of the Russian Federation economy.

93. NIKESTO INVESTMENTS LTD (a.k.a. NIKESTO INVESTMENTS LIMITED), Road Town, Tortola, Virgin Islands, British; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 2013; Company Number 1627765 (Virgin Islands, British) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the marine sector of the Russian Federation economy.

94. JOVE HK LIMITED, 3/F Won Chung Ming Commercial House, 14-16 Wyndham Street, Central, Hong Kong, China; 68-70 Wellington Street, 3/F, Hong Kong, China; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 20 Jun 2011; Company Number 1618862 (Hong Kong); Business Registration Number 58538021 (Hong Kong) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

95. JST GROUP LIMITED, 3/F Wong Chung Ming Commercial House, 16 Wyndham St., China; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 24 Nov 2017; Company Number 2613289 (Hong Kong); Business Registration Number 68540456 (Hong Kong) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

96. OOO VEKTOR GRUPP (a.k.a. VEKTOR GRUPP), per. Studenetskii, d. 3, floor/pomeshch. 1/7A, Moscow 127300, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7703438390 (Russia); Registration Number 5177746281720 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

97. ZG OPTIQUE SA, Rue de Fin-De-Praz 24, Saint-Aubin Sauges 2024, Switzerland; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 102945998 (Switzerland); Registration Number ch-645.1.009.280-5 (Switzerland) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

98. AO NPO ANGSTREM, d. 2, str. 3, kom. 129, pl. Shokina, Moscow 124498, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7735575858 (Russia); Registration Number 1117746142502 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

99. SOTIS, per. Partiinyi d. 1, k. 58 str. 3, floor 3, pomeshch. i, office 323, Moscow 115093, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7706816379 (Russia); Registration Number 5147746290038 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

100. TELECOM INTEGRATION LIMITED LIABILITY COMPANY, proezd Nauchnyi d. 17, Moscow 117246, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7731642944 (Russia); Registration Number 1107746029874 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

101. ZAKRYTOE AKTSIONERNOE OBSHCHESTVO MPO ELEKTROMONTAZH, ul. Planernaya d. 6, k. 2, Moscow 125481, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7719079370 (Russia); Registration Number 1037700089052 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

102. AGM SYSTEMS LLC (a.k.a. OOO AGM SISTEMY), Ul. Im Frunze D. 22/1, Krasnodar 350063, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 23 Dec 2015; Tax ID No. 2312238002 (Russia); Registration Number 1152312014777 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the aerospace sector of the Russian Federation economy.

103. AREA JOINT STOCK COMPANY (a.k.a. AO PLOSHCHAD), Ul. Chahginskaya, D. 4, Str. 13, Pomeshch 9/3, Moscow 109380, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 10 Jul 2023; Tax ID No. 9723203841 (Russia); Registration Number 1237700463032 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the aerospace sector of the Russian Federation economy.

104. CENTER FOR UNMANNED SYSTEMS OF THE TULA REGION (a.k.a. OOO TSENTR BESPILOTNYKH SISTEM; a.k.a. "TSBS"), Ul. Kirova, D. 135, K. 1, Pomeshch 9, Pomeshch 15, Tula 300004, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 08 Feb 2023; Tax ID No. 7100032961 (Russia); Registration Number 1237100001467 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the aerospace sector of the Russian Federation economy.

105. JOINT STOCK COMPANY AIRCRAFT SERVICE COMPANY (a.k.a. "AO ASK"), Ul. Vereiskaya, D. 39, Moscow 121357, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 03 Jun 2008; Tax ID No. 7731595540 (Russia); Registration Number 1087746709423 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the aerospace sector of the Russian Federation economy.

106. JOINT STOCK COMPANY ENGINEERING CENTER IKAR (a.k.a. IKAR GROUP; a.k.a. JSC IKAR; a.k.a. "ICAR COMPANY"), Ul. Khutorskaya 2-YA D. 38A, Str. 9, Moscow 127287, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 14 Jan 2003; Tax ID No. 7710449682; Registration Number 1037710001493 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the aerospace sector of the Russian Federation economy.

107. JOINT STOCK COMPANY LASERSERVICE (a.k.a. AO LAZERSERVIS), Ul. Vereiskaya, D. 39, Moscow 121357, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 11 Oct 2000; Tax ID No. 7731280660 (Russia); Registration Number 1047731013857 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the aerospace sector of the Russian Federation economy.

108. JOINT STOCK COMPANY MOSCOW SCIENTIFIC AND PRODUCTION COMPLEX OF AVIONICA O V USPENSKY (a.k.a. JOINT STOCK COMPANY AVIONICA; a.k.a. JOINT STOCK COMPANY OTKRYTOVO TIPA MOSKOVSKIY NAUCHNO PROIZVODSTVENNYY KOMPLEKS AVIONIKA; a.k.a. MNPK AVIONIKA), 7 Obraztsova Street, Moscow 127055, Russia; Secondary sanctions risk:

See Section 11 of Executive Order 14024.; Tax ID No. 7715003820 (Russia); Registration Number 1027739158402 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the aerospace sector of the Russian Federation economy.

109. LIMITED LIABILITY COMPANY AEROMAKS (a.k.a. AEROMAX GROUP; a.k.a. AEROMAX LTD), Per. Milyutinskii D. 13, Str. 1, Floor 5, Pomeshch 1, Kom. 12, Moscow 101000, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 09 Jan 2017; Tax ID No. 7725347482 (Russia); Registration Number 1177746007900 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the aerospace sector of the Russian Federation economy.

110. LIMITED LIABILITY COMPANY HORIZON AERO (a.k.a. GORIZONT AERO), Ul. Malaya Proletarskaya, D. 41, KV. 23, Yaroslavl 150001, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 13 Nov 2023; Tax ID No. 7604394537 (Russia); Registration Number 1237600011043 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the aerospace sector of the Russian Federation economy.

111. LIMITED LIABILITY COMPANY JSC UNMANNED TECHNOLOGIES (a.k.a. OOO AO BESPILOTNYE TEKHNOLOGII; a.k.a. "BPLA TECH"), Proezd Khlebozavodskii, D. 7, Str. 9, Pomeshch 19/N, Office 2412, Moscow 115230, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 24 Jan 2023; Tax ID No. 9724118500 (Russia); Registration Number 1237700049180 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the aerospace sector of the Russian Federation economy.

112. LIMITED LIABILITY COMPANY KB ATAMANOVA (a.k.a. ATAMANOV DESIGN BUREAU), Ul. Ryabinova, D. 53, Moscow 121471, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 21 Jul 2023; Tax ID No. 7734481300 (Russia); Registration Number 1237700493161 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the aerospace sector of the Russian Federation economy.

113. LIMITED LIABILITY COMPANY KONSTRUKTORSKOE BYURO VALKIRIYA (a.k.a. KB VALKIRIYA; a.k.a. VALKYRIE CONSTRUCTION BUREAU), DVLD 1A, Borisovo 141342, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 31 Oct 2022; Tax ID No. 5042160830 (Russia); Registration Number 1225000121686 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the aerospace sector of the Russian Federation economy.

114. LIMITED LIABILITY COMPANY KRIOGENAVIA NN, Ul. Koreiskaya, D. 24, Office 2, Nizhny Novgorod 603081, Russia; Ul. Larina, D. 13, Office 2, Nizhny Novgorod 603512, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 06 Mar 2003; Tax ID No. 5261036956 (Russia); Registration Number 1035205638676 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the aerospace sector of the Russian Federation economy.

115. LIMITED LIABILITY COMPANY MOLOT AERO, Ul. Svobody, D. 106, KV. 1, Pomeshch 6, Kirov 610002, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 14 Feb 2023; Tax ID No. 4345522911 (Russia); Registration Number 1234300001110 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the aerospace sector of the Russian Federation economy.

116. LIMITED LIABILITY COMPANY NEBESNAYA MEKHANIKA (a.k.a. SKYMEC), Ul. Profsoyuznaya, D. 84/32, K. 1, Pomeshch 1/3, Moscow 117485, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 25 Aug 2014; Tax ID No. 7723918518 (Russia); Registration Number 1147746964144 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the aerospace sector of the Russian Federation economy.

117. LIMITED LIABILITY COMPANY NPO UTESOV, Ul. Professorov Bogoslavskikh, 5A, Office 312, Donetsk 283045, Ukraine; Tula, Russia; Slavyansky Boulevard, Moscow, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 25 Apr 2023; Tax ID No. 9308024040 (Russia); Registration Number 1239300004206 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the aerospace sector of the Russian Federation economy.

118. LIMITED LIABILITY COMPANY PTERO, B-R Ramenskii, D. 1, Moscow 119607, Russia; Vernadskogo Ave. 12D, Moscow 119415, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 13 Apr 2017; Tax ID No. 7714989706 (Russia); Registration Number 1177746381086 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the aerospace sector of the Russian Federation economy.

119. LIMITED LIABILITY COMPANY RUSSKAYA LABORATORIYA VOZDUSHNOGO TRANSPORTA (a.k.a. RUSSIAN AIR TRANSPORT LABORATORY LLC; a.k.a. "RLVT"), Ul. Ryazanskaya, D. 3D, Office 3, Tula 300026,

Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 28 Sep 2022; Tax ID No. 7100027464 (Russia); Registration Number 1227100012369 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the aerospace sector of the Russian Federation economy.

120. LIMITED LIABILITY COMPANY UNMANNED TECHNOLOGIES OF MORDOVIA (a.k.a. OOO BESPILOTNYE TEKHNOLOGII MORDOVII; a.k.a. "BTM"), Ul. Lodygina, D. 3, Pomeshch 36, Saransk 430034, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 10 Aug 2023; Tax ID No. 1300007070 (Russia); Registration Number 1231300003373 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the aerospace sector of the Russian Federation economy.

121. LIMITED LIABILITY COMPANY VOZDUSHNYI TRAKTAT (a.k.a. OOO VOZDUSHNY TRAKT), MVR Levoberezhnyi, Proezd Uyutnyi, D. 1, KV. 34, Vysokaya Gora 300045, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 28 Nov 2022; Tax ID No. 7100046925 (Russia); Registration Number 1237100015767 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the aerospace sector of the Russian Federation economy.

122. CLOSED JOINT STOCK COMPANY TESTRON ASSOCIATION, Pr-kt Lyubotinskii D. 8a, Saint Petersburg 196084, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7802166998 (Russia); Registration Number 1027801525784 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

123. LIMITED LIABILITY COMPANY ADVANTA M SPB, Ul. Samoilovoi D. 5, Lit. S, Office 10, Pom. 21N-12, Saint Petersburg 192102, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7811692203 (Russia); Registration Number 1187847122121 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

124. LIMITED LIABILITY COMPANY DELAZIYA (a.k.a. DELASIA), Ul. Vasi Alekseeva D. 6, Lit. A, Pomeshch. 1-N, Office 322, Saint Petersburg 198188, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7810778923 (Russia); Registration Number 1197847214685 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

125. LIMITED LIABILITY COMPANY INZHINIRINGOVYI TSENTR PO OSNASHCHENIYU PROIZVODSTV (a.k.a. ENGINEERING CENTER FOR INDUSTRIAL EQUIPMENT), Pr-kt Svetlanovskii D. 121, K. 1 Str. 1, Pomeshch. #71-N, Saint Petersburg 195297, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7814766333 (Russia); Registration Number 1197847201903 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

126. LIMITED LIABILITY COMPANY LIONTECH S (a.k.a. LIONTEKH S), Pr-kt Leninskii D. 153, Pom.286N, Saint Petersburg 196247, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7810521798 (Russia); Registration Number 1089847262977 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

127. LIMITED LIABILITY COMPANY MAPPER, Pr-kt Volgogradskii D. 42, Korp. 5, Moscow 109316, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7743859476 (Russia); Registration Number 1127746548126 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

128. LIMITED LIABILITY COMPANY MASHEKS SERVICE (a.k.a. MASHEX SERVICE), Sh. Kashirskoe D. 3, K. 2 Str. 9, Pomeshch 1/4, Moscow 115230, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 9724026730 (Russia); Registration Number 1207700407848 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

129. LIMITED LIABILITY COMPANY MASTER RM, Ul. Privolnaya D. 70, K. 1, E/Pom/Komn 2/XII/45, Moscow 109431, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7721755900 (Russia); Registration Number 1127746299780 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

130. LIMITED LIABILITY COMPANY MEEHANITE (a.k.a. "MECHANITE"), Sh. Yuzhnoe D. 16v, Nizhniy Novgorod 603123, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 5256089670 (Russia); Registration Number 1095256004370 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

131. LIMITED LIABILITY COMPANY MELYTEC TESTING, Ul. Obrucheva D. 34/63, Str. 2, Pomeshch. I, Kom. 2,2A, Moscow 117342, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 9728043214 (Russia); Registration Number 1217700369303 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

132. LIMITED LIABILITY COMPANY OPYTNO KONSTRUKTORSKOE BYURO SOKOL, Ul. Luch D. 24/1a, Pomeshch. 115, Zhukovskiy, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 9723163892 (Russia); Registration Number 1227700478587 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

133. LIMITED LIABILITY COMPANY PK KOMPRESSOR CHLB (a.k.a. PK COMPRESSOR LLC), Ul. Neglinnaya D. 21, Office 1, Chelyabinsk 454106, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7448177081 (Russia); Registration Number 1157448002700 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

134. LIMITED LIABILITY COMPANY REOLGREID SERVICE, Ul Ekvatornaya D. 8, Novosibirsk 630060, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 5408277505 (Russia); Registration Number 1105473000896 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

135. LIMITED LIABILITY COMPANY RESEARCH AND PRODUCTION CENTER KROPUS PO (a.k.a. SCIENTIFIC AND PRODUCTION CENTER OF NON DESTRUCTIVE TESTING), Ul. 200-Letiya Goroda D.2, Noginsk 142400, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 5031052390 (Russia); Registration Number 1035006104363 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

136. LIMITED LIABILITY COMPANY STROITELNYE I KOMMUNALNYE TEKHNOLOGII (a.k.a. VOLL INDUSTRIAL), Sh. Varshavskoe D. 150, K. 1, Moscow 117534, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7727435631 (Russia); Registration Number 1197746730642 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

137. LIMITED LIABILITY COMPANY TEKHNOLOGIYA RAZVITIYA OTKRYTYKH SISTEM (a.k.a. "TECHNOLOGY OF OPEN SYSTEMS DEVELOPMENT"), Ul. Bolshaya Pochtovaya D. 26 V, Str. 1, Kom. 401, Moscow 105082, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7706818288 (Russia); Registration Number 51477464256 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

138. LIMITED LIABILITY COMPANY TM TECH, Ul. Bolshaya Pochtovaya D. 26 V, Str. 1, Kom. 403, Moscow 105082, Russia; Moskovskoe sh., 20, Ryazan, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7719898900 (Russia); Registration Number 5147746464234 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

139. LIMITED LIABILITY COMPANY TSK GRANDAVTO, Sh. Severnoe D. 17I, Krasnoyarsk 660118, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 2452200390 (Russia); Registration Number 1112452001584 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

140. LIMITED LIABILITY COMPANY VEGA OM, Ul. Gertsena D. 270, Omsk 644116, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 5503061471 (Russia); Registration Number 1025500737987 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

141. AKTSIONERNOE OBSHCHESTVO AKUSTICHESKI INSTITUT IMENI AKADEMIKA NN ANDREEVA (a.k.a. JOINT STOCK COMPANY ANDREYEV ACOUSTICS INSTITUTE; a.k.a. "AO AKIN"; a.k.a. "JSC AKIN"), ul. Shvernika d. 4, Moscow 117449, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7727804367 (Russia); Registration Number 1137746376074 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

142. AKTSIONERNOE OBSHCHESTVO KAZANSKII ZAVOD SINTETICHESKOGO KAUCHUKA (a.k.a. KAZAN SYNTHETIC RUBBER PLANT JSC; a.k.a. "AO KZSK"), ul. Lebedeva d. 1, pomeshch. 4, Kazan 420054, Russia;

Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7608030523 (Russia); Registration Number 1177627028039 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

143. AO NPP ZVEZDA, ul. Gogolya d. 39, Lyubertsy 140070, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 5027030107 (Russia); Registration Number 1025003219515 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

144. AO VOLZHSKII DIZEL IMENI MAMINYKH (a.k.a. ZAKRYTOE AKTSIONERNOE OBSHCHESTVO VOLZHSKII DIZEL IMENI MAMINYKH), ul. Kommunisticheskaya d. 124, Balakovo 413850, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 6439038107 (Russia); Registration Number 1026401407251 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

145. ARMALIT JOINT STOCK COMPANY (a.k.a. AKTSIONERNOE OBSHCHESTVO MASHINOSTROITELNY ZAVOD ARMALIT; a.k.a. ARMALIT 1 INC; a.k.a. "AO ARMALIT"), ul. Trefoleva d. 2, Saint Petersburg 198097, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7805148130 (Russia); Registration Number 1027802712530 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

146. GIT SISTEMS (a.k.a. KARNEEV SYSTEMS), sh. Entuziastov d. 56, str. 32, of. 429, Moscow 111123, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7719478367 (Russia); Registration Number 1187746462419 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

147. JOINT STOCK COMPANY CORDIANT, ul. Sovetskaya 69, Yaroslavl 150003, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7601001509 (Russia); Registration Number 1027600842972 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

148. JSC FAB RASSVET, ul. Bolshevolzhskaya d. 21, Dubna 141981, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No.

5010061227 (Russia); Registration Number 1235000068346 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

149. MAGNITOGORSKII ELEKTRODNYI ZAVOD (a.k.a. "LLC MEZ"), sh. Beloretskoe d. 5, kabinet 1, Magnitogorsk 455022, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7456037049 (Russia); Registration Number 1177456061771 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

150. NEW TECHNOLOGIES (a.k.a. NOVYE TEKHNOLOGII), ul. Admiralteiskaya, d. 3, floor 2, pomeshch. 1013, Kazan 420030, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 1656069657 (Russia); Registration Number 1131690023178 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

151. OTKRYTOE AKTSIONERNOE OBSHCHESTVO ELEKTROMASHINOSTROITELNYI ZAVOD VELKONT, ul. Lenina d. 1B, Kirovo-Chepetsk 613047, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 4341009610 (Russia); Registration Number 1024300749087 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

152. PNEVMORESURS (a.k.a. ARMATUREN GROUP LIMITED COMPANY; a.k.a. LIMITED LIABILITY COMPANY PNEUMORESURS), ul. Yakornaya d. 13, lit. a, pomeshch. 8-n, kom. # 30, office # 401B, Saint Petersburg 195027, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7839380885 (Russia); Registration Number 1089847164230 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

153. PNEVMORESURS LLC, d. 39a, Novokruchininskiy 173021, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 5310019787 (Russia); Registration Number 1155321001604 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

154. RESTART LIMITED LIABILITY COMPANY, ul. Novatorov, d. 4, kv. 51, Moscow 119421, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 9728092356 (Russia); Registration Number 1237700252624 (Russia)

[RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

155. SAINT PETERSBURGS AVIATION REPAIR COMPANY ZAO (a.k.a. AO SPARK), ul. Pilotov d. 12, Saint Petersburg 196210, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7810209170 (Russia); Registration Number 1037821027221 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

156. SHPINNER, Ul. Selskokhozyaistvennaya d. 17, k. 7, et 1, pom. 1 kom 9, Moscow 129226, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7715980551 (Russia); Registration Number 5137746009990 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

157. SPETS PROZHEKT GRUPP (a.k.a. "APIT"), ul. Leninskaya Sloboda, d. 9 pomeshch. 1/1, Moscow 115280, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 3305797523 (Russia); Registration Number 1173328011890 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

158. STD RADIKS OOO, pr-d 3-i Perova Polya d. 8, str. 11, Moscow 111141, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7720790926 (Russia); Registration Number 1137746828746 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

159. TOS VARNSDORF RUS CO LTD, ul. Tallinskaya d. 7, lit. k, Saint Petersburg 195196, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7806448672 (Russia); Registration Number 1117847046833 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

160. LIMITED LIABILITY COMPANY RESEARCH INSTITUTION ISON ORBITAL DYNAMICS (a.k.a. RDI ISON OD), Pr-kt Gagarina, d. 3/8, pomeshch. 010, Lyubertsy 140015, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 5027327002 (Russia); Registration Number 1245000032970 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

161. AKTSIONERNOE OBSHCHESTVO STALEPROMYSHLENNAYA KOMPANIYA (a.k.a. JOINT STOCK COMPANY STEEL INDUSTRIAL COMPANY; a.k.a. "AO SPK"; a.k.a. "JSC SPK"), Ul. Akademicheskaya D. 18, Yekaterinburg 620137, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 6671197148 (Russia); Registration Number 1069671052868 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

162. COMPANY LIMITED KOMAX (a.k.a. CO LTD KOMAX), Ul. Smolnaya D. 14, Pomeshch. 1, Kom 1322, Moscow 125493, Russia; Klyazyma quarter, 1B, industrial park Sheremetyevo, Khimki 141400, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7743022247 (Russia); Registration Number 1147748140891 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

163. ETS SIBERIA (a.k.a. ITS SIBIR; a.k.a. LLC ITS SIBIR), Severnoe shosse D 31, Krasnoyarsk 660020, Russia; Severnoye highway, 16a, Krasnoyarsk, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 2466208907 (Russia); Registration Number 1082468021910 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

164. JOINT STOCK COMPANY YAROSLAVSKY EXPERIMENTAL MACHINES PLANT (a.k.a. AO YARZOM), Ul. Polushkina Roshcha D. 11, Yaroslavl 150044, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7606002055 (Russia); Registration Number 1027600853543 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

165. JSC FINVAL ENERGY (a.k.a. AO FINVAL ENERGO; a.k.a. JSC FINVAL ENERGO), Volgogradskii Prospekt D.32 K.11, Moscow 109316, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7721609835 (Russia); Registration Number 1087746104907 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

166. KAMSKII KABEL (a.k.a. KAMKABEL; a.k.a. KAMSKIY KABEL LLC; a.k.a. LLC KAMSKY KABEL; a.k.a. OOO KAMSKIJ KABEL), Ul. Gaivinskaya D. 105, Perm 614030, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 5904184047 (Russia); Registration Number 1085904004779 (Russia)

[RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

167. KHROMOS ENGINEERING (a.k.a. KHROMOS INZHINIRING), Lermontova street, house 16, Dzerzhinsk 606000, Russia; BTs Neo Geo, Butlerova street, house 17, Moscow 117342, Russia; Dzhebel Ali Industrial Zone 1, Street 95, Building 05, Dubai, United Arab Emirates; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 5249111131 (Russia); Registration Number 1105249006235 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

168. LIMITED LIABILITY COMPANY ELEKTROPROFI, Ul. Mira D. 65/2, 3 et, Novosibirsk 630024, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 5407222077 (Russia); Registration Number 1025403195476 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

169. LIMITED LIABILITY COMPANY ENERGO ARSENAL, Ul. Mashinnaya D. 3 A, kv. 78, Yekaterinburg 620142, Russia; 194 March 8th Street, Yekaterinburg, Sverdlovsk Region 620142, Russia; Ul. Bisertskaya D. 34, Yekaterinburg 620024, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 6674369395 (Russia); Registration Number 1106674022729 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

170. LIMITED LIABILITY COMPANY STM, Ul. Nizhnyaya Krasnoselskaya D. 40/12, K. 20, Moscow 105066, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7719844990 (Russia); Registration Number 1137746418776 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

171. LLC ARSENAL (Cyrillic: ООО АРСЕНАЛ), Ul. Bashilovskaya Zd. 18, str. 69, Krasnoyarsk 660111, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 2465316804 (Russia); Registration Number 1142468044179 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

172. LLC DELION (a.k.a. "ECOGET"), Ul. Artilleriiskaya D. 111, Office 2, Chelyabinsk 454007, Russia; Secondary sanctions risk: See Section 11 of Executive

Order 14024.; Tax ID No. 7447228801 (Russia); Registration Number 1137447009908 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

173. METALLOTORGOVAYA KOMPANIYA KRASO (a.k.a. LLC MTK KRASO; a.k.a. METAL TRADING COMPANY KRASO), Pr-kt Druzhby D. 55, Novokuznetsk 654000, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Registration ID 1104217000645 (Russia); Tax ID No. 4217121858 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

174. NAUCHNO PROIZVODSTVENNOE PREDPRIYATIE IRVIS (a.k.a. NPP IRVIS), Ul. Vosstaniya D. 98N, Office 204, Kazan 420084, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 1659005490 (Russia); Registration Number 1021603475816 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

175. RUSSKAYA MEKHANIKA JOINT STOCK COMPANY, Ul. Tolbukhina D. 22, Rybinsk 152914, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7610062924 (Russia); Registration Number 1047601613652 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

176. SMOLENSKOE PROIZVODSTVENNOE OBYEDINENIE ANALITPRIBOR (a.k.a. FSUE SPA ANALITPRIBOR; a.k.a. SPO ANALITPRIBOR), Ul. Babushkina 3, Smolensk 214031, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type State-Owned Enterprise; Tax ID No. 6731002766 (Russia); Registration Number 1026701427774 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

177. ZAVOD GORELTEX CO LTD (a.k.a. COMPANY LIMITED CORTEM GORELTEX), Sh. Revolyutsii D. 18, Lit. A, Pom. 4-N Office 1, Saint Petersburg 195176, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type State-Owned Enterprise; Tax ID No. 7806155468 (Russia); Registration Number 1047811013183 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

178. PROMSVYAZRADIO, per. Oktyabrskii d. 12, et 4 kom 25, Moscow 127018, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No.

7724372285 (Russia); Registration Number 1167746644724 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

179. VENTRADE DOO, Brace Radica 158/41, Subotica 24000, Serbia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; V.A.T. Number 112969405 (Serbia); Registration Number 21779555 (Serbia) [RUSSIA-EO14024] (Linked To: PROMSVYAZRADIO).

Designated pursuant to section 1(a)(vi)(B) of E.O. 14024 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, PROMSVYAZRADIO, a person whose property and interests in property are blocked pursuant to E.O. 14024.

180. ZAO BUDAPHONE LTD, per. Oktyabrskii d. 12, Moscow 127019, Russia; nab. Berezhkovskaya d. 16, k. 2, kom. 507, Moscow 121059, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7710015364 (Russia); Registration Number 1027739590999 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

181. CENTRE CHINOIS DE DEVELOPPEMENT ECONOMIQUE ET COMMERCIAL AU BENIN SARL, Placodji Kpodji 133, Lot 541-A,, Porte 8, Rue 657, Et 864B, Cotonou, Benin; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 25 Jul 2008; Registration Number RB/COT/08B3414 (Benin) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

182. GOLDVAST ENTERPRISES COMPANY LIMITED, Room 803, Chevalier House 45-51 Chatham Road South, Tsim Sha Tsui, Kun, Hong Kong, China; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 29 Sep 2009; Company Number 51222825 (Hong Kong); Business Registration Number 1377834 (Hong Kong) [RUSSIA-EO14024] (Linked To: LIMITED LIABILITY COMPANY ENGINEERING FIRM AB UNIVERSAL).

Designated pursuant to section 1(a)(vi)(B) of E.O. 14024 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, LIMITED LIABILITY COMPANY ENGINEERING FIRM AB UNIVERSAL, a person whose property and interests in property are blocked pursuant to E.O. 14024.

183. KAZSTANEX, Mkr Shanyrak -1, Ul. Otcmisuly D. 166, Almaty, Kazakhstan; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 25 Mar 2011; Business Number 110340017087 (Kazakhstan) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

184. OOO UZSTANEX, Yashnobod Region, Tashkent, Uzbekistan; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 05 Jul 2018; Registration Number 305636913 (Uzbekistan) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

185. SHANGHAI WINSUN IMP AND EXP CO LTD, Room A, 22nd Floor, No. 2000 Pudong Avenue, Pilot Free Trade Zone, Pudong New Area, Shanghai 200135, China; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 15 Mar 2002; Registration Number 310115000664487 (China); Unified Social Credit Code (USCC) 91310000736692003K (China) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

186. FEDERAL STATE BUDGETARY INSTITUTION OF SCIENCE INSTITUTE OF PROBLEMS OF MECHANICS NAMED AFTER A YU ISHLINSKY RUSSIAN ACADEMY OF SCIENCES (a.k.a. INSTITUTE OF MECHANICS NAMED AFTER A YU ISHLINSKY RAS; a.k.a. IPMECH RAS; a.k.a. IPMEKH RAN INSTITUT PROBLEM MEKHANIKI IM A YU ISHLINSKOGO RAN; a.k.a. ISHLINSKY INSTITUTE FOR PROBLEMS IN MECHANICS OF THE RUSSIAN ACADEMY OF SCIENCES), Prosp Vernadskogo D 101, Korp 1, Moscow 119526, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type State-Owned Enterprise; Tax ID No. 7729138338 (Russia); Registration Number 1037739426735 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

187. INSTITUTE FOR INFORMATION TRANSMISSION PROBLEMS OF THE RUSSIAN ACADEMY OF SCIENCES (a.k.a. FEDERAL STATE BUDGETARY SCIENTIFIC INSTITUTION INSTITUTE FOR INFORMATION TRANSMISSION PROBLEMS NAMED AFTER A A KHARKEVICH OF THE RUSSIAN ACADEMY OF SCIENCES; a.k.a. IPPI RAN; a.k.a. KHARKEVICH INSTITUTE), Per Bolshoi Karetnyi D 19, Str 1, Moscow 127994, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type State-Owned Enterprise; Tax ID No. 7707020131 (Russia); Registration Number 1037700064940 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

188. INSTITUTE FOR SYSTEM PROGRAMMING OF THE RUSSIAN ACADEMY OF SCIENCES (a.k.a. FEDERAL STATE BUDGETARY SCIENTIFIC INSTITUTION V P IVANNIKOV INSTITUTE FOR SYSTEM PROGRAMMING OF THE RUSSIAN ACADEMY OF SCIENCES; a.k.a. INSTITUTE OF SYSTEM PROGRAMMING NAMED AFTER V P IVANNIKOV RAN; a.k.a. "ISP RAN"), Ul Aleksandra

Solzhenitsyna D 25, Moscow 109004, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type State-Owned Enterprise; Tax ID No. 7709006125 (Russia); Registration Number 1037700067327 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

189. JOINT STOCK COMPANY RESEARCH INSTITUTE OF SEMICONDUCTOR DEVICES (a.k.a. "JSC NIIPP"; a.k.a. "JSC RISD"), Ul. Krasnoarmeiskaya D. 99A, Tomsk 634034, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type State-Owned Enterprise; Tax ID No. 7017084932 (Russia); Registration Number 1037000170690 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

190. JOINT STOCK COMPANY SCIENCE AND PRODUCTION ENTERPRISE AIR AND MARINE ELECTRONICS (a.k.a. JSC SPE AME; a.k.a. "NPP AME"), d. 29 litera O pom. 7-N ofis 70, ul. Marshala Govorova, Saint Petersburg 198095, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7819029855 (Russia); Registration Number 1037841007896 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

191. JSC CSPA LENINETZ (a.k.a. JOINT STOCK COMPANY CENTRAL SCIENTIFIC PRODUCTION ASSOCIATION LENINETZ; a.k.a. PJSC CSPA LENINETZ), Pr-kt Yuriya Gagarina D. 34, Saint Petersburg 196143, Russia; Pr-kt Moskovskii D. 212, Lit. A, Office 0031, Saint Petersburg 196066, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7810240719 (Russia); Registration Number 1027804858146 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

192. JSC MODELING AND DIGITAL DOUBLES (a.k.a. JSC MTSD; a.k.a. SIMULATION & DIGITAL TWIN; a.k.a. SIMULATION AND DIGITAL TWIN), Ul. Suzdalskaya D.46, Office 203, Moscow 111672, Russia; Ul. Viktorenko D. 5, Str. 1, Floor 11, Pomeshch. 11.01, Moscow 125167, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7720666171 (Russia); Registration Number 1097746511334 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

193. KRIP TEKHNO (a.k.a. ALEKSANDROVSKY PLANT OF SEMICONDUCTOR DEVICES), Ul. Institutskaya D. 23A, Office 492 Floor 3, Aleksandrov 601654, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 3301035524 (Russia); Registration Number 1173328012330 (Russia) [RUSSIA-

EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

194. LAVRENTYEV INSTITUTE OF HYDRODYNAMICS OF SIBERIAN BRANCH OF RUSSIAN ACADEMY OF SCIENCES (a.k.a. FEDERAL STATE BUDGETARY INSTITUTE OF SCIENCE INSTITUTE OF HYDRODYNAMICS NAMED AFTER M A LAVRENTYEV OF THE SIBERIAN BRANCH OF THE RUSSIAN ACADEMY OF SCIENCES; a.k.a. "IGIL SO RAN"), Prosp Akademika Lavrentyeva 15, Novosibirsk 630090, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type State-Owned Enterprise; Tax ID No. 5408100064 (Russia); Registration Number 1025403648600 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

195. LIMITED LIABILITY COMPANY AFM SERVERS, Pr-Kt Leningradskii D. 72/4, Moscow, Russia; Sh. Volokolamskoe D. 2, Et 16 Pom.I Kom 6, Moscow 125080, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7725150863 (Russia); Registration Number 1037739570989 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

196. LIMITED LIABILITY COMPANY AXALIT LAB, Ul. Mamina-Sibiryaka Str. 101, Pomeshch. 11/1, Yekaterinburg 620000, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 6670518783 (Russia); Registration Number 1236600056098 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

197. LIMITED LIABILITY COMPANY AXALIT SOFT, Ul. Smazchikov D. 3, Kv. 307, Yekaterinburg 620041, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 6670451183 (Russia); Registration Number 1176658028315 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

198. LIMITED LIABILITY COMPANY EMT, Pr-kt Leningradskii D. 80, Korp. G, Of. 801, Moscow 125190, Russia; Pr-d Staropetrovskii D. 7A, Str. 6, Office 710, Moscow 125130, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7714582188 (Russia); Registration Number 1047796965754 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

199. LIMITED LIABILITY COMPANY ORGANIC AND PRINTED ELECTRONICS TECHNOLOGIES (a.k.a. LIMITED LIABILITY COMPANY ORGANIC & PRINTED ELECTRONICS TECHNOLOGIES; a.k.a. "TOPE"), Sh. Shchelkovskoe D.77, Office 1602, Moscow 107207, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7718809369 (Russia); Registration Number 1107746454749 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

200. LIMITED LIABILITY COMPANY TEKHSPETSKOMPLEKT (a.k.a. "LLC TSK"), Pr-d Garazhnyy, D. 1, Liter U, Office 2-3, Saint Petersburg 192289, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7810090372 (Russia); Registration Number 1077847031118 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

201. OOO FABRIKON, domovladenie 6 str. 1 kom. 95, km. 22-1, Kievskoe Sh., Moscow 108811, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7751146052 (Russia); Registration Number 1187746685048 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

202. STOCK COMPANY MORION INC (a.k.a. AO MORION), Pr. Kima D. 13A, Saint Petersburg 199155, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type State-Owned Enterprise; Tax ID No. 7801016421 (Russia); Registration Number 1037800001304 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

203. V A TRAPEZNIKOV INSTITUTE OF CONTROL SCIENCES OF RUSSIAN ACADEMY OF SCIENCES (a.k.a. FEDERAL STATE BUDGETARY SCIENTIFIC INSTITUTION INSTITUTE FOR CONTROL PROBLEM NAMED AFTER V A TRAPEZNIKOV OF THE RUSSIAN ACADEMY OF SCIENCES; a.k.a. "ICS RAS"), Ul. Profsoyuznaya D.65, Moscow 117997, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type State-Owned Enterprise; Tax ID No. 7728013512 (Russia); Registration Number 1037739269590 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

204. ABLEFAST LOGISTICS SHENZHEN LIMITED (a.k.a. ABLE FAST AIR FREIGHT LIMITED; a.k.a. ABLE FAST LOGISTICS LIMITED; a.k.a. ABLE FAST LOGISTICS SHENZHEN LIMITED), 1702 A, Block C, Tian'an International Building, 3012 Renmin South, Luohu District, Shenzhen, China; Room 1607, 16/F, No 93-103 Wing Lok Street, Hong Kong, China; Room C, 26/F, Shield Industrial Centre, No 84-92 Chai Wan Kok Street, Hong Kong, China; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Type: Wholesale of electronic and telecommunications equipment and parts [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

205. CRESTA LOJISTIK ITHALAT IHRACAT TICARET SIRKETI (a.k.a. CRESTA LOJISTIK ITHALAT IHRACAT TICARET LIMITED SIRKETI), 34662 Barbaros Mah Mutevelli Cesme Cad No: 15 C Uskudar, Istanbul, Turkey; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 2150611577 (Turkey) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

206. NANCHANG KUDOS IMPORT AND EXPORT COMPANY LIMITED, R616, 6th Floor, E-commerce Building, #86 East Jiefang Road, Qingshahu District, Nanchang, Jiangxi Province 330012, China; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Type: Wholesale of other machinery and equipment [RUSSIA-EO14024] (Linked To: JIANGXI LIANSHENG TECHNOLOGY CO., LTD).

Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, JIANGXI LIANSHENG TECHNOLOGY CO., LTD, a person whose property and interests in property are blocked pursuant to E.O. 14024.

207. 3K GROUP LIMITED, Unit 205, Unit C, 2/F, Hong Kong, China; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 07 Mar 2023; Company Number 3242285 (Hong Kong); Business Registration Number 74947060 (Hong Kong) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

208. ELMAK, Proezd Okurzhnoi D. 30A, Moscow 105187, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7719486431 (Russia); Registration Number 1197746104302 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

209. GROUP YEOH LIMITED (a.k.a. YEOH GROUP CO LIMITED), Rm 89, 3/F Yau Lee Ctr, Kwun Tong, Hong Kong, China; Room 401, 4/F, Wanchai Central Building, 89 Lockhart Road, Wan Chai, Hong Kong, China; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 14 Jun 2023;

Company Number 75417923 (Hong Kong); Business Registration Number 3289158 (Hong Kong) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

210. HK LINK ASIA ELECTRONICS LIMITED, Hong Kong, China; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 15 Jul 2022; Business Registration Number 74241183 (Hong Kong) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

211. RICHTEK HONGKONG ELECTRONIC CO LIMITED (a.k.a. RICHTEK HK ELECTRONIC CO LTD), Hong Kong, China; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 02 Dec 2013; Business Registration Number 62427284 (Hong Kong) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

212. ROFO TRADING CO LTD, No. 10, East Xieyuda Road, Huizhou District, Huangshan City, Anhui, China; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Type: Wholesale of other machinery and equipment [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

213. SHANGHAI ZHANJIA TRADING CO LTD, Room 307, No. 413 West Meilong Rd, Shanghai, China; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Type: Wholesale of other machinery and equipment [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

214. SHENZHEN A TECHNOLOGY CO LTD (a.k.a. SHENZHEN AIYI TECHNOLOGY COMPANY LIMITED), No. 18, Zima, Qianhai Shenzhen Hong Kong Cooperation Zone, Qianhai Xiangbin Building, Shenzhen 1101-A010, China; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 20 Sep 2022; Company Number 440300217595868 (China); Unified Social Credit Code (USCC) 91440300MA5HGXD28E (China) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

215. SHENZHEN ONE WORLD INTERNATIONAL LOGISTICS CO LTD, Rm 3005, 30/F, Hongchang Sq B, Shennan East Roa, Luohu District, Shenzhen, 518002, China; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization

Type: Wholesale of electronic and telecommunications equipment and parts [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

216. SUNSHINE LOGISTICS SHENZHEN CO LTD, Room B1, Floor 13, Block A/B, Nanfang Securities Building, No. 2016 Jianshe Road, Luohu District, Shenzhen, 518005, China; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Type: Wholesale of electronic and telecommunications equipment and parts [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

217. SANLITUN YATIRIM DIS TICARET LIMITED SIRKETI (a.k.a. SANLITUN YATIRIM DIS TIC LTD), Kocasinan Merkez mah. Kemaliye sok. Celik, Ap. Blok No: 5A Bahcelievler, Istanbul, Turkey; Website www.sanlitun.com.tr; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 26 Apr 2022; Tax ID No. 7441088515 (Turkey); Registration Number 377146-5 (Turkey) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

218. ABHAR TECHNOLOGIES AND SERVICES PRIVATE LIMITED, Tenth Floor, Rmz Latitude, Commercial, Bellary Road, Hebbal, Bengaluru 560092, India; No 6, 80feet Road Koramangala, 4th Block, Bengaluru 560034, India; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. AAOCA4544Q (India); Registration Number U74999KA2016PTC093825 (India) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

219. GALAXY BEARINGS LTD, Pariseema Complex, A-53/54, C.G. Road, Ellisbridge, Ahmedabad 380009, India; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. AAACG5617Q (India); Registration Number L29120GJ1990PLC014385 (India) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

220. KDG ENGINEERING PRIVATE LIMITED, A-62, Second Floor, Okhla Industrial Area Phase II, New Delhi, Okhla Industrial Estate, South Delhi, Delhi 110020, India; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. AADCK6206E (India); Registration Number U29253DL2009PTC188102 (India) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

221. ORBIT FINTRADE LLP, Plot No 2233_35A&B, Rajkot, Gujarat 360021, India; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. AAHFO8722E (India); Registration Number UDYAM-GJ-20-0118268 (India) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

222. SHARPLINE AUTOMATION PRIVATE LIMITED, No. 19, Vishnu Nagar, TTC-MIDC Industrial Area, Digha, Navi Mumbai 400708, India; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. AADCS0425M (India); Registration Number U30000MH1995PTC094653 (India) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

223. SHAURYA AERONAUTICS PRIVATE LIMITED, T-15, 2nd Floor, Green Park Main, Delhi 110016, India; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. AAFSC3675P (India); Registration Number U74899DL2000PTC108725 (India) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

224. SHREEGEE IMPEX PRIVATE LIMITED (a.k.a. "DARWIN PLUS"), 45 Gandhi Nagar Garh Road, Meerut 250001, India; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. AAHCS2336R (India); Registration Number U17221UP2003PTC027553 (India) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

225. AVINEX GLOBAL LIMITED, Room 1005C, Fortune Harbor International Center, No. 1084, Baoyuan Road, Xixiang Street, Baoan District, Shenzhen 518102, China; Rm A1-13, Blk A 3/F, Yee Lim Ind Ctr, 2-28 Kwai Lok St,, Kwai Chung, NT, Hong Kong, China; Website avinextech.com; Email Address sales@avinextech.com; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 06 Apr 2023; C.R. No. 3267782 (Hong Kong); Business Registration Number 75202722 (Hong Kong) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

226. DENVAS SERVICES PRIVATE LIMITED, No. 124, A 2/42, Gupta Palace, Rajouri Garden, New Delhi 110015, India; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 04 Jan 2008; Tax ID No. AACCD7605D (India); Registration Number U93030DL2008PTC172286 (India) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

227. EMSYSTECH, 7/14, Jaya Residency, 5th Main Puttenahalli no. 1/2, 1st Floor, Bangalore, Bengaluru 560078, India; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 2007; Organization Type: Manufacture of computers and peripheral equipment [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

228. INNOVIO VENTURES, 944 Block C, Sushant Lok Phase 1, Gurgaon 122001, India; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Registration Number AAFFI1755F (India) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

229. KHUSHBU HONING PRIVATE LIMITED, F24/1 MIDC Shiroli, Kolhapur, Mahrashtra 416122, India; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 20 May 2020; Tax ID No. AAICK0855G (India); Registration Number U36990PN2020PTC190864 (India) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

230. LOKESH MACHINES LIMITED, B-29, EEIE, Stage II, Hyderabad, Telangana 500037, India; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 17 Dec 1983; Tax ID No. AAACL4244L (India); Registration Number L29219TG1983PLC004319 (India) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

231. POINTER ELECTRONICS, 211 Rg Trade Tower, Nsp Pritampura, New Delhi 110034, India; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 14 Mar 2022; Registration Number UDYAM-DL-06-0096395 (India) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

232. RRG ENGINEERING TECHNOLOGIES PRIVATE LIMITED, No. 8, Prajay Meadows, No. 12, Banjara Hills, Hyderabad 500034, India; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 23 Apr 2008; Tax ID No. AAECR0362B (India); Registration Number U29219TG2008PTC058777 (India) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

233. GNO INVESTMENT LTD OOD, 40, Ami Bue Street/Boulevard, Krasno Selo District, Floor 2, Apartment 3 Sofia, 1606, Stolichna, Bulgaria; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 03 Oct 2018; Tax ID No. BG205319107 (Bulgaria); Government Gazette Number 205319107 (Bulgaria) [RUSSIA-EO14024] (Linked To: CELIK, Ozgur Hasan).

Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, Ozgur Hasan Celik, a person whose property and interests in property are blocked pursuant to E.O. 14024.

234. MIREX BG LTD OOD, 205, Slivnitsa Boulevard Serdika District, Floor 3 Sofia, 1202, Stolichna, Bulgaria; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 27 Nov 2018; Tax ID No. BG205412119 (Bulgaria); Government Gazette Number 205412119 (Bulgaria) [RUSSIA-EO14024] (Linked To: CELIK, Ozgur Hasan).

Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, Ozgur Hasan Celik, a person whose property and interests in property are blocked pursuant to E.O. 14024.

235. MIREX HAVACILIK VE SAVUNMA SANAYI TICARET ANONIM SERKETI, Koc Kuleleri A Blok, Sogutozu Man., Sogutozu Cad., No: 2A/13-Cancana, Ankara, Turkey; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 6201345216 (Turkey); Business Registration Number 466011 (Turkey) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the defense and related materiel sector of the Russian Federation economy.

236. NEW WAY GROUP GLOBAL DANISMANLIK TICARET LIMITED SIRKETI, Gurpinar Mah, Filiz SK, No: 3/1, Beylikduzu, Istanbul, Turkey; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 25 Oct 2021; Chamber of Commerce Number 1326252 (Turkey); Business Registration Number 335915-5 (Turkey); Central Registration System Number 0631-1609-4070-0001 (Turkey) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the defense and related materiel sector of the Russian Federation economy.

237. ACS SYSTEMS LIMITED, Rm 706, 7/F, South Seas Ctr Twr 2, Tsim Shai Tsui, Hong Kong, China; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 12 Jan 2017; Business Registration Number 67154789 (Hong Kong) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

238. AUSPICIOUS SUN LIMITED, Rm 12, 19/F, Ho King Coml CTR, Mongkok, Hong Kong, China; Secondary sanctions risk: See Section 11 of Executive Order 14024.;

Organization Established Date 28 Apr 2023; Business Registration Number 75271646 (Hong Kong) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

239. BEYOND CENTER LIMITED, Rm 321, 3/F Kwai Shing Indl Bldg G Ph 2, Kwai Chung, Hong Kong, China; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 07 Jul 2021; Business Registration Number 73158119 (Hong Kong) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

240. BHOOMI HK LIMITED, Hong Kong, China; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 07 Nov 2023; Business Registration Number 75886764 (Hong Kong) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

241. CARGO LINKEDIN INTERNATIONAL LIMITED, Hong Kong, China; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 16 Oct 2012; Business Registration Number 60483090 (Hong Kong) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

242. CHIPGOO ELECTRONICS LIMITED, Rm A29, 24/F, Regent's Park, Prince Indl BD, Hong Kong, China; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 22 Nov 2022; Business Registration Number 74629125 (Hong Kong) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

243. EK IMPORT, Pl. Konstitutsii D. 3, K. 2, Lit. A, Pomeshch 40-N, Chast Pomeshcheniya #1, Saint Petersburg 196247, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Tax ID No. 7839078314 (Russia); Commercial Registry Number 1177847045430 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

244. ELE TECHNOLOGY CO LTD, No: 3712 Duhuixuan Building, Shennan Road, Futian Area, Shenzhen, China; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Type: Wholesale of other machinery and equipment [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

245. FK HK LIMITED, Rm 705, 7/F, FA Yuen Coml Bldg, Mongkok, Hong Kong, China; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 07 Feb 2023; Business Registration Number 74821422 (Hong Kong) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

246. HONESTWIN TECHNOLOGY CO LIMITED, Rm A, 12/F, ZJ 300 Wan Chai, Hong Kong, China; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 31 Aug 2022; Business Registration Number 74383498 (Hong Kong) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

247. HONG KONG QISU ELECTRONIC TECHNOLOGY CO LIMITED, Rm 705, 7/F, FA Yuen Coml Bldg, Mongkok, Hong Kong, China; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 12 Oct 2021; Business Registration Number 73439107 (Hong Kong) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

248. JIAXING YONGCHI MECHANICAL AND ELECTRICAL CO LTD, North of Shiwei Road (201, Building 3, Darong Lock Co Ltd), Yuxin Town, Nanhu District, Jiaxing, Zhejiang 314400, China; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 24 Jan 2013; Unified Social Credit Code (USCC) 91330401062011696W (China) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the manufacturing sector of the Russian Federation economy.

249. MINHOO LOGISTICS LIMITED, Hong Kong, China; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 24 Nov 2017; Business Registration Number 68542042 (Hong Kong) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

250. LLC AM LOGISTICS (Cyrillic: ООО АМ ЛОГИСТИКА) (a.k.a. LIMITED LIABILITY COMPANY AM LOGISTICS (Cyrillic: ОБЩЕСТВО С ОГРАНИЧЕННОЙ ОТВЕТСТВЕННОСТЬЮ АМ ЛОГИСТИКА)), d. 11 kv. 3, ul. 4-Ya Krasnoarmeiskaya, St. Petersburg 190005, Russia; Website amlogistics.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 31 Oct 2013; Tax ID No. 7839486793 (Russia); Government Gazette Number 31906071 (Russia); Business Registration Number 1137847419599 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the transportation sector of the Russian Federation economy.

251. SLD LOJISTIK LC VE DIS TICARET LIMITED SIRKETI (a.k.a. SLD LOGISTICS AND TRADING LLC), Merkez Mah. Harvest Sk., Cabin No: 52, Sisli, Istanbul 34381, Turkey; Website https://sld-logistics.org; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 29 Jun 2022; Tax ID No. 7721498346 (Turkey); Registration Number 390801 (Turkey) [RUSSIA-EO14024] (Linked To: LLC AM LOGISTICS).

Designated pursuant to section 1(a)(vi)(B) of E.O. 14024 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, LLC AM LOGISTICS, a person whose property and interests in property are blocked pursuant to E.O. 14024.

Lisa M. Palluconi,

Acting Director, Office of Foreign Assets Control.

[FR Doc. 2024–27799 Filed 11–26–24; 8:45 am]

BILLING CODE 4810–AL–C

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Action

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List (SDN List) based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: This action was issued on November 21, 2024. See **SUPPLEMENTARY INFORMATION** section for relevant dates.

FOR FURTHER INFORMATION CONTACT: OFAC: Associate Director for Global Targeting, 202–622–2420; or *https://ofac.treasury.gov/contact-ofac.*

SUPPLEMENTARY INFORMATION:

Electronic Availability

The SDN List and additional information concerning OFAC sanctions programs are available on OFAC's website: *https://ofac.treasury.gov.*

Notice of OFAC Actions

On November 21, 2024, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authorities listed below.

BILLING CODE 4180–AL–P

Individuals

1. CHISTYUKHIN, Vladimir, Russia; DOB 20 Jan 1973; POB Moscow, Russia; nationality Russia; Gender Male; Secondary sanctions risk: See Section 11 of Executive Order 14024. (individual) [RUSSIA-EO14024].

   Designated pursuant to section 1(a)(i) of Executive Order 14024 of April 15, 2021, "Blocking Property With Respect To Specified Harmful Foreign Activities of the Government of the Russian Federation," 86 FR 20249, 3 CFR, 2021 Comp., p. 542 (Apr. 15, 2021) (E.O. 14024) as amended by Executive Order 14114 of December 22, 2023, "Taking Additional Steps With Respect to the Russian Federation's Harmful Activities," 88 FR 89271, 3 CFR, 2023 Comp., p. 721 (Dec. 22, 2023) (E.O. 14114), for operating or having operated in the financial services sector of the Russian Federation economy.

2. DANILOVA, Elizaveta, Russia; DOB 16 Nov 1984; POB Moscow, Russia; nationality Russia; Gender Female; Secondary sanctions risk: See Section 11 of Executive Order 14024. (individual) [RUSSIA-EO14024].

   Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

3. KHAIDARSHINA, Gulnara, Russia; DOB 29 Aug 1983; POB Pskov, Russia; nationality Russia; Gender Female; Secondary sanctions risk: See Section 11 of Executive Order 14024. (individual) [RUSSIA-EO14024].

   Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

4. KOVRIGIN, Mikhail Anatolyevich, Russia; DOB 28 Jan 1976; nationality Russia; Gender Male; Secondary sanctions risk: See Section 11 of Executive Order 14024. (individual) [RUSSIA-EO14024].

   Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

5. LOZGACHEVA, Ekaterina, Russia; DOB 23 Mar 1984; POB Dzerzhinsk, Russia; nationality Russia; Gender Female; Secondary sanctions risk: See Section 11 of Executive Order 14024. (individual) [RUSSIA-EO14024].

   Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

6. MOROZOV, Alexandr, Russia; DOB 28 Mar 1965; POB Elektrostal, Russia; nationality Russia; Gender Male; Secondary sanctions risk: See Section 11 of Executive Order 14024. (individual) [RUSSIA-EO14024].

   Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

7. POLYAKOVA, Olga Vasilyevna, Russia; DOB 1970; POB Moscow, Russia; nationality Russia; Gender Female; Secondary sanctions risk: See Section 11 of Executive Order 14024. (individual) [RUSSIA-EO14024].

   Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

8. PRONIN, Kirill, Russia; DOB 14 Aug 1979; POB Kazan, Russia; nationality Russia; Gender Male; Secondary sanctions risk: See Section 11 of Executive Order 14024. (individual) [RUSSIA-EO14024].

   Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

9. SHABLYA, Bogdan, Russia; DOB 08 Nov 1972; nationality Russia; Gender Male; Secondary sanctions risk: See Section 11 of Executive Order 14024. (individual) [RUSSIA-EO14024].

   Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

10. TULIN, Dmitry, Russia; DOB 26 Mar 1956; POB Moscow, Russia; nationality Russia; Gender Male; Secondary sanctions risk: See Section 11 of Executive Order 14024. (individual) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

11. ANISIMOV, Andrei (a.k.a. ANISIMOV, Andrey), New Delhi, India; DOB 14 Mar 1984; POB Shturm, Russia; nationality Russia; Gender Male; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Passport 550869419 (Russia) expires 07 Oct 2032; National ID No. 0704331276 (Russia) (individual) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

12. FEDKINA, Elena, Shanghai, China; DOB 31 May 1993; POB Lipetsk, Russia; nationality Russia; Gender Female; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Passport 761827549 (Russia) expires 28 Oct 2029 (individual) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

13. HAINDL, Daniel, Russia; DOB 30 Aug 1977; POB Rostov Na Donu, Russia; nationality Czech Republic; Gender Male; Secondary sanctions risk: See Section 11 of Executive Order 14024.; National ID No. 7708309906 (Czech Republic) (individual) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

14. LISHENKO, Ilya (a.k.a. LISHENKO, Ilia), Shanghai, China; DOB 02 Mar 1990; POB Krasnoyarsk-45, Russia; nationality Russia; Gender Male; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Passport 767980925 (Russia) expires 01 Jul 2032; National ID No. 0409925444 (Russia) (individual) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

15. LOGOV, Roman, Shanghai, China; DOB 24 Dec 1982; nationality Russia; Gender Male; Secondary sanctions risk: See Section 11 of Executive Order 14024. (individual) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

16. BAKINA, Alla, Russia; DOB 19 Feb 1971; POB Moscow, Russia; nationality Russia; Gender Female; Secondary sanctions risk: See Section 11 of Executive Order 14024. (individual) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

Entities

1. BCS BANK AO, Building 1, Prospect Mira, 69, Moscow 105064, Russia; SWIFT/BIC BCSBRU55; Website bank.bcs.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 5460000016 (Russia); Legal Entity Number 253400AU1YFUM0C4QG84; Registration Number 1055400000369 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

2. CENTROCREDIT BANK, Bld. 1, St Pyatnitskaya, 31/2, Moscow 119017, Russia; SWIFT/BIC CKBBRUMM; Website www.ccb.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 1027739198387 (Russia); Legal Entity Number 253400ES6B5GGK2A4506; Registration Number 1027739198387 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

3. COMMERCIAL BANK KREMLYOVSKIY, Per. Nikoloshchepovsky 1st, 6. Page 1, Moscow 121099, Russia; SWIFT/BIC KREMRUMM; Website www.kremlinbank.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7706006720 (Russia); Registration Number 1027739881223 (Russia) [RUSSIA-EO14024].

   Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

4. FORA BANK JOINT STOCK COMMERCIAL BANK, Zubovsky Boulevard, 25, Moscow 119021, Russia; SWIFT/BIC FOJSRUMM; Website www.forabank.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7704113772 (Russia); Legal Entity Number 253400USPWD55XXK2223; Registration Number 1027739553764 (Russia) [RUSSIA-EO14024].

   Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

5. GARANT INVEST BANK JOINT STOCK (a.k.a. GARANT INVEST COMMERCIAL BANK JSC), 1st Kolobovsky Pereulok, 23, Moscow 127048, Russia; SWIFT/BIC GAINRUMM; Website www.gibank.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7723168657 (Russia); Legal Entity Number 253400NBDAA1ADSSA189; Registration Number 1037739429320 (Russia) [RUSSIA-EO14024].

   Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

6. JOINT STOCK COMMERCIAL BANK NATIONAL RESERVE BANK JOINT STOCK COMPANY, 60 Letiya Oktyabrya Blvd., 10A, Moscow 117292, Russia; SWIFT/BIC NARNRUMM; Website www.nrb.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7703211482 (Russia); Legal Entity Number 253400HTRLA4RF06MG88; Registration Number 1027700458224 (Russia) [RUSSIA-EO14024].

   Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

7. JOINT STOCK COMPANY BANK DOM RF, St. Vozdvizhenka 10, Moscow 125009, Russia; SWIFT/BIC BDRFRUMM; Website www.domrfbank.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7725038124 (Russia); Legal Entity Number 253400QBQPWTFL8FAS39; Registration Number 1037739527077 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

8. JOINT STOCK COMPANY BANK UNITED CAPITAL, Bldg. 2, Letter A, Gzhatskaya, 21, Saint Petersburg 195220, Russia; SWIFT/BIC UNCLRU2P; Website www.okbank.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7831001013 (Russia); Legal Entity Number 25340011K39ECHPV7N75; Registration Number 1027800003505 (Russia) [RUSSIA-EO14024].

   Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

9. JSC EXI BANK (a.k.a. EKSI BANK AO), Ul. Professora Popova D. 23, Saint Petersburg 197376, Russia; SWIFT/BIC JXIBRU2P; Website www.exibank.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7831000940 (Russia); Registration Number 1027800000942 (Russia) [RUSSIA-EO14024].

   Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

10. KAMSKY COMMERCIAL BANK (a.k.a. LIMITED LIABILITY COMPANY KAMA KOMMERCIAL; a.k.a. "KAMCOMBANK"), Gidrostroiteley Street, Building 21, Naberezhnyye Chelny 423800, Russia; SWIFT/BIC KACORU21; Website www.kamkombank.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 1650025163 (Russia); Legal Entity Number 25300F1C0J3H75V5935; Registration Number 2021600000840 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

11. MB BANK (a.k.a. BANK MELLI IRAN ZAO; a.k.a. JOINT STOCK COMPANY MIR BUSINESS BANK; a.k.a. JSC MB BANK; a.k.a. MB BANK, AO; a.k.a. MIR BIZNES BANK; a.k.a. MIR BIZNES BANK, AO; a.k.a. MIR BUSINESS BANK (Cyrillic: МИР БИЗНЕС БАНК); a.k.a. MIR BUSINESS BANK ZAO), 9/1 ul Mashkova, Moscow 105062, Russia; Russia; 9/1 Mashkova St., Moscow 105062, Russia; 6a Lenin Square Bld. A, Astrakhan 414000, Russia; Prechistenka Street, 36, Building 1, Moscow 119034, Russia; SWIFT/BIC MRBBRUMM; Website www.mbbru.com; Additional Sanctions Information - Subject to Secondary Sanctions; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7744002363 (Russia); Legal Entity Number 253400XSDD336BT6BJ60; Registration Number 1027739669726 (Russia) [SDGT] [SYRIA] [IFSR] [RUSSIA-EO14024] (Linked To: BANK MELLI IRAN; Linked To: GLOBAL VISION GROUP).

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

12. NATIONAL STANDARD BANK JOINT STOCK COMPANY, Building 57-Building 2-3, Party Lane 1, Moscow 115093, Russia; SWIFT/BIC CBNNRUMM; Website www.ns-bank.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7750056688 (Russia); Legal Entity Number 25340031R6A1E6TW7M44; Registration Number 1157700006650 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

13. NEW MOSCOW BANK, Bolshoy Savvinsky Per., D. 2-4-6, P. 10, Moscow 119435, Russia; SWIFT/BIC NEWMRUMM; Website www.nmbank.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7703008207 (Russia); Legal Entity Number 253400DPF6NDJQ654T78; Registration Number 1027700128796 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

14. PUBLIC JOINT STOCK COMPANY BANK SINARA, Kuibyshev Str., 75, Yekaterinburg 620026, Russia; SWIFT/BIC SKBERU4E; Website www.sinara.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 6608003052 (Russia); Legal Entity Number 253400WD8ULWSUGGXP64; Registration Number 1026600000460 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

15. PUBLIC JOINT STOCK COMPANY NATIONAL BANK TRUST (a.k.a. NATIONAL BANK TRUST), Mozhaysky Val Str., 8, Moscow 121148, Russia; SWIFT/BIC NBTRRUMM; Website www.trust.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7831001567 (Russia); Legal Entity Number 253400QR501VVARKW142; Registration Number 1027800000480 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

16. RUSSIAN UNIVERSAL BANK (a.k.a. RUSUNIVERSALBANK), M. Kazannyj Per., 14, Str. 1, Moscow 105064, Russia; SWIFT/BIC RUNIRUMM; Website www.rubank.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7718120593 (Russia); Legal Entity Number 253400YYHA5GJQB46R62; Registration Number 1027739671288 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

17. WAYBANK JSC (a.k.a. CB RENTA BANK JSC), Pyatnitskaya street, 57, b.1., Moscow 115184, Russia; SWIFT/BIC WJCMRUMM; Website waybank.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7744003007 (Russia); Legal Entity Number 253400MZGXN18GHCN57; Registration Number 1027744003231 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

18. INTERSTATE BANK (a.k.a. MEZHGOSUDARSTVENNYI BANK), 15, Shukov Street, Moscow 115162, Russia; SWIFT/BIC INEARUMM; Website www.isbnk.org; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; alt. Target Type State-Owned Enterprise; Tax ID No. 7700076777 (Russia); Legal Entity Number 253400RP1GTPC8W8AT76; Registration Number 1027739567228 (Russia) [RUSSIA-EO14024].
    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

19. AKTSIONERNOE OBSHCHESTVO AGENTSTVO REGIONALNYI NEZAVISIMYI REGISTRATOR (a.k.a. AO AGENTSTVO RNR), Ul. Demonstratsii D. 27, Korp. 1, Tula 300034, Russia; Ul. 9-GO Maya D. 10, K. B, Lipetsk 398017, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7107039003 (Russia); Registration Number 1027100964527 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

20. AKTSIONERNOE OBSHCHESTVO INDEPENDENT SPECIALIZED DEPOSITORY (a.k.a. AO NSD (Cyrillic: АКЦИОНЕРНОЕ ОБЩЕСТВО НЕЗАВИСИМЫЙ СПЕЦИАЛИЗИРОВАННЫЙ ДЕПОЗИТАРИЙ); a.k.a. "JOINT STOCK COMPANY INVESTMENT COMPANY PEKO INVEST"), Ul. Kuznetskii Most D. 21/5, Office Et. 5 Pom. I Kom. 1-18, Moscow 107996, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7715159793 (Russia); Registration Number 102773947019 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

21. AKTSIONERNOE OBSHCHESTVO PROFESSIONALNYI REGISTRATSIONNYI TSENTR (a.k.a. AO PRTS), Balaklavskii Pr. D. 28, Str. V, Moscow 117452, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 3821010220 (Russia); Registration Number 1023802254574 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

22. AKTSIONERNOE OBSHCHESTVO REGISTRATOR KAPITAL (a.k.a. AO REGISTRATOR KAPITAL), Per. Tramvainyi D. 15, KV. 101, Yekaterinburg 620041, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 6659035711 (Russia); Registration Number 1026602947414 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

23. AKTSIONERNOE OBSHCHESTVO SURGUTINVESTNEFT (a.k.a. AO SURGUTINVESTNEFT), Ul. Entuziastov 52, Korp. 1, Surgut 628400, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 8602039063 (Russia); Registration Number 1028600588246 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

24. AKTSIONERNOE OBSHCHESTVO VEDENIE REESTROV KOMPANII (a.k.a. AO VRK), Prosp. Lenina D. 28, Yekaterinburg 620014, Russia; Ul. Dobrolyubova D. 16, Floor 5, Yekaterinburg 620014, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 6661049239 (Russia); Registration Number 1026605227923 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

25. AO REESTR (a.k.a. ZAO REESTR), Per. Bolshoi Balkanskii D. 20, Str. 1, Moscow 129090, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7704028206 (Russia); Registration Number 1027700047275 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

26. JOINT STOCK COMPANY RDC PARITET (a.k.a. JSC RDC PARITET), Per. 2-I Kozhevnicheskii D. 12, Str. 2, Floor 3, Pomeshch. XVI, Komnata 4, Moscow 115114, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7723103642 (Russia); Registration Number 1027700534806 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

27. JOINT STOCK COMPANY REGISTRY SOCIETY STATUS (a.k.a. AO STATUS), Ul. Novorogozhskaya D. 32, Str. 1, Moscow 109544, Russia; Ul. Novokhokhlovskaya D. 23, Str. 1, Pomeshch. 1, Moscow 109052, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type

Financial Institution; Tax ID No. 7707179242 (Russia); Registration Number 1027700003924 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

28. JSC REPUBLICAN SPECIALREGISTRAR YAKUT FUND CENTER (a.k.a. AO RSR YAFTS), Per. Glukhoi D. 2, Korp. 1, Yakutsk 677007, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 1435001668 (Russia); Registration Number 1021401046160 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

29. JSC RT REGISTRAR (a.k.a. AO RT REGISTRATOR), Ul. Donskaya D. 13, Et. 1A, Pom. XII, Kom. 11, Moscow 119049, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 5407175878 (Russia); Registration Number 1025403189790 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

30. JSC SERVICE REESTR (a.k.a. AO SERVICE REESTR), Ul. Sretenka D. 12, Moscow 107045, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 8605006147 (Russia); Registration Number 1028601354055 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

31. LIMITED LIABILITY COMPANY SPECIAL DEPOSITORY PARTNER (a.k.a. SD PARTNER LLC), Ul. Mashi Poryvaevoi D. 34, Moscow 107078, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7707177816 (Russia); Registration Number 1027739461551 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

32. LIMITED LIABILITY COMPANY SPECIALIZED DEPOSITORY COMPANY GARANT (a.k.a. SDK GARANT), Nab. Krasnopresnenskaya D. 8, Et. 10, Office 1032, Moscow 123100, Russia; Ul. Sokolnicheskii Val D. 37, Moscow 107113, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7714184726 (Russia); Registration Number 1027739142463 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

33. OBSHCHESTVO S OGRANICHENNOY OTVETSTVENNOSTYU OBORONREGISTR (a.k.a. OBORONREGISTR), Ul. Staraya Basmannaya D. 19, Str. 12, Kom. 22, Moscow 105066, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7731513346 (Russia); Registration Number 1047796702843 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

34. OOO PARTNER (Cyrillic: ООО ПАРТНЁР), Prosp. Pobedy D. 22, Cherepovets 162606, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 28 Jun 1994; Target Type Financial Institution; Tax ID No. 3528218586 (Russia); Registration Number 1143528009712 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

35. OOO REESTR RN, Per. Podkopaevskii D 2/6, Str. 3-4, Moscow 109028, Russia; Per. 1-I Shchipkovskii D. 20, Moscow 115093, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7705397301 (Russia); Registration Number 1027700172818 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

36. OOO REGISTRATOR GARANT, Nab. Krasnopresnenskaya D. 8, Et. 2, Pom. 228, Moscow 123100, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7703802628 (Russia); Registration Number 5137746173296 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

37. SPETSIALIZIROVANNYI REGISTRATOR REKOM (a.k.a. SR REKOM), Mkr. Koroleva D. 37, Staryy Oskol 309502, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 3128060841 (Russia); Registration Number 1073128002056 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

38. TSENTR UCHETA I REGISTRATSII (a.k.a. "TSUR"), Pl. Rastrelli D. 2, Str. 1, Pomeshch. 3-N, Kom. 2.58, Saint Petersburg 191124, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7842521215 (Russia); Registration Number 1147847198806 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

39. YUZHNO REGIONALNYI REGISTRATOR (a.k.a. YURR), Ul. Menzhinskogo 2/1, Floor 3, Rostov-na-Donu 344029, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 6166032022 (Russia); Registration Number 1026104025716 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

40. BRATSKY NARODNY BANK JSC, ul. Komsomolskaya 43, Bratsk 665717, Russia; SWIFT/BIC BRATRU6B; Website www.ankb.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 3803202031 (Russia); Registration Number 1023800000069 (Russia); Global Intermediary Identification Number 6FCAP1.99999.SL.643 [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

41. COMMERCIAL BANK ENERGOTRANSBANK JOINT STOCK COMPANY, ul. Klinicheskaya 83a, Kaliningrad 236016, Russia; SWIFT/BIC ENGORU2K; Website www.energotransbank.com; alt. Website www.etbank.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 3906098008 (Russia); Legal Entity Number 253400UEEJPNF0G35X65; Registration Number 1023900000080 (Russia); Global Intermediary Identification Number GAEQE9.99999.SL.643 [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

42. COMMERCIAL JOINT STOCK BANK VIKING, Vladimirsky Av 17, Saint Petersburg 191002, Russia; SWIFT/BIC VKNGRU2P; Website www.vikingbank.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7831000098 (Russia); Legal Entity Number 253400FBCYVAJS5W8Q06; Registration Number 1027800000250 (Russia); Global Intermediary Identification Number S2VA6X.99999.SL.643 [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

43. JOINT STOCK COMMERCIAL BANK SLAVIA JOINT STOCK COMPANY (a.k.a. JOINT STOCK COMMERCIAL BANK SLAVIYA CLOSED JOINT STOCK COMPANY; a.k.a. JSCB SLAVIA), ul. Kedrova 5A, Moscow 117292, Russia; SWIFT/BIC SJSMRUMM; Website www.slaviabank.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial

Institution; Tax ID No. 7726000596 (Russia); Legal Entity Number 2534004K7RR0YWR1QL22; Registration Number 1027739228758 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

44. JOINT STOCK COMMERCIAL MORTGAGE BANK AKIBANK PUBLIC JOINT STOCK COMPANY (a.k.a. COMMERCIAL JOINT STOCK MORTGAGE BANK AKIBANK), 88a Mira Avenue, Naberezhnye Chelny 423827, Russia; SWIFT/BIC AKOARU22; Website www.akibank.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 1650002455 (Russia); Legal Entity Number 253400CM1NDPRTJUJQ96 (Russia); Registration Number 1021600000839 (Russia); Global Intermediary Identification Number 2A5KLS.99999.SL.643 [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

45. JOINT STOCK COMPANY AUTO FINANCE BANK (a.k.a. "CLOSED JOINT STOCK COMPANY BANK SIBIR"; a.k.a. "JOINT STOCK COMPANY RN BANK"), 29 Serebryanicheskaya nab., Moscow 109028, Russia; SWIFT/BIC RNBKRUMM; Website autofinancebank.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 5503067018 (Russia); Legal Entity Number 25340001RLM1RS3CX190; Registration Number 1025500003737 (Russia); Global Intermediary Identification Number 1MWB9D.99999.SL.643 [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

46. JOINT STOCK COMPANY GUTA BANK, Building 3, Orlikov Lane 5, Moscow 107078, Russia; SWIFT/BIC TJSBRUMM; Website www.gutabank.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 6905011218 (Russia); Legal Entity Number 253400C9UUE0CK2K7D34; Registration Number 1026900005307 (Russia); Global Intermediary Identification Number YE7BYQ.99999.SL.643 [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

47. JOINT STOCK COMPANY ROYAL CREDIT BANK (a.k.a. "DZEMGI"), 100 letiya Vladivostoku Avenue, 155, 3rd Floor, Letter B, Vladivostok 690068, Russia; SWIFT/BIC ROCERU33; Website www.royal-bank.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 2703006553 (Russia); Registration Number 1022700000685 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

48. LIMITED LIABILITY COMPANY BANK ROUND (a.k.a. FERROBANK LLC; a.k.a. SEVERO VOSTOCHNY INVESTICIONNY BANK), Shosse Rublevskoe 28, Moscow 121609, Russia; SWIFT/BIC SVIBRUMM; Website www.round.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7712002554 (Russia); Legal Entity Number 2534007K00A37GLA3D37; Registration Number 1027700140753 (Russia); Global Intermediary Identification Number WMPFR8.99999.SL.643 [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

49. LIMITED LIABILITY COMPANY KRONA BANK (a.k.a. COMMERCIAL BANK TRUSTCOMBANK LIMITED LIABILITY COMPANY), ul. Dzerzhinskogo 29, Irkutsk 664007, Russia; SWIFT/BIC TRUKRU61; Website www.krona-bank.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 3807000886 (Russia); Registration Number 1023800000245 (Russia); Global Intermediary Identification Number GMVGE1.99999.SL.643 [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

50. NK BANK JOINT STOCK COMPANY (a.k.a. NATSIONALNY KOSMICHESKI BANK), Miusskaya Sq 2, Moscow 125047, Russia; SWIFT/BIC NASPRUMM; Website www.nkbank.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7734205131 (Russia); Legal Entity Number 253400GTA5PKPW4J0X50; Registration Number 1027739028536 (Russia); Global Intermediary Identification Number EQCQ2M.99999.SL.643 [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

51. PUBLIC JOINT STOCK COMPANY BANK ALEXANDROVSKY (a.k.a. PUBLIC JOINT STOCK COMPANY BANK ALEKSANDROVSKY; a.k.a. TEKHNOKHIMBANK), Zarorodniy Prospekt 46, korp 2, liter B, Saint Petersburg 19119, Russia; SWIFT/BIC ITEHRU2P; Website www.alexbank.ru; alt. Website www.abank.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7831000080 (Russia); Legal Entity Number 253400D38E021531V531; Registration Number 1027800000194 (Russia); Global Intermediary Identification Number 9QJDEC.99999.SL.643 [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

52. PUBLIC JOINT STOCK COMPANY METKOMBANK, ul. Oktyabrskaya 36, Kamensk-Uralskiy 623406, Russia; SWIFT/BIC MTKCRUMM; Website www.metcom.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 6612010782 (Russia); Legal Entity Number 253400D6K5L2K3M4R485; Registration Number 1026600000195 (Russia); Global Intermediary Identification Number 9LG9H8.99999.SL.643 [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

53. PUBLIC JOINT STOCK SOCIAL COMMERCIAL BANK OF PRIMORYE PRIMSOTSBANK, Partizansky Avenue 44, Vladivostok 690106, Russia; SWIFT/BIC PRMTRU8V; Website www.pskb.com; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 2539013067 (Russia); Legal Entity Number 253400URAPVQ3J1HQG33; Registration Number 1022500001061 (Russia); Global Intermediary Identification Number 3U6UFF.99999.SL.643 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

54. ROSSITA BANK (a.k.a. RUSSITA BANK; a.k.a. RUSSITABANK LTD), ul. 1-ya Brestskaya 22, Moscow 125047, Russia; SWIFT/BIC RICIRUMM; Website www.russitabank.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7730067441 (Russia); Legal Entity Number 253400D9TTHM66P87109; Registration Number 1027739254036 (Russia) [RUSSIA-EO14024].
    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

55. RUSSIAN PUBLIC JOINT STOCK COMMERCIAL ROADS BANK (a.k.a. ROSDORBANK), Dubininskaya Street 86, Moscow 115093, Russia; SWIFT/BIC ROSORUMM; Website www.rdb.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7718011918 (Russia); Legal Entity Number 253400D214P5D31NSL16; Registration Number 1027739857958 (Russia); Global Intermediary Identification Number BSLLB8.99999.SL.643 [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

56. GAZPROMBANK (SWITZERLAND) LTD (a.k.a. GAZPROMBANK SCHWEIZ AG; a.k.a. RUSSISCHE KOMMERZIAL BANK AG), Zollikerstrasse 183, Zurich 8008, Switzerland; Zollikerstrasse 183, Zurich 8032, Switzerland; SWIFT/BIC RKBZCHZZ; Website www.gazprombank.ch; Executive Order 13662 Directive Determination - Subject to Directive 1; Secondary sanctions risk: Ukraine-/Russia-Related Sanctions Regulations, 31 CFR 589.201 and/or 589.209; alt. Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; alt. Target Type State-Owned Enterprise; Legal Entity Number 529900I9DRT12XN43G84; For more information on directives, please

visit the following link: https://ofac.treasury.gov/sanctions-programs-and-country-information/ukraine-russia-related-sanctions#directives [UKRAINE-EO13662] [RUSSIA-EO14024] (Linked To: GAZPROMBANK JOINT STOCK COMPANY).

Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, GAZPROMBANK JOINT STOCK COMPANY, a person whose property and interests in property are blocked pursuant to E.O. 14024.

57. GAZPROMBANK JOINT STOCK COMPANY (Cyrillic: ГАЗПРОМБАНК АКЦИОНЕРНОЕ ОБЩЕСТВО) (a.k.a. BANK GPB JSC; f.k.a. GAZPROMBANK OPEN JOINT STOCK COMPANY; f.k.a. JOINT STOCK BANK OF THE GAS INDUSTRY GAZPROMBANK), 16 Nametkina Street, Bldg. 1, Moscow 117420, Russia; 6 Enh-Taivan St., Ulaanbaatar 14250, Mongolia; 6 Floor, Business Center Q, Block A, Building 15A, Kabanbay Batyra Avenue, Astana 010000, Kazakhstan; 10/48 Malcha Marg, Diplomatic Enclave, Chanakyapuri, Delhi 110021, India; Central International Trade Center, Suite No. 1205, Tower C, No. 6A Jianguomenwai Avenue, Chaoyang, Liaoning 100022, China; SWIFT/BIC GAZPRUMM; Website www.gazprombank.ru; Executive Order 13662 Directive Determination - Subject to Directive 1; Secondary sanctions risk: Ukraine-/Russia-Related Sanctions Regulations, 31 CFR 589.201 and/or 589.209; alt. Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 31 Jul 1990; alt. Organization Established Date 31 Jul 1990; Target Type Financial Institution; alt. Target Type State-Owned Enterprise; Executive Order 14024 Directive Information - For more information on directives, please visit the following link: https://home.treasury.gov/policy-issues/financial-sanctions/sanctions-programs-and-country-information/russian-harmful-foreign-activities-sanctions#directives; Executive Order 14024 Directive Information Subject to Directive 3 - All transactions in, provision of financing for, and other dealings in new debt of longer than 14 days maturity or new equity where such new debt or new equity is issued on or after the 'Effective Date (EO 14024 Directive)' associated with this name are prohibited.; Listing Date (EO 14024 Directive 3): 24 Feb 2022; Effective Date (EO 14024 Directive 3): 26 Mar 2022; Tax ID No. 7744001497 (Russia); Legal Entity Number 253400WSS48YWMBUA688; Registration Number 1027700167110 (Russia); For more information on directives, please visit the following link: https://ofac.treasury.gov/sanctions-programs-and-country-information/ukraine-russia-related-sanctions#directives [UKRAINE-EO13662] [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

58. GPB AFRICA AND MIDDLE EAST PTY LTD, Katherine Towers 1st Floor, Sandton, Johannesburg 2196, South Africa; P.O. Box 784440, Sandton, Johannesburg 2146, South Africa; Website gpbamc.com/en; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; alt. Target Type State-Owned Enterprise; Tax ID No. 9453663172 (South Africa); Registration Number 2014/043520/07 (South Africa) [RUSSIA-EO14024] (Linked To: GAZPROMBANK JOINT STOCK COMPANY).

Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, GAZPROMBANK JOINT STOCK COMPANY, a person whose property and interests in property are blocked pursuant to E.O. 14024.

59. GPB FINANCIAL SERVICES HONG KONG LIMITED, 31/F, Tower Two, Times Square, 1 Matheson Street, Hong Kong, China; Room 1307-8, Dominion Center 43-59, Queen's Road East, Hong Kong, China; Suite 5711, Two International Finance Centre, 8 Finance Street, Hong Kong, China; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; alt. Target Type State-Owned Enterprise; Company Number 2045244 (Hong Kong); Legal Entity Number 254900ITGX90ZPLVYA65; Business Registration Number 62825785 (Hong Kong) [RUSSIA-EO14024] (Linked To: GAZPROMBANK JOINT STOCK COMPANY).

    Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, GAZPROMBANK JOINT STOCK COMPANY, a person whose property and interests in property are blocked pursuant to E.O. 14024.

60. GPB FINANCIAL SERVICES LIMITED, Arianthi Court, 2nd floor, 50 Agias Zonis Street, Limassol 3090, Cyprus; Agios Athanasios, 46, Interlink Hermes Plaza, Floor 1, Limassol 4102, Cyprus; Spyrou Kyprianou 65, Crystalserve Business Center, Floor 2, Limassol 4003, Cyprus; Website www.gpbfs.com.cy; Executive Order 13662 Directive Determination - Subject to Directive 1; Secondary sanctions risk: Ukraine-/Russia-Related Sanctions Regulations, 31 CFR 589.201 and/or 589.209; alt. Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; alt. Target Type State-Owned Enterprise; Registration ID HE 246301 (Cyprus); Tax ID No. 10246301D (Cyprus); Legal Entity Number 213800NW35DTWHTMX505; Registration Number C246301 (Cyprus); For more information on directives, please visit the following link: https://ofac.treasury.gov/sanctions-programs-and-country-information/ukraine-russia-related-sanctions#directives [UKRAINE-EO13662] [RUSSIA-EO14024] (Linked To: GAZPROMBANK JOINT STOCK COMPANY).

    Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, GAZPROMBANK JOINT STOCK COMPANY, a person whose property and interests in property are blocked pursuant to E.O. 14024.

61. GPB INTERNATIONAL SA, 15, Rue Bender, Luxembourg 1229, Luxembourg; SWIFT/BIC GAZPLULL; Website www.gazprombank.lu; Executive Order 13662 Directive Determination - Subject to Directive 1; Secondary sanctions risk: Ukraine-/Russia-Related Sanctions Regulations, 31 CFR 589.201 and/or 589.209; alt. Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; alt. Target Type State-Owned Enterprise; Registration ID B178974 (Luxembourg); Legal Entity Number 529900VVDOKMRRAHZ894; For more information on directives, please visit the following link: https://ofac.treasury.gov/sanctions-programs-and-country-information/ukraine-

russia-related-sanctions#directives [UKRAINE-EO13662] [RUSSIA-EO14024] (Linked To: GAZPROMBANK JOINT STOCK COMPANY).

Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, GAZPROMBANK JOINT STOCK COMPANY, a person whose property and interests in property are blocked pursuant to E.O. 14024.

62. GPB-DI HOLDINGS LIMITED (a.k.a. SIRITIA VENTURES LTD), Glafkos Tower, Floor 4, Flat 401, 3 Menandrou, Nicosia 1066, Cyprus; Executive Order 13662 Directive Determination - Subject to Directive 1; Secondary sanctions risk: Ukraine-/Russia-Related Sanctions Regulations, 31 CFR 589.201 and/or 589.209; alt. Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type State-Owned Enterprise; Tax ID No. CY10145737M (Cyprus); Legal Entity Number 2138004OMEVX71IU7E09; Registration Number HE145737 (Cyprus); For more information on directives, please visit the following link: https://ofac.treasury.gov/sanctions-programs-and-country-information/ukraine-russia-related-sanctions#directives [UKRAINE-EO13662] [RUSSIA-EO14024] (Linked To: GAZPROMBANK JOINT STOCK COMPANY).

Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, GAZPROMBANK JOINT STOCK COMPANY, a person whose property and interests in property are blocked pursuant to E.O. 14024.

63. AKTSIONERNOE OBSHCHESTVO BANK AGROROS, Ul. Chernyshevskogo, 90, Saratov 410017, Russia; SWIFT/BIC AGZARUM1; Website www.agroros.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 6453033870 (Russia); Registration Number 1026400001770 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

64. BANK ITURUP LLC, Pr-kt Kommunisticheskii D. 32, Yuzhno-Sakhalinsk 693020, Russia; SWIFT/BIC ITRORU8Y; Website www.iturupbank.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 6501021443 (Russia); Registration Number 1026500002286 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

65. COMMERCIAL BANK KHLYNOV JOINT STOCK COMPANY, Ul. Uritskogo 40, Kirov 610002, Russia; SWIFT/BIC KHOARU22; Website www.bank-hlynov.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 4346013603 (Russia); Legal Entity Number 253400W3H9DQ3UWGF192; Registration Number 1024300000042 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

66. CORPORATE FINANCE BANK LLC, 2/10, Build., St. Krasnaya Presnya, 24, Moscow 123376, Russia; SWIFT/BIC FABARUMM; Website www.cfb.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7704111969 (Russia); Legal Entity Number 2534003AVNMLD4D2KU43; Registration Number 1027739542050 (Russia) [RUSSIA-EO14024].
Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

67. JOINT STOCK COMPANY BANK ACCEPT, 14 Ul Sovetskaya, Novosibirsk 630099, Russia; SWIFT/BIC AJSCRU55; Website www.akcept.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 5405114781 (Russia); Legal Entity Number 253400VYARQB5WNTUU06; Registration Number 1025400000427 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

68. JOINT STOCK COMPANY BANK FINSERVICE, 2nd Floor, Office 1 Room No. 1, 23A, Tarasa Sherchenko Quay, Moscow 121151, Russia; SWIFT/BIC KOMXRUMM; Website www.finsb.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7750004270 (Russia); Legal Entity Number 253400BT1SKX0A889G06 (Russia); Registration Number 1087711000013 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

69. JOINT STOCK COMPANY COALMETBANK (a.k.a. UGLEMETBANK), Ul. Molodogvardeitsev D. 17B, Chelyabinsk 454138, Russia; SWIFT/BIC UGZARU55; Website www.coalmetbank.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 4214005204 (Russia); Legal Entity Number 2534001KM4BYJLLGW123; Registration Number 1024200006434 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

70. JOINT STOCK COMPANY COMMERCIAL BANK URAL FD, 64 Ul Lenina, Perm 614990, Russia; SWIFT/BIC JSCORU4P; Website www.uralfd.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 5902300072 (Russia); Legal Entity Number 2534003K6II2IIYV034349; Registration Number 1025900000048 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

71. JOINT STOCK COMPANY NS BANK (a.k.a. NS BANK), Dobrovolcheskaya 20 – 2, Moscow, 109004, Russia; SWIFT/BIC INUORUMM; Website www.nsbank.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7744001024 (Russia); Legal Entity Number 253400R2XBUSENB00758; Registration Number 1027739198200 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

72. JOINT STOCK COMPANY PUBLIC TRUST BANK (a.k.a. JSC NDBANK), St. Dubininskaya, 57, Building 1, Moscow 115054, Russia; SWIFT/BIC NADORUMM; Website www.ndb24.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7708018456 (Russia); Legal Entity Number 25400B8Y0FNJP628S19; Registration Number 1027739461694 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

73. JOINT STOCK COMPANY SEVERGAZBANK (a.k.a. AO BANK SGB), 3, Blagoveschenskaya Ul., Vologda 160001, Russia; SWIFT/BIC SGAZRU22; Website www.severgazbank.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 3525023780 (Russia); Legal Entity Number 2534005FGCP61AM3L807; Registration Number 1023500000160 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

74. JOINT STOCK INVESTMENT COMMERCIAL BANK ENISEISK UNITED BANK, Pom. 25-26-27, 62 Karla Marksa Ul., Krasnoyarsk 660049, Russia; SWIFT/BIC EUJKRU55; Website www.united.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 2447002227 (Russia); Legal Entity Number 253400QH144H9FB5UK28; Registration Number 1022400000160 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

75. JSCB ENERGOBANK, 13/52, Pushkina Street, Kazan 420111, Russia; SWIFT/BIC TRCBRU2K; Website www.energobank.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 1653011835 (Russia); Legal Entity Number 253400A1C30ARX8W0205; Registration Number 1021600000289 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

76. LIMITED LIABILITY COMPANY BANK ORANGE, Letter a, Room 13-H, Ul. Ruzovskaya, 16, Lit. A, Saint Petersburg 190013, Russia; SWIFT/BIC PRSBRU2P; Website www.bankorange.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 3803202000 (Russia); Legal Entity Number 253400D0R1WTEK19WM57; Registration Number 1023800000322 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

77. PRIMORSKY TERRITORIAL COMMERCIAL BANK SOCIETY WITH LIMITED LIABILITY (a.k.a. PRIMTERKOMBANK), Ul. Semenovskaya D. 6G, Vladivostok 690091, Russia; SWIFT/BIC PTCBRU8V; Website www.ptkb.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 2540015598 (Russia); Legal Entity Number 2534001D5K0GYG98VH27; Registration Number 1022500001325 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

78. PUBLIC JOINT STOCK COMMERCIAL BANK DERZHAVA, 2 Bldg 9 Bolshoy Savvinskiy Lane, Moscow 119435, Russia; SWIFT/BIC DERZRUMM; Website www.derzhava.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7729003482 (Russia); Legal Entity Number 253400K8490BM0R69348; Registration Number 1027739120199 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

79. PUBLIC JOINT STOCK COMPANY FINSTAR BANK (a.k.a. PJSC BANK SIAB; a.k.a. PUBLIC JOINT STOCK COMPANY SAINT PETERSBURG INDUSTRIAL JOINT STOCK BANK), Ul Chernigovskaya, pom., 8a, 1N, St. Petersburg 196084, Russia; SWIFT/BIC SAOARU2P; Website www.siab.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 2465037737 (Russia); Legal Entity Number 253400WE18BBLQFEX189; Registration Number 1022400003944 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

80. VITABANK PJSC, Room 2, Ulyanovykh Street, 1, Podolsk 142116, Russia; SWIFT/BIC VITARU2P; Website www.vitabank.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7831000147 (Russia); Legal Entity Number

253400V0NM3W1NJVVD50; Registration Number 1027800000183 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

81. AKTSIONERNOE OBSHCHESTVO DEPOZITARNAYA KOMPANIYA REGION (a.k.a. AO DK REGION; a.k.a. "DEPOSITORY COMPANY REGION"), Ul. Krymskii Val D. 3, Str. 2, Antresol 3, Pomeshch. I, Kom 32-57, Moscow 107023, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7708213619 (Russia); Registration Number 1037708002144 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

82. AKTSIONERNOE OBSHCHESTVO MEZHREGIONALNYI REGISTRATORSKII TSENTR (a.k.a. "AO MRTS"), Per. Podsosenskii D. 26, Str. 2, Moscow 105062, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 1901003859 (Russia); Registration Number 1021900520883 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

83. AKTSIONERNOE OBSHCHESTVO NATSIONALNAYA SPETSIALIZIROVANNAYA FINANSOVAYA KOMPANIYA (a.k.a. AO NSFK), PR-KT Krasnyi ZD. 157/1, Office 608.4, Novosibirsk 630049, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 5402077860 (Russia); Registration Number 1235400017423 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

84. AKTSIONERNOE OBSHCHESTVO NEZAVISIMAYA REGISTRATORSKAYA KOMPANIYA R.O.S.T. (a.k.a. AO NRK ROST), Ul. Stromynka D. 18, Korp. 13, Moscow 107996, Russia; Ul. Stromynka D. 18, K. 5B, Pomeshch. IX, Moscow 107076, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7726030449 (Russia); Registration Number 1027739216757 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

85. AKTSIONERNOE OBSHCHESTVO REGISTRATSIONNAYA KOMPANIYA TSENTR INVEST (a.k.a. AO RK TSENTR INVEST; a.k.a. "CENTER INVEST"), Ul. Timiryazeva D. 7, Irkutsk 664003, Russia; Per. Mazhorov D. 14, Str. 7, Moscow 107023, Russia; Secondary sanctions risk: See Section 11 of

Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7726050935 (Russia); Registration Number 1026901729205 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

86. AKTSIONERNOE OBSHCHESTVO SPETSIALIZIROVANNYI REGISTRATOR KOMPAS (a.k.a. AO SRK), PR-T Stroitelei D. 57, Novokuznetsk 654000, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 4217027573 (Russia); Registration Number 1024201467510 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

87. AO SPETSIALIZIROVANNYI DEPOZITARII INFINITUM (a.k.a. INFINITUM ASSET SERVICES), Ul. Shabolovka D. 31, B, Moscow 115162, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7705380065 (Russia); Registration Number 1027739039283 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

88. EVROAZIATSKII REGISTRATOR (a.k.a. "EAR"), Ul. Nikolaya Stolbova D. 2, Kazan 420021, Russia; Ul. Zinina D. 10A, Office 41, Kazan 420097, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 1660055801 (Russia); Registration Number 1021603631224 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

89. JOINT STOCK COMPANY AKTIV (a.k.a. AO AKTIV), Nab. Kanala Griboedova D. 6/2, Lit. A, Saint Petersburg 191186, Russia; PR-KT Malyi V.O.D. 43, K. 2, Lit. V, Floor 2, Pomeshch. 31, Saint Petersburg 199178, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7813067004 (Russia); Registration Number 1027806881585 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

90. JOINT STOCK COMPANY INDUSTRIA REESTR (a.k.a. AO INDUSTRIYA REESTR), Ul. Khromova D. 1, Moscow 107601, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 3302021034 (Russia); Registration Number 1023301289153 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

91. JOINT STOCK COMPANY REGISTRATOR INTRACO (a.k.a. AO REGISTRATOR INTRAKO), Ul. Lenina 64, Perm 614990, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 5903027161 (Russia); Registration Number 1025900763063 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

92. JSC DRAGA (a.k.a. AO DRAGA), Ul. Novocheremushkinskaya D. 71/32, Moscow 117420, Russia; Ul. Bolshaya Zelenina D. 8, K. 2, Lit. A, Pomeshch. 42N, Saint Petersburg 197110, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7704011964 (Russia); Registration Number 1037739162240 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

93. JSC NOVIY REGISTRATOR (a.k.a. AO NOVYI REGISTRATOR), Ul. Buzheninova D. 30, Str. 1, Et/Pom/Kom 2/VI/32, Moscow 107996, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7719263354 (Russia); Registration Number 1037719000384 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

94. KORPORATIVNAYA REGISTRATORSKAYA KOMPANIYA (a.k.a. "KRK"), Ul. Vasilisy Kozhinoi D. 1, Et/Pom/Kom 4/I/75, Moscow 121096, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7730253529 (Russia); Registration Number 1197746576125 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

95. LIMITED LIABILITY COMPANY DEPOSITARY AND CORPORATE TECHNOLOGIES (a.k.a. "DCT LTD"), Ul. Stromynka D. 4, Korp. 1, Moscow 107014, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7729520219 (Russia); Registration Number 1057746181272 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

96. MOSKOVSKII FONDOVYI TSENTR, Per Orlikov D. 5, Str. 3, Moscow 107078, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7708822233 (Russia); Registration Number 5147746153847 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

97. NATIONAL CUSTODIAL COMPANY STOCK CLOSED CORPORATION (a.k.a. AO NKK), Ul. Sushchevskii Val D. 16, Str. 3, Kom. 2, Floor 3, Moscow 127018, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7707592234 (Russia); Registration Number 1067746739554 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

98. REGISTRATOR KRTS, Ul. Turgeneva D. 107, Krasnodar 350049, Russia; Ul. Rashpilevskaya D. 157, Lit. A, Floor 4, Pomeshcheniya 2-17, 19, 22-27, Krasnodar 350020, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 2311144802 (Russia); Registration Number 1122311003650 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

99. SPETSIALIZIROVANNYI DEPOZITARII DEPO PLAZA (a.k.a. SD DEPO PLAZA), Ul. 2-YA Magistralnaya D. 8A, Str. 1, Kabinet 4, Tekhnicheskii Floor, Moscow 123290, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7731530091 (Russia); Registration Number 1057748104996 (Russia) [RUSSIA-EO14024]. Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

100. ZAKRYTOE AKTSIONERNOE OBSHCHESTVO PERVYI SPETSIALIZIROVANNYI DEPOZITARII (a.k.a. ZAO PRSD), 4-YA Ul. 8 Marta D. 6A, Moscow 125167, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 7710198911 (Russia); Registration Number 1027700373678 (Russia) [RUSSIA-EO14024].

    Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

101. BBR BANK JOINT STOCK COMPANY (a.k.a. BALTIC DEVELOPMENT BANK CLOSED JOINT STOCK COMPANY; a.k.a. BBR BANK CLOSED JOINT STOCK COMPANY), 1-st Nikoloshchepovsky Pereulok, Stroyenie, 6, 1, Moscow 121099, Russia; SWIFT/BIC BADJRUMM; Website www.bbr.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Tax ID No. 3900001002

(Russia); Legal Entity Number 253400MF70R9W1E92E58; Registration Number 1027700074775 (Russia) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

102. EVROFINANCE MOSNARBANK (a.k.a. BANK EVROFINANCE), 29, ul. Novy Arbat, Moscow 121099, Russia; SWIFT/BIC EVRFRUMM; Website www.evrofinance.ru; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Target Type Financial Institution; Registration ID 1027700565970 (Russia); Tax ID No. 7703115760 (Russia); Legal Entity Number 253400R9321UP8XXUB33 [VENEZUELA-EO13850] [RUSSIA-EO14024] (Linked To: PETROLEOS DE VENEZUELA, S.A.).

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy.

Lisa M. Palluconi,

Acting Director, Office of Foreign Assets Control.

[FR Doc. 2024–27801 Filed 11–26–24; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Foreign Account Tax Compliance Act Collections

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning the foreign account tax compliance act collection requirements.

DATES: Written comments should be received on or before January 27, 2025 to be assured of consideration.

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224 or by email to *pra.comments@irs.gov.* Include OMB Control number 1545–2246 or Forms: 8957, 8966, 8966–C, 8809–I, and 8508–I.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form should be directed to Molly Stasko, at (202) 317–6206 or Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *Molly.J.Stasko@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Foreign Account Tax Compliance Act (FATCA).

OMB Number: 1545–2246.

Form Numbers: 8957, 8966, 8966–C, 8809–I, and 8508–I.

Regulation Project Numbers: IRS Notice 2023–11, IRS Notice 2024–78, and TD 9610.

Abstract: Internal Revenue Code (IRC) section 1471–1474 is part of the Foreign Account Tax Compliance Act (FATCA) legislative framework to obtain reporting from foreign financial institutions on the accounts held in their institutions by US persons. The IRS developed forms and regulations under these authorities of IRC. TD 9610 includes the regulations related to the reporting on the forms and the associated recordkeeping requirements.

Form 8957, Foreign Account Tax Compliance Act (FATCA) Registration, information is to be used by a foreign financial institution to apply for status as a foreign financial institution (FFI) as defined in IRC 1471(b)(2). Form 8966, FATCA Report, is used by a responsible officer of a foreign institution to report information with respect to U.S. accounts or persons based on their IRC chapter 4 status. Form 8966–C is used to authenticate the paper-filed Forms 8966 and to ensure the ability to identify discrepancies between the number of forms received versus those claimed to have been sent by the filer. Taxpayers use Form 8508–I to request a waiver from filing Form 8966 electronically. Form 8809–I is used to request an initial or additional extension of time to file 8966 for the current year. IRS Notice 2023–11 and IRS Notice 2024–78 allow FFIs to obtain temporary relief from reporting missing required U.S. taxpayer identification numbers for certain preexisting accounts, when they comply with the procedures described within each notice. Publication 5124 provides directions on how Model 1 Intergovernmental Agreements report information directly to the IRS.

Current Actions: IRS is adding the Publication 5124, IRS Notice 2023–11 and 2024–78 to the OMB approval for 1545–2246. There are not changes to the requirements. This is an administrative change to count the burden within 1545–2246.

Type of Review: Revision of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 5,561,180.

Estimated Time per Response: 7 minutes up to 8 hours, 7 minutes for the various collection requirements.

Estimated Total Annual Burden Hours: 2,912,282.

The following paragraph applies to all the collections of information covered by this notice.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained if their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax

return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: November 21, 2024.

Molly J. Stasko,

Senior Tax Analyst.

[FR Doc. 2024–27792 Filed 11–26–24; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

Veterans and Community Oversight and Engagement Board, Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act (FACA), 5 U.S.C. ch. 10, that the Veterans and Community Oversight and Engagement Board will meet virtually on December 13, 2024. The meeting sessions will begin, and end as follows:

Date:	Time:
Friday, December 13, 2024	9:00 a.m. to 3:00 p.m. Pacific Standard Time (PST).

The meetings are open to the public and will be recorded.

The Board was established by the West Los Angeles Leasing Act of 2016 on September 29, 2016. The purpose of the Board is to provide advice and make recommendations to the Secretary of Veterans Affairs on: identifying the goals of the community and Veteran partnership; improving services and outcomes for Veterans, members of the Armed Forces, and the families of such Veterans and members; and on the implementation of the Draft Master Plan approved by the Secretary on January 28, 2016, and on the creation and implementation of any successor master plans.

On December 13, the agenda will include opening remarks from the Committee Chair and the Executive Sponsor. There will be a general update from VA Greater Los Angeles Healthcare System (VAGLAHS). The West Los Angeles Veterans Collective will provide a status briefing all activities since June 2024. The Urban Land Institute will present the results of their Implementation Technical Assistance Panel (ITAP) study. An update on the status and projected efforts related to Master Plan 2025, and an overview of the VA Survey on Veteran Preferences results will be presented by (VAGLAHS) staff. The Board's subcommittees on Outreach and Community Engagement with Services and Outcomes, and Master Plan with Services and Outcomes will report on activities since the last meeting. Subcommittee reports will be followed by an out brief to the full Board on any draft recommendations considered for forwarding to the Secretary.

Time will be allocated for receiving public comments on December 13, starting at 9:40 a.m. PST. Individuals wishing to make public comments are requested to submit a 1–2-page summary of their comments for inclusion in the official meeting record or would like to share information with the Committee should contact Mr. Chihung Szeto, Alternate Designated Federal Officer, at (562) 708–9959, at *Chihung.Szeto@va.gov* or *VEOFACA@va.gov.* Only those members of the public (first 6 public comment registrants) who have confirmed registrations to provide public comment will be allowed to provide public comment. In the interest of time, each speaker will be held to 5-minute time limit. The Committee will accept written comments from interested parties on issues outlined in the meeting agenda, from December 11, 2024 to December 15, 2024.

Members of the public can attend the meeting via WEBEX by joining from the meeting link below. The link will be active from 8:45 a.m.–3:30 p.m. PST, December 13, 2024.

Veteran and Community Oversight and Engagement Board (VCOEB)

Hosted by Walsh, Margaret K. (ERPI).

https://veteransaffairs.webex.com/veteransaffairs/j.php?MTID=mef5d2ad406348e108778e341fcbbf891.

Friday, December 13, 2024, 9:00 a.m. | 6 hours | Pacific Time (US & Canada).

Meeting number: 2831 720 3971.

Password: sJMpM2pJ*32.

Any member of the public seeking additional information should contact Mr. Eugene W. Skinner Jr. at (202) 631–7645 or at *Eugene.Skinner@va.gov.*

Dated: November 22, 2024.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2024–27868 Filed 11–26–24; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0783]

Agency Information Collection Activity: Nonprofit Research and Education Corporations (NPCs)—Annual Report, Remediation Plans & Assessment Questionnaires

AGENCY: Veterans Health Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veterans Health Administration (VHA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice. DATES: Comments must be received on or before January 27, 2025.

ADDRESSES: Comments must be submitted through *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT:

Program-Specific information: Rebecca Mimnall, 202–695–9434, *vhacopra@va.gov.*

VA PRA information: VA PRA Clearance Office, 202–461–8900, *vacopaperworkreduact@va.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VHA invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of VHA's functions, including whether the information will have practical utility; (2) the accuracy of VHA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Nonprofit Research and Education Corporations (NPCs)—Annual Report, Remediation Plans & Assessment Questionnaires (VA Forms 10–10073, 10–10073A, 10–10073B, and 10–10073C).

OMB Control Number: 2900–0783. *https://www.reginfo.gov/public/do/PRASearch* (Once at this link, you can enter the OMB Control Number to find the historical versions of this Information Collection).

Type of Review: Revision of a currently approved collection.

Abstract: Federal law at 38 U.S.C. 7366, Accountability and Oversight, states ''(b) each such corporation (NPC) shall submit to the Secretary (Department of Veterans Affairs (DVA)) an annual report providing a detailed statement of its operations, activities, and accomplishments during that year.'' The individual NPC annual reports are combined into one NPC Annual Report to Congress. VA oversight of NPCs includes reviews, audits, self-assessments, and remediation plans. This information collection is used for oversight of NPCs and includes the following:

a. NPC Annual Report Template, VA Form 10–10073
b. NPC Audit Actions Items Remediation Plans, VA Form 10–10073A
c. NPPO Internal Control Questionnaire, VA Form 10–10073B
d. NPPO Operations Oversight Questionnaire, VA Form 10–10073C

NPC Annual Report Template, VA Form 10–10073

Since 1988, when the enabling legislation for the NPCs was passed, annual reports have been obtained from each NPC and combined into an NPC Annual Report to Congress. Congress uses the combined NPC Annual Report to Congress to monitor the progress of the overall NPC program it created. The NPC Annual Report to Congress is also used by top-level VA executives to evaluate the program and to recommend changes where needed. VHA's Nonprofit Oversight Board and the Nonprofit Program Office (NPPO) use both the combined NPC Annual Report to Congress and the individual NPC Annual Report Templates to monitor and oversee the NPCs. Trend analyses and other financial information are analyzed for each NPC and judgments made about each NPC's progress, financial viability, stewardship of assets, and accomplishments.

NPC Audit Actions Items Remediation Plans, VA Form 10–10073A

The NPC Audit Action Items Remediation Plans information collection is used to review the NPCs' remedies for audit deficiencies and recommendations. The major objective of the information collection is to help ensure proper corrective action. If any of the remediation plans submitted are inadequate, then the NPPO will make recommendations for sound, workable remedies.

NPPO Internal Control Questionnaire, VA Form 10–10073B

The NPPO Internal Control Questionnaire, or portions of it, will be used in conducting reviews, audits, and investigations of the NPCs. The major objective of the questionnaire is to uncover weaknesses and lapses in internal controls. The NPPO will then make recommendations for improved internal controls wherever there are weaknesses or lapses. The questionnaire also may be used as a voluntary self-assessment by the NPCs.

NPPO Operations Oversight Questionnaire, VA Form 10–10073C

The NPPO Operations Oversight Questionnaire, or portions of it, will be used in conducting operational reviews of the NPCs. The major objective of the questionnaire is to uncover operating problems and areas that need improvement. The NPPO will then make recommendations for operations improvements wherever problems or opportunities for improvement are found. The questionnaire also may be used as a voluntary self-assessment by the NPCs.

VHA does not anticipate any changes to the annual number of responses or burden hours. However, there are some minor updates to the forms for clarification and to comply with current guidance on standard PRA language.

Total Annual Burden: 858 hours.

Total Annual Responses: 300.

Affected Public: Individuals or Households.

Estimated Annual Burden:

a. NPC Annual Report Template—301 hours.
b. NPC Audit Actions Items Remediation Plans—84 hours.
c. NPPO Internal Control Questionnaire—344 hours.
d. NPPO Operations Oversight Questionnaire—129 hours.

Estimated Average Burden Per Respondent:

a. NPC Annual Report Template—210 minutes.
b. NPC Audit Actions Items Remediation Plans—120 minutes.
c. NPPO Internal Control Questionnaire—240 minutes.
d. NPPO Operations Oversight Questionnaire—90 minutes.

Frequency of Response: Once annually.

Estimated Number of Respondents:

a. NPC Annual Report Template—86.
b. NPC Audit Actions Items Remediation Plans—42.
c. NPPO Internal Control Questionnaire—86.
d. NPPO Operations Oversight Questionnaire—86.

Authority: 44 U.S.C. 3501 *et seq.*

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration/Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2024–27728 Filed 11–26–24; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0587]

Agency Information Collection Activity Under OMB Review: Equipment Operation and Maintenance Manuals

AGENCY: Procurement Policy and Warrant Management Service (PPS), Office of Procurement Policy, Systems and Oversight, Office of Acquisition and Logistics, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of

1995, this notice announces that the Procurement Policy and Warrant Management Service, Office of Procurement Policy, Systems and Oversight, Office of Acquisition and Logistics, Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden, and it includes the actual data collection instrument.

DATES: Comments and recommendations for the proposed information collection should be sent by December 27, 2024.

ADDRESSES: To submit comments and recommendations for the proposed information collection, please type the following link into your browser: *www.reginfo.gov/public/do/PRAMain,* select ''Currently under Review—Open for Public Comments'', then search the list for the information collection by Title or ''OMB Control No. 2900–0587.''

FOR FURTHER INFORMATION CONTACT: VA PRA information: VA PRA Clearance Office, 202–461–8900, *vacopaperworkreduact@va.gov.*

SUPPLEMENTARY INFORMATION:

Title: VAAR Clause 852.211–70, Equipment Operation and Maintenance Manuals.

OMB Control Number: 2900–0587 *https://www.reginfo.gov/public/do/PRASearch.*

Type of Review: Revision of a currently approved collection.

Abstract: The contracting officer shall insert the clause at 852.211–70, Equipment Operation and Maintenance Manuals, in solicitations and contracts for technical medical equipment, and other technical and mechanical equipment and devices where the requiring activity determines manuals are a necessary requirement for operation and maintenance of the equipment. Contractors are required to furnish both operation manuals and maintenance/repair manuals with the equipment provided to the Government. This clause sets forth those requirements and the minimum standards those manuals must meet to be acceptable. Generally, this is the same operation manual furnished with each piece of equipment sold to the general public and the same repair manual used by company technicians in repairing the company's equipment. The cost of the manuals is included in the contract price or listed as separately priced line items on the purchase order. The operation manual will be used by the individual actually operating the equipment to ensure proper operation and cleaning. The repair manual will be used by VA equipment repair staff to repair the equipment.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 89FR76193, September 17, 2024.

Affected Public: Individuals or Households.

Estimated Annual Burden: 745 hours.

Estimated Average Burden per Respondent: 2 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 22,337.

Authority: 44 U.S.C. 3501 *et seq.*

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration, Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2024–27863 Filed 11–26–24; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Notice of Plans for Department of Veterans Affairs to Assess Exposures and Conditions of Interest for Veterans Who Served At Karshi-Khanabad Air Base and To Solicit Public Comment

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Department of Veterans Affairs (VA) announces that it plans to conduct an assessment of scientific literature and historical claims data to determine whether there is an association between military environmental exposure to toxic substances related to military service at Camp Stronghold Freedom in Karshi-Khanabad (K2) in Uzbekistan from 2001 to 2005 and medical conditions. VA entered into an agreement with the Center for Disease Control and Prevention's Agency for Toxic Substances and Disease Registry and published a Report to Congress in 2022 that identified the known health consequences associated with the identified toxic substances, chemicals, and airborne hazards at K2. As part of a continuing effort to assess the health risks that may be associated with military service at K2, VA is soliciting public comment on environmental exposures at K2 and medical conditions developed by Veterans who served there. This notice provides an opportunity for Veterans, caregivers, survivors, and the public to share relevant information with VA to inform decisions regarding presumptive benefits that could impact the roughly 16,000 Veterans who served at K2.

DATES: Comments must be received on or before December 27, 2024.

ADDRESSES: Comments must be submitted through *www.regulations.gov.* Except as provided below, comments received before the close of the comment period will be available as soon as possible after they have been received at *www.regulations.gov* for public viewing, inspection, or copying, including any personally identifiable or confidential business information that is included in a comment. VA will not post public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. VA encourages individuals not to submit duplicative comments. We will post comments from multiple unique commenters even if the content is identical or nearly identical to other comments. Any public comment received after the comment period's closing date is considered late and will not be considered in any potential future rulemaking.

FOR FURTHER INFORMATION CONTACT: Peter D. Rumm, M.D., MPH, Director of Policy, Health Outcomes Military Exposures, Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, at 202–461–7297. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: Camp Stronghold Freedom was established at a former Soviet Air Base in K2 located in Southwest Uzbekistan in October 2001 and occupied by U.S. forces through the middle of 2005. During this period, several environmental site surveys were conducted by the Department of Defense (DOD) to assess contaminants that could impact the operational readiness of U.S. military operations and the safety of U.S. forces that deployed to K2. These surveys identified several contaminants, such as dust and particulate matter, underground jet fuel plumes, surface dirt with traces of asbestos, depleted uranium, benzene, chromium, and others. The Public Health website of the Defense Health Agency of the DOD lists contaminants of concern it identified at K2 [1].

Since 2021, VA has been assessing the potential health effects, including respiratory conditions and cancers, among K2 Veterans. Section 2010 of the Johnny Isakson and David P. Roe, M.D.

Veterans Health Care and Benefits Improvement Act of 2020, Public Law 116–315 (the Isakson and Roe Act) [2], directed VA to engage the Center for Disease Control and Prevention's Agency for Toxic Substances and Disease Registry to describe the known health effects associated with the toxic substances, chemicals, airborne hazards, and other substances DOD identified at K2. This effort has been completed, and a report was submitted to Congress in January 2022, which documented the DOD identified contaminants of concern, medium of exposure, along with the potential cancer and noncancer health effects. The findings from this report can be found on VA's K2 website [3]. The Department of Defense has also studied the mortality among K2 Service members and found that a more in-depth study of health issues is necessary [4]. Section 2010 of the Isakson and Roe Act also directed VA to assess the health effects associated with deployment to K2, with a final report due to Congress no later than 2030 [2]. VA created a public health surveillance program to address this requirement. Analyses are underway and data are updated annually on all K2 Veterans to allow VA to address new information on adverse health outcomes and health concerns of veterans as they become known.

The purpose of this Notice is to provide the K2 community (K2 Veterans, their caregivers, and their survivors) and the broader public the opportunity to share relevant information for VA to determine if VA should recognize the unique environmental exposures (individually and in combination) and medical conditions as presumptive based on a Veteran's service at K2. VA encourages the K2 community and broader public to submit thoughts, recommendations, and requests regarding the exposures and health conditions they feel are related to K2 service and warrant specific consideration by VA as a presumptive condition. VA also invites the public to submit information, evidence, and suggestions that may help VA assess potential exposures at K2 and health effects that may be associated with such exposures.

In accordance with 38 U.S.C. 1172, as created by section 202 of the Sergeant First Class Heath Robinson Honoring our Promise to Address Comprehensive Toxics Act of 2022 (PACT Act), VA is publishing this notice about its planned scientific assessment of the possibility of a relationship between all medical conditions and military environmental exposures related to service at Camp Stronghold Freedom in K2 from 2001 to 2005. Pursuant to section 202, the VA Secretary must determine whether to establish or remove presumptions for service connections based on military environmental exposure and the evaluation of adverse health outcomes. VA's procedure includes issuing a public notice regarding reviews, soliciting public comment, and recommendations for corrections to the Secretary from the working group subject matter experts to better reflect Veterans and dependents. Here, in recognition of the unique exposure environment at K2, Secretary McDonough directed a PACT Act presumptive process to formally solicit stakeholder input and demonstrate the rigor VA continues to apply to important questions concerning the contaminants present at K2 and the conditions that K2 Veterans developed following service there.

In accordance with 38 U.S.C. 1119 and 1120, as created by the PACT Act, Uzbekistan is included as an eligible country covered under the PACT Act for certain presumptions of exposure and service connection. Thus, K2 Veterans are eligible for hundreds of individual presumptive conditions encompassed by the 23 disease categories designated under this landmark legislation [5]. Additionally, K2 Veterans are eligible to receive health care from the Veterans Health Administration, regardless of whether they have filed a claim for disability [6]. VA encourages all K2 Veterans to register for health care and encourages all K2 Veterans and their survivors to submit a claim for any adverse health outcome, even if not covered under the PACT Act, that they feel is related to their military service at K2 or elsewhere.

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, signed and approved this document on November 15, 2024, and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Jeffrey M. Martin,

Assistant Director, Office of Regulation Policy & Management, Office of General Counsel, Department of Veterans Affairs.

References

1. Karshi-Khanabad Airbase Exposures, (2024). *https://ph.health.mil/topics/envirohealth/hrasm/Pages/K2-Airbase-Exposures.aspx*
2. Johnny Isakson and David P. Roe, M.D. Veterans Health Care and Benefits Improvement Act of 2020, Public Law 116–315, § 2010. *https://www.congress.gov/116/plaws/publ315/PLAW-116publ315.pdf*
3. Karshi-Khanabad (K2) Air Base in Uzbekistan Potential Historical Contaminants of Concern (COCs) (2022). *https://www.publichealth.va.gov/docs/exposures/K2_Contaminants.pdf#.*
4. Environmental Hazards Study: Mortality Among U.S. Service Members Deployed to Karshi-Khanabad Air Base, Uzbekistan (2024). *https://health.mil/Military-Health-Topics/Health-Readiness/Environmental-Exposures/Environmental-Hazards-Study-K2*
5. Exposure to Burn Pits and Other Specific Environmental Hazards (2024). *https://www.va.gov/disability/eligibility/hazardous-materials-exposure/specific-environmental-hazards/*
6. Eligibility for VA Health Care (2024). Eligibility For VA Health Care √ Veterans Affairs.

[FR Doc. 2024–27833 Filed 11–26–24; 8:45 am]

BILLING CODE 8320–01–P



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42 CFR Part 406, 407, 410, et al.

Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, Including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicaid Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 406, 407, 410, 411, 416, 419, 435, 440, 457, 482, and 485

[CMS–1809–FC]

RIN 0938–AV35

Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, Including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicaid Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period revises the Medicare Hospital Outpatient Prospective Payment System (OPPS) and the Medicare Ambulatory Surgical Center (ASC) payment system for calendar year 2025 based on our continuing experience with these systems. We describe the changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system. Also, this final rule updates the requirements for the Hospital Outpatient Quality Reporting Program, Rural Emergency Hospital Quality Reporting Program, Ambulatory Surgical Center Quality Reporting Program, and Hospital Inpatient Quality Reporting Program. We also summarize information received in response to a Request for Information on potential modifications to the Safety of Care measure group in the Overall Hospital Quality Star Rating methodology. In this final rule, we are also finalizing our proposal to narrow the description of ''custody'' in the Medicare payment exclusion rule and to revise the special enrollment period criteria for formerly incarcerated individuals. We are also finalizing our Medicaid and Children's Health Insurance Program (CHIP) continuous eligibility provisions. We are also finalizing the proposal to reduce the review timeframe for standard prior authorization requests for certain covered outpatient department services paid under the OPPS from 10-business days to 7-calendar days. Further, this rule finalizes updates to the Conditions of Participation (CoPs) for hospitals and critical access hospitals (CAHs) in an effort to advance the health and safety of pregnant, birthing, and postpartum women. This rule also finalizes our proposed policy to separately pay Indian Health Service (IHS) and Tribal hospitals for high-cost drugs furnished in hospital outpatient departments through an add-on payment in addition to the all-inclusive rate (AIR) under the authorities used to calculate the AIR starting January 1, 2025. Finally, we are finalizing exceptions to the Medicaid clinic services four walls requirement for IHS and Tribal clinics, and, at state option, for behavioral health clinics and clinics located in rural areas.

DATES:

Effective date: The provisions of this rule are effective January 1, 2025.

Implementation date: Except as set forth in this section, the regulations at §§ 482.43(c), 482.55(c), and 485.618(e) must be implemented by July 1, 2025; the regulations at §§ 482.59(a) and (b) and 485.649(a) and (b) must be implemented by January 1, 2026; and the regulations at §§ 482.21(b)(4) and (e), 482.59(c), 485.641(d)(4) and (e)(2), and 485.649(c) must be implemented by January 1, 2027.

Comment period: To be assured consideration, comments must be received at one of the addresses provided below, by December 31, 2024.

ADDRESSES: In commenting, please refer to file code CMS–1809–FC.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *https://www.regulations.gov*. Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1809–FC, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1809–FC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Regulation coordination questions at *OPPS-ASC-Rulemaking@cms.hhs.gov* or Elise Barringer (410) 786, 9222.

Advisory Panel on Hospital Outpatient Payment (HOP Panel), contact the HOP Panel mailbox at *APCPanel@cms.hhs.gov*.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program policies, contact Anita Bhatia via email at *Anita.Bhatia@cms.hhs.gov*.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program measures, contact Marsha Hertzberg via email at *Marsha.Hertzberg@cms.hhs.gov*.

All-Inclusive Rate (AIR) Add-On Payment for High-Cost Drugs Provided by Indian Health Service (IHS) and Tribal Facilities, contact Nate Vercauteren via email at *Nathan.Vercauteren@cms.hhs.gov*.

Blood and Blood Products, contact Au'Sha Washington via email at *AuShaWashington@cms.hhs.gov* or Nicole Marcos via email at *Nicole.Marcos@cms.hhs.gov*.

Cancer Hospital Payments, contact Scott Talaga via email at *Scott.Talaga@cms.hhs.gov*.

CMS Web Posting of the OPPS and ASC Payment Files, contact Gil Ngan via email at *Gil.Ngan@cms.hhs.gov*.

Medicaid Clinic Services Four Walls Exceptions, contact Sheri Gaskins via email at *Sheri.Gaskins@cms.hhs.gov* or Ryan Tisdale via email at *Ryan.Tisdale@cms.hhs.gov*.

Composite APCs (Multiple Imaging and Mental Health) and Comprehensive APCs (C–APCs), via email at Elise Barringer via email at *Elise.Barringer@cms.hhs.gov*.

Device-Intensive Status and No Cost/Full Credit and Partial Credit Devices, contact Scott Talaga via email at *Scott.Talaga@cms.hhs.gov*.

Domestic Personal Protection Equipment RFI, contact Jesse Hawkins via email at *jesse.hawkins@hhs.gov*

Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals, contact The Clinical Standards Group, *HealthandSafetyInquiries@cms.hhs.gov*

Hospital Inpatient Quality Reporting (IQR) Program policies, contact Julia Venanzi via email at *julia.venanzi@cms.hhs.gov*.

Hospital Inpatient Quality Reporting (IQR) Program measures, contact Melissa Hager via email at *melissa.hager@cms.hhs.gov* or Ngozi Uzokwe via email at *ngozi.uzokwe@cms.hhs.gov*.

Hospital Outpatient Quality Reporting (OQR) Program policies, contact Kimberly Go via email at *Kimberly.Go@cms.hhs.gov*.

Hospital Outpatient Quality Reporting (OQR) Program measures, contact Janis Grady via email at *Janis.Grady@cms.hhs.gov*.

Hospital Outpatient Visits (Emergency Department Visits and Critical Care Visits), contact Elise Barringer via email at *Elise.Barringer@cms.hhs.gov*.

IHS Outpatient Encounter Rate available to all American Indian and Alaska Native (AI/AN) Outpatient Programs Request for Information, contact Lisa Parker via email at *Lisa.Parker1@cms.hhs.gov*.

Inpatient Only (IPO) Procedures List, contact Abigail Cesnik via email at *Abigail.Cesnik@cms.hhs.gov*.

Medicaid and CHIP Continuous Eligibility Policy, contact Cassie Lagorio via email at *Cassandra.Lagorio@cms.hhs.gov*.

New Technology Intraocular Lenses (NTIOLs), contact Scott Talaga via email at *Scott.Talaga@cms.hhs.gov*.

No Legal Obligation to Pay Payment Exclusion, contact Frederick Grabau via email at *Frederick.Grabau@cms.hhs.gov*.

Non-Opioid Policy or Implementation of Section 4135 of the Consolidated Appropriations Act (CAA), 2023, contact Cory Duke via email at *Cory.Duke@cms.hhs.gov*.

OPPS Brachytherapy, contact Cory Duke via email at *Cory.Duke@cms.hhs.gov* and Scott Talaga via email at *Scott.Talaga@cms.hhs.gov*.

OPPS Data (APC Weights, Conversion Factor, Copayments, Cost-to-Charge Ratios (CCRs), Data Claims, Geometric Mean Calculation, Outlier Payments, and Wage Index), contact Erick Chuang via email at *Erick.Chuang@cms.hhs.gov* or Scott Talaga via email at *Scott.Talaga@cms.hhs.gov*.

OPPS Dental Policy, contact Nicole Marcos via email at *Nicole.Marcos@cms.hhs.gov*.

OPPS Drugs, Radiopharmaceuticals, Biologicals, and Biosimilar Products, contact Gil Ngan via email at *Gil.Ngan@cms.hhs.gov*, Cory Duke via email at *Cory.Duke@cms.hhs.gov*, or Tonya Gierke via email at *Tonya.Gierke@cms.hhs.gov*.

OPPS New Technology Procedures/Services, contact the New Technology APC mailbox at *NewTechAPCapplications@cms.hhs.gov*.

OPPS Packaged Items/Services, contact Cory Duke via email at *Cory.Duke@cms.hhs.gov*.

OPPS Pass-Through Devices, contact the Device Pass-Through mailbox at *DevicePTapplications@cms.hhs.gov*.

OPPS Status Indicators (SI) and Comment Indicators (CI), contact Marina Kushnirova via email at *Marina.Kushnirova@cms.hhs.gov*.

Outpatient Department Prior Authorization Process, contact Kelly Wojciechowski via email at *Kelly.Wojciechowski@cms.hhs.gov*.

Overall Hospital Quality Star Rating Request for Information, contact Tyson Nakashima Sr. via email at *Tyson.Nakashima@cms.hhs.gov*.

Partial Hospitalization Program (PHP), Intensive Outpatient (IOP), and Community Mental Health Center (CMHC) Issues, contact the PHP Payment Policy Mailbox at *PHPPaymentPolicy@cms.hhs.gov*.

Payment Policy for Devices in Category B Investigational Device Exemption Clinical Trials Policy and Drugs with a Medicare Coverage with Evidence Development (CED) Designation, contact Cory Duke via email at *Cory.Duke@cms.hhs.gov* and Nicole Marcos via email at *Nicole.Marcos@cms.hhs.gov*.

Remote Services, contact Elise Barringer via email at *Elise.Barringer@cms.hhs.gov* or Nate Vercauteren via email at *Nathan.Vercauteren@cms.hhs.gov*.

Rural Emergency Hospital Quality Reporting (REHQR) Program policies, contact Anita Bhatia via email at *Anita.Bhatia@cms.hhs.gov*.

Rural Emergency Hospital Quality Reporting (REHQR) Program measures, contact Melissa Hager via email at *Melissa.Hager@cms.hhs.gov*.

Special Enrollment Period for Formerly Incarcerated Individuals, contact Steve Manning via email at *Steve.Manning@cms.hhs.gov*.

All Other Issues Related to Hospital Outpatient Payments Not Previously Identified, contact the OPPS mailbox at *OutpatientPPS@cms.hhs.gov*.

All Other Issues Related to the Ambulatory Surgical Center Payments Not Previously Identified, contact the ASC mailbox at *ASCPPS@cms.hhs.gov*.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *https://www.regulations.gov*. Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a plain language summary of this rule may be found at *https://www.regulations.gov/*.

Severability of Provisions: We are clarifying and emphasizing our intent that if any provision of this final rule is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further action, it shall be severable from other parts of this final rule, and from rules and regulations currently in effect, and not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances. If any provision is held to be invalid or unenforceable, the remaining provisions which could function independently should take effect and be given the maximum effect permitted by law. Through this rule, we adopt provisions that are intended to and will operate independently of each other, even if each serves the same general purpose or policy goal. Where a provision is necessarily dependent on another, the context generally makes that clear.

Addenda Available Only Through the Internet on the CMS Website

In the past, a majority of the Addenda referred to in our OPPS/ASC proposed and final rules were published in the **Federal Register** as part of the annual rulemakings. However, beginning with the calendar year (CY) 2012 OPPS/ASC proposed rule, all of the Addenda no longer appear in the **Federal Register** as part of the annual OPPS/ASC proposed and final rules to decrease administrative burden and reduce costs associated with publishing lengthy tables. Instead, these Addenda are published and available only on the CMS website. The Addenda relating to the OPPS are available at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*. The Addenda relating to the ASC payment

system are available at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-regulations-and-notices*.

Current Procedural Terminology (CPT) Copyright Notice

Throughout this final rule with comment period, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2024 American Medical Association (AMA). All Rights Reserved. CPT is a registered trademark of the AMA. Applicable Federal Acquisition Regulations and Defense Federal Acquisition Regulations apply.

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I. Summary and Background

A. Executive Summary of This Document

1. Purpose

We are updating the payment policies and payment rates for services furnished to Medicare beneficiaries in hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs), beginning January 1, 2025. Section 1833(t) of the Social Security Act (the Act) requires us to annually review and update the payment rates for services payable under the Hospital Outpatient Prospective Payment System (OPPS). Specifically, section 1833(t)(9)(A) of the Act requires the Secretary of the Department of Health and Human Services (the Secretary) to review certain components of the OPPS not less often than annually, and to revise the groups, the relative payment weights, and the wage and other adjustments to take into account changes in medical practice, changes in technology, and the addition of new services, new cost data, and other relevant information and factors. In addition, under section 1833(i)(D)(v) of the Act, we annually review and update the ASC payment rates. This final rule with comment period also includes additional policy changes made in accordance with our experience with the OPPS and the ASC payment system and recent changes in our statutory authority. We describe these and various other statutory authorities in the relevant sections of this final rule with comment period. Also, this final rule with comment period updates the requirements for the Hospital Outpatient Quality Reporting (OQR) Program, the Rural Emergency Hospital Quality Reporting (REHQR) Program, the Ambulatory Surgical Center Quality Reporting (ASCQR) Program, and the Hospital Inpatient Quality Reporting (IQR) Program. We summarize information received in response to a Request for Information on potential modifications of the Safety of Care measure group in the Overall Hospital Quality Star Rating methodology. Given that the maternal health crisis in the United States is among the highest in high-income countries and also disproportionately impacts racial and ethnic minorities, we are finalizing updates to the CoPs for hospitals and CAHs in an effort to advance the health and safety of pregnant, birthing, and post-partum women. We are also finalizing an implementation approach in phases that allows additional time for hospitals and CAHs to comply with the requirements of the rule. In addition, we are narrowing the description of ''custody'' for the purposes of Medicare's no legal obligation to pay payment exclusion at § 411.4(b), providing an illustrative list of individuals who are not considered to be in custody, adding a definition of ''penal authority,'' reorganizing the regulation, and making certain technical edits. This rule also revises the eligibility requirements in the special enrollment period (SEP) for formerly incarcerated individuals at §§ 406.27(d) (Premium Part A) and 407.23(d) (Part B) to tie the eligibility for this SEP to the determination made by the Social Security Administration (SSA) that they are no longer incarcerated for releases beginning on January 1, 2025, and limit the current eligibility criteria for the SEP, with reference to ''custody'' associated with § 411.4(b) to releases between January 1, 2023, and December 31, 2024. Additionally, we are finalizing our proposed revisions to Medicaid and CHIP regulations to codify the requirement within the CAA, 2023 to require States to provide 12 months of continuous eligibility to children under the age of 19 in Medicaid and CHIP, with limited exceptions.

Finally, we are finalizing our proposed exceptions to the Medicaid clinic services benefit four walls requirement, to authorize Medicaid payment for clinic services provided outside the four walls of the clinic for IHS/Tribal clinics, and at State option, behavioral health clinics and clinics located in rural areas. Our current regulation at 42 CFR 440.90(b) includes an exception to the four walls requirement under the Medicaid clinic services benefit only for clinic services furnished to individuals who are unhoused. We believe finalizing these additional exceptions will help maintain and improve access for the populations served by IHS/Tribal clinics, behavioral health clinics, and clinics located in rural areas.

2. Summary of the Major Provisions

• *OPPS Update:* For CY 2025, we are increasing the payment rates under the OPPS by an Outpatient Department (OPD) fee schedule increase factor of 2.9 percent. This increase factor is based on the final inpatient hospital market basket percentage increase of 3.4 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS) reduced by a final productivity adjustment of 0.5 percentage point. Based on this update, we estimate that total payments to OPPS providers (including beneficiary cost sharing and estimated changes in enrollment, utilization, and case mix) for calendar year (CY) 2025 will be approximately $87.7 billion, an increase of approximately $4.7 billion compared to estimated CY 2024 OPPS payments. We are continuing to implement the statutory 2.0 percentage point reduction in payments for hospitals that fail to meet the hospital outpatient quality reporting requirements by applying a reporting factor of 0.9806 to the OPPS payments and copayments for all applicable services.

• *ASC Payment Update:* For CYs 2019 through 2023, we adopted a policy to update the ASC payment system using the hospital market basket update. In light of the impact of the COVID–19 public health emergency (PHE) on healthcare utilization, we extended our policy to update the ASC payment system using the hospital market basket update an additional 2 years—through CYs 2024 and 2025. Using the hospital market basket methodology, for CY 2025, we increased payment rates under the ASC payment system by 2.9 percent for ASCs that meet the quality reporting requirements under the ASCQR Program. This increase is based on a final hospital market basket percentage increase of 3.4 percent reduced by a productivity adjustment of 0.5 percentage point. Based on this final update, we estimate that total payments to ASCs (including beneficiary cost sharing and estimated changes in enrollment, utilization, and case-mix) for CY 2025 will be approximately $7.4 billion, an increase of approximately $308 million compared to estimated CY 2024 Medicare payments.

• *Device Pass-Through Payment Applications:* For CY 2025, we received 14 complete applications for device pass-through payments. We sought public comment on these applications and make final determinations on these applications in this final rule with comment period.

• *Changes to the List of ASC Covered Surgical Procedures and Ancillary Services Lists:* For CY 2025, we are adding 21 medical and dental procedures to the ASC covered procedures list (CPL) and ancillary services lists, based upon existing criteria at § 416.166.

• *Changes to the Inpatient Only (IPO) List:* For CY 2025, we are finalizing adding three liver allograft services for which codes were newly created by the AMA CPT Editorial Panel for CY 2025 to the IPO list. Additionally, we are finalizing removing a pelvic fixation code (CPT code 22848) from the IPO list for CY 2025.

• *Remote Services:* For CY 2025, we are clarifying our policies for remotely furnished outpatient therapy services, Diabetes Self-Management Training and Medical Nutrition Therapy services and mental health services furnished remotely to beneficiaries in their homes by hospital staff to maintain alignment across payment systems.

• *Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Hospitals:* For CY 2025, we are finalizing our policy to separately pay IHS and tribal hospitals for high-cost drugs furnished in hospital outpatient departments through an add-on payment in addition to the AIR under the authorities used to calculate the AIR.

• *Clinical Trials Coding and Payment:* We are finalizing a clarification to our Category B clinical trials coding and payment policy for devices and procedures to specify that our policy applies only to IDE studies with a control arm and where a payment adjustment is necessary to preserve the scientific validity of such a study. We are not finalizing our proposal to extend our coding and payment policy to drugs and devices that are being studied in clinical trials under a Coverage with Evidence Development (CED) National Coverage Determination (NCD),[1] for which the trial includes a treatment and control arm for CY 2025. We are taking additional time to consider the broad implications of a payment methodology for clinical trials for CED drugs and devices.

• *Payment for HIV Pre-Exposure Prophylaxis (PrEP) in Hospital Outpatient Departments:* For CY 2025, we are finalizing paying for HIV PrEP drugs covered as an additional preventive service and related services under the OPPS. We are finalizing a site neutral policy where products are generally paid similar rates under the OPPS and Physician Fee Schedule.

[1] *https://www.cms.gov/medicare/coverage/evidence.*

• *Diagnostic Radiopharmaceuticals Separate Payment:* We are finalizing a policy to pay separately for diagnostic radiopharmaceuticals with per day costs above a threshold of $630, which is approximately two times the volume weighted average cost amount currently associated with diagnostic radiopharmaceuticals in the Nuclear Medicine APCs. We also are finalizing updating the $630 threshold in CY 2026 and subsequent years by the Producer Price Index (PPI) for Pharmaceutical Preparations. Finally, we are finalizing payment for separately payable diagnostic radiopharmaceuticals based on their Mean Unit Cost (MUC) derived from OPPS claims for CY 2025.

• *Exclusion of Cell and Gene Therapies from Comprehensive Ambulatory Payment Classification (C–APC) Packaging:* We are finalizing a policy to exclude qualifying cell and gene therapies from C–APC packaging.

• *Add-on Payment for Radiopharmaceutical Technetium-99m (Tc-99m) Derived from Domestically Produced Mo-99:* For CY 2025, an add-on payment applies to radiopharmaceuticals that use Tc-99m produced without use of highly enriched uranium (HEU). For CY 2026, we are finalizing replacing the add-on payment for radiopharmaceuticals produced without the use of Tc-99m derived from non-HEU sources with an add-on payment for radiopharmaceuticals that use Tc-99m derived from domestically produced Mo-99.

• *Changes to the Review Timeframes for the Hospital Outpatient Department (OPD) Prior Authorization Process:* We are changing the current review timeframe for prior authorization requests for OPD services from 10-business days to 7-calendar days for standard reviews.

• *Health Equity Measures for the Hospital Outpatient Quality Reporting (OQR), Rural Emergency Hospital Quality Reporting (REHQR), and Ambulatory Surgical Center Quality Reporting (ASCQR) Programs:* We are finalizing: (1) adoption of the Hospital Commitment to Health Equity (HCHE) measure in the Hospital OQR and the REHQR Programs, and adoption of the Facility Commitment to Health Equity (FCHE) measure in the ASCQR Program, beginning with the CY 2025 reporting period/CY 2027 payment or program determinations; (2) adoption of the Screening for Social Drivers of Health (SDOH) measure in all three programs beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028

payment or program determinations; and (3) adoption of the Screen Positive Rate for SDOH measure in all three programs beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment or program determinations.

• *Modification of the Immediate Measure Removal Policy for the Hospital OQR and ASCQR Programs:* We are finalizing modification of the immediate measure removal policy to an immediate measure suspension policy to increase transparency regarding the process for removing adopted measures in the Hospital OQR and ASCQR Programs beginning with CY 2025.

• *Hospital Outpatient Quality Reporting (OQR) Program:* In addition to the cross-program measures and policies, we are finalizing: (1) adoption of the Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance Measure (Information Transfer PRO–PM) beginning with voluntary reporting for the CY 2026 reporting period followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2029 payment determination; (2) removal of the MRI Lumbar Spine for Low Back Pain measure beginning with the CY 2025 reporting period/CY 2027 payment determination; (3) removal of the Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery measure beginning with the CY 2025 reporting period/CY 2027 payment determination; (4) the requirement that electronic health record (EHR) technology be certified to all electronic clinical quality measures (eCQMs) available to report beginning with the CY 2025 reporting period/CY 2027 payment determination; and (5) public reporting of the Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients measure—Psychiatric/Mental Health Patients stratification on Care Compare beginning with CY 2025.

• *Rural Emergency Hospital Quality Reporting (REHQR) Program:* In addition to the cross-program measures, we are finalizing: (1) extension of the reporting period for the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery measure from 1 year to 2 years beginning with the CY 2027 program determination; and (2) when, after status conversion, REHs are required to report data under the REHQR Program.

• *Ambulatory Surgical Center Quality Reporting (ASCQR) Program:* In addition to finalizing the cross-program measures and policies, we summarize comments received on the potential development of frameworks for specialty focused reporting and minimum case number for required reporting under the ASCQR Program.

• *Hospital Inpatient Quality Reporting (IQR) Program:* We are finalizing the voluntary reporting of the core clinical data elements (CCDEs) and linking variables for both the Hybrid Hospital-Wide Readmission (HWR) and Hybrid Hospital-Wide Standardized Mortality (HWM) measures, for the performance period of July 1, 2023, through June 30, 2024, impacting the FY 2026 payment determination for the Hospital IQR Program. Additionally, we are extending voluntary reporting of CCDEs and linking variables for an additional year for the performance period of July 1, 2024, through June 30, 2025, impacting the FY 2027 payment determination for the Hospital IQR Program.

• *Overall Hospital Quality Star Rating:* We summarize comments received on potential modifications to the Safety of Care measure group in the Overall Hospital Quality Star Rating methodology.

• *Medicare FFS No Legal Obligation to Pay Payment Exclusion and Incarceration:* We are narrowing the description of ''custody'' for purposes of Medicare's no legal obligation to pay payment exclusion at § 411.4(b), stating explicitly in regulatory text that individuals who are released to the community pending trial (including those in pretrial community supervision and those released pursuant to cash bail), on parole, probation, or home detention, or required to reside in halfway houses are not considered to be in ''custody'' for purposes of the payment exclusion, adding a definition of ''penal authority,'' reorganizing the regulation, and making certain technical edits.

• *Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals:* We are finalizing the eligibility requirements in the special enrollment period (SEP) for formerly incarcerated individuals at §§ 406.27(d) and 407.23(d) to remove the reference to ''custody'' associated with § 411.4(b) and instead tie the eligibility for this SEP to the determination made by SSA that they are no longer incarcerated. We are also expanding the SEP eligibility criteria to include individuals released from confinement to residency in halfway houses.

• *Continuous Eligibility in Medicaid and CHIP:* We are finalizing our proposed revisions to Medicaid and CHIP regulations to codify the requirement within the CAA, 2023 for States to provide 12 months of continuous eligibility to children under the age of 19 in Medicaid and CHIP, with limited exceptions. Specifically, we are finalizing the removal of the option to provide continuous eligibility to a subgroup of Medicaid and CHIP enrollees and for a time period of less than 12 months. For CHIP, we are finalizing the removal of the option to disenroll children from CHIP during a continuous eligibility period for failure to pay premiums.

• *Medicaid Clinic Services Four Walls Exceptions:* We are finalizing three exceptions to the Medicaid clinic services benefit four walls requirement at 42 CFR 440.90. Our current regulation at 42 CFR 440.90(b) allows for Medicaid payment for clinic services furnished outside of the four walls of the clinic only to individuals who are unhoused. Our final rule adds a mandatory exception to the four walls requirement for IHS/Tribal clinics at 42 CFR 440.90(c) and optional exceptions for behavioral health clinics and clinics located in rural areas at 42 CFR 440.90(d) and (e), respectively.

• *Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals:* We are finalizing new Conditions of Participation (CoPs) for hospitals and CAHs for obstetrical services, including new requirements for maternal quality assessment and performance improvement (QAPI), as well as baseline standards for the organization, staffing, and delivery of care within obstetrical units, and staff training on evidence-based best practices every 2 years. We are finalizing revisions to the emergency services CoP related to emergency readiness for hospitals and CAHs that provide emergency services. In addition, we are finalizing revisions to the Discharge Planning CoP for all hospitals related to transfer protocols. Further, we are finalizing a phased-in implementation to provide hospitals and CAHs with additional time to come into compliance with the requirements. Lastly, we sought comments in the proposed rule on whether these requirements should also apply to rural emergency hospitals (REHs), which we discuss below.

3. Summary of Costs and Benefits

In section XXVIII of this final rule with comment period, we set forth a detailed analysis of the regulatory and federalism impacts that the proposed

changes would have on affected entities and beneficiaries. Key estimated impacts are described below.

a. Impacts of All OPPS Changes

Table 201 in section XXVIII.C of this final rule with comment period displays the distributional impact of all the OPPS changes on various groups of hospitals and CMHCs for CY 2025 compared to all estimated OPPS payments in CY 2024. We estimate that the final policies in this final rule with comment period would result in a 3.0 percent overall increase in OPPS payments to providers. We estimate that total OPPS payments for CY 2025, including beneficiary cost-sharing, to the approximately 3,500 facilities paid under the OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and CMHCs) would increase by approximately $1.98 billion compared to CY 2024 payments, excluding our estimated changes in enrollment, utilization, and case-mix.

We estimated the isolated impact of our OPPS policies on CMHCs because CMHCs have historically only been paid for partial hospitalization services under the OPPS. Beginning CY 2024, they are also paid for intensive outpatient program (IOP) services under the OPPS. Continuing the provider-specific structure we adopted beginning in CY 2011, and basing payment fully on the type of provider furnishing the service, we estimate a 11.9 percent increase in CY 2025 payments to CMHCs relative to their CY 2024 payments.

b. Impacts of the Updated Wage Indexes

We estimate that our update of the wage indexes based on the fiscal year (FY) 2025 IPPS final rule wage indexes will result in a 0.1 percent increase for urban hospitals under the OPPS and a 0.9 percent increase for rural hospitals. These wage indexes include continued implementation of the Office of Management and Budget (OMB) labor market area delineations based on 2020 Decennial Census data, with updates, as discussed in section II.C of this final rule with comment period.

c. Impacts of the Rural Adjustment and the Cancer Hospital Payment Adjustment

For CY 2025, we are continuing to provide additional payments to cancer hospitals so that a cancer hospital's payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for the other OPPS hospitals using the most recently submitted or settled cost report data. Section 16002(b) of the 21st Century Cures Act requires that this weighted average PCR be reduced by 1.0 percentage point. In light of the COVID–19 PHE impact on claims and cost data used to calculate the target PCR, we had maintained the CY 2021 target PCR of 0.89 through CYs 2022 and 2023. However, in CY 2024, we finalized a policy to reduce the target PCR by 1.0 percentage point each calendar year until the target PCR equals the PCR of non-cancer hospitals using the most recently submitted or settled cost report data. For CY 2024, we finalized a target PCR of 0.88. For CY 2025, we are finalizing a target PCR of 0.87 to determine the CY 2025 cancer hospital payment adjustment to be paid at cost report settlement. That is, the payment adjustments would be the additional payments needed to result in a PCR equal to 0.87 for each cancer hospital.

d. Impacts of the OPD Fee Schedule Increase Factor

For the CY 2025 OPPS/ASC, we are establishing an OPD fee schedule increase factor of 2.9 percent and applying that increase factor to the conversion factor for CY 2025. As a result of the OPD fee schedule increase factor and other budget neutrality adjustments, we estimate that urban hospitals will experience an increase in payments of approximately 3.2 percent and that rural hospitals will experience an increase in payments of 3.2 percent. Classifying hospitals by teaching status, we estimate non-teaching hospitals will experience an increase in payments of 3.3 percent, minor teaching hospitals will experience an increase in payments of 3.5 percent, and major teaching hospitals will experience an increase in payments of 2.7 percent. We also classified hospitals by the type of ownership. We estimate that hospitals with voluntary ownership will experience an increase of 3.1 percent in payments, while hospitals with government ownership will experience an increase of 2.6 percent in payments. We estimate that hospitals with proprietary ownership will experience an increase of 4.9 percent in payments.

e. Impacts of the ASC Payment Update

For impact purposes, the surgical procedures on the ASC covered surgical procedure list are aggregated into surgical specialty groups using CPT and HCPCS code range definitions. The percentage change in estimated total payments by specialty groups under the CY 2025 payment rates, compared to estimated CY 2024 payment rates, generally ranges between an increase of 3 percent and an increase of 4 percent, depending on the service, with some exceptions. We estimate the impact of applying the inpatient hospital market basket update to ASC payment rates will increase payments by $193 million under the ASC payment system in CY 2025.

f. Impacts of Medicaid Clinic Services Four Walls Exceptions

We estimate that the finalized exceptions to the four walls requirement under the Medicaid clinic services benefit for IHS/Tribal clinics, behavioral health clinics, and clinics located in rural areas will increase total expenditures by $1.18 billion from FY 2025 through 2029. Our estimate includes a Federal impact of $1.15 billion and impact to States of $30 million. These estimates are discussed in more detail in section XXVIII of this final rule.

g. Impacts of Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals

We are finalizing maternal health focused revisions to the CoPs for hospitals and CAHs, which are estimated to increase burden on hospitals and CAHs by $423 million annually with total costs estimated at $4.23 billion over 10 years. We expect an average annual cost of $67,103 per hospital and CAH. As discussed in detail in section XXVIII of this final rule with comment period, we expect the benefits of these policies to include reduced maternal morbidity and mortality, leading to financial benefits for patients, their families, and payors. We also expect that the policies are likely to reduce inequality in maternal health outcomes among pregnant and postpartum women from different groups and lead to overall improvements in patient care.

h. Impacts of the Medicaid and CHIP Continuous Eligibility Requirements

We are finalizing our proposed revisions to Medicaid and CHIP regulations to codify the requirement within the CAA, 2023 for States to provide 12 months of continuous eligibility to children under the age of 19 in Medicaid and CHIP, with limited exceptions. For CHIP, we are finalizing the removal of the option to disenroll children from CHIP during a continuous eligibility period for failure to pay premiums. Requiring 12months of continuous eligibility in Medicaid and CHIP is estimated to increase annual average enrollment in Medicaid and CHIP by approximately 124,000 by 2028 (75,000 in Medicaid and 49,000 in CHIP). The total estimated impact of this requirement over 5 years is $2,466 million, including Federal impact of

$1,592 million and State impact of $874 million.

B. Legislative and Regulatory Authority for the Hospital OPPS

When Title XVIII of the Act was enacted, Medicare payment for hospital outpatient services was based on hospital-specific costs. In an effort to ensure that Medicare and its beneficiaries pay appropriately for services and to encourage more efficient delivery of care, the Congress mandated replacement of the reasonable cost-based payment methodology with a prospective payment system (PPS). The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) added section 1833(t) to the Act, authorizing implementation of a PPS for hospital outpatient services. The OPPS was first implemented for services furnished on or after August 1, 2000. Implementing regulations for the OPPS are located at 42 CFR parts 410 and 419.

The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) made major changes in the hospital OPPS. The following Acts made additional changes to the OPPS: the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554); the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173); the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171), enacted on February 8, 2006; the Medicare Improvements and Extension Act under Division B of Title I of the Tax Relief and Health Care Act of 2006 (MIEA–TRHCA) (Pub. L. 109–432), enacted on December 20, 2006; the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) (Pub. L. 110–173), enacted on December 29, 2007; the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275), enacted on July 15, 2008; the Patient Protection and Affordable Care Act (Pub. L. 111–148), enacted on March 23, 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (HCERA, Pub. L. 111–152), enacted on March 30, 2010 (these two public laws are collectively known as the Affordable Care Act); the Medicare and Medicaid Extenders Act of 2010 (MMEA, Pub. L. 111–309); the Temporary Payroll Tax Cut Continuation Act of 2011 (TPTCCA, Pub. L. 112–78), enacted on December 23, 2011; the Middle Class Tax Relief and Job Creation Act of 2012 (MCTRJCA, Pub. L. 112–96), enacted on February 22, 2012; the American Taxpayer Relief Act of 2012 (Pub. L. 112–240), enacted January 2, 2013; the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) enacted on December 26, 2013; the Protecting Access to Medicare Act of 2014 (PAMA, Pub. L. 113–93), enacted on March 27, 2014; the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 (Pub. L. 114–10), enacted April 16, 2015; the Bipartisan Budget Act of 2015 (Pub. L. 114–74), enacted November 2, 2015; the Consolidated Appropriations Act, 2016 (Pub. L. 114–113), enacted on December 18, 2015, the 21st Century Cures Act (Pub. L. 114–255), enacted on December 13, 2016; the Consolidated Appropriations Act, 2018 (Pub. L. 115–141), enacted on March 23, 2018; the Substance Use Disorder—Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (Pub. L. 115–271), enacted on October 24, 2018; the Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94), enacted on December 20, 2019; the Coronavirus Aid, Relief, and Economic Security Act (Pub. L. 116–136), enacted on March 27, 2020; the Consolidated Appropriations Act, 2021 (Pub. L. 116–260), enacted on December 27, 2020; the Inflation Reduction Act, 2022 (Pub. L. 117–169), enacted on August 16, 2022; and the Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–238), enacted December 29, 2022.

Under the OPPS, we generally pay for hospital Part B services on a rate-per-service basis that varies according to the APC group to which the service is assigned. We use the Healthcare Common Procedure Coding System (HCPCS) (which includes certain Current Procedural Terminology (CPT) codes) to identify and group the services within each APC. The OPPS includes payment for most hospital outpatient services, except those identified in section I.C of this final rule with comment period. Section 1833(t)(1)(B) of the Act provides for payment under the OPPS for hospital outpatient services designated by the Secretary (which includes partial hospitalization services furnished by CMHCs), and certain inpatient hospital services that are paid under Medicare Part B.

The OPPS rate is an unadjusted national payment amount that includes the Medicare payment and the beneficiary copayment. This rate is divided into a labor-related amount and a nonlabor-related amount. The labor-related amount is adjusted for area wage differences using the hospital inpatient wage index value for the locality in which the hospital or CMHC is located.

All services and items within an APC group are comparable clinically and with respect to resource use, as required by section 1833(t)(2)(B) of the Act. In accordance with section 1833(t)(2)(B) of the Act, subject to certain exceptions, items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest median cost (or mean cost, if elected by the Secretary) for an item or service in the APC group is more than 2 times greater than the lowest median cost (or mean cost, if elected by the Secretary) for an item or service within the same APC group (referred to as the ''2 times rule''). In implementing this provision, we generally use the cost of the item or service assigned to an APC group.

For new technology items and services, special payments under the OPPS may be made in one of two ways. Section 1833(t)(6) of the Act provides for temporary additional payments, which we refer to as ''transitional pass-through payments,'' for at least 2 but not more than 3 years for certain drugs, biological agents, brachytherapy devices used for the treatment of cancer, and categories of other medical devices. For new technology services that are not eligible for transitional pass-through payments, and for which we lack sufficient clinical information and cost data to appropriately assign them to a clinical APC group, we have established special APC groups based on costs, which we refer to as New Technology APCs. These New Technology APCs are designated by cost bands which allow us to provide appropriate and consistent payment for designated new procedures that are not yet reflected in our claims data. Similar to pass-through payments, an assignment to a New Technology APC is temporary; that is, we retain a service within a New Technology APC until we acquire sufficient data to assign it to a clinically appropriate APC group.

C. Excluded OPPS Services and Hospitals

Section 1833(t)(1)(B)(i) of the Act authorizes the Secretary to designate the hospital outpatient services that are paid under the OPPS. While most hospital outpatient services are payable under the OPPS, section 1833(t)(1)(B)(iv) of the Act excludes payment for ambulance, physical and occupational therapy, and speech-language pathology services, for which payment is made under a fee schedule. It also excludes screening mammography, diagnostic mammography, and effective January 1, 2011, an annual wellness visit providing personalized prevention plan services. The Secretary exercises the authority granted under the statute to also exclude from the OPPS certain services that are

paid under fee schedules or other payment systems. Such excluded services include, for example, the professional services of physicians and nonphysician practitioners paid under the Medicare Physician Fee Schedule (MPFS); certain laboratory services paid under the Clinical Laboratory Fee Schedule (CLFS); services for beneficiaries with end-stage renal disease (ESRD) that are paid under the ESRD prospective payment system; and services and procedures that require an inpatient stay that are paid under the hospital IPPS. In addition, section 1833(t)(1)(B)(v) of the Act does not include applicable items and services (as defined in subparagraph (A) of paragraph (21)) that are furnished on or after January 1, 2017, by an off-campus outpatient department of a provider (as defined in subparagraph (B) of paragraph (21)). We set forth the services that are excluded from payment under the OPPS in regulations at 42 CFR 419.22.

Under § 419.20(b) of the regulations, we specify the types of hospitals that are excluded from payment under the OPPS. These excluded hospitals are:

- Critical access hospitals (CAHs);
- Hospitals located in Maryland and paid under Maryland's All-Payer or Total Cost of Care Model;
- Hospitals located outside of the 50 States, the District of Columbia, and Puerto Rico;
- Indian Health Service (IHS) hospitals; and
- Rural emergency hospitals (REH).

D. Prior Rulemaking

On April 7, 2000, we published in the **Federal Register** a final rule with comment period (65 FR 18434) to implement a prospective payment system for hospital outpatient services. The hospital OPPS was first implemented for services furnished on or after August 1, 2000. Section 1833(t)(9)(A) of the Act requires the Secretary to review certain components of the OPPS, not less often than annually, and to revise the groups, the relative payment weights, and the wage and other adjustments to take into account changes in medical practices, changes in technology, the addition of new services, new cost data, and other relevant information and factors.

Since initially implementing the OPPS, we have published final rules in the **Federal Register** annually to implement statutory requirements and changes arising from our continuing experience with this system. These rules can be viewed on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*.

E. Advisory Panel on Hospital Outpatient Payment (the HOP Panel or the Panel)

1. Authority of the Panel

Section 1833(t)(9)(A) of the Act, as amended by section 201(h) of Public Law 106–113, and redesignated by section 202(a)(2) of Public Law 106–113, requires that we consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to annually review (and advise the Secretary concerning) the clinical integrity of the payment groups and their weights under the OPPS. In CY 2000, based on section 1833(t)(9)(A) of the Act, the Secretary established the Advisory Panel on Ambulatory Payment Classification Groups (APC Panel) to fulfill this requirement. In CY 2011, based on section 222 of the Public Health Service Act (the PHS Act), which gives discretionary authority to the Secretary to convene advisory councils and committees, the Secretary expanded the panel's scope to include the supervision of hospital outpatient therapeutic services in addition to the APC groups and weights. To reflect this new role of the panel, the Secretary changed the panel's name to the Advisory Panel on Hospital Outpatient Payment (the HOP Panel). The HOP Panel is not restricted to using data compiled by CMS, and in conducting its review, it may use data collected or developed by organizations outside the Department.

2. Establishment of the Panel

On November 21, 2000, the Secretary signed the initial charter establishing the Panel, and, at that time, named the APC Panel. This expert panel is composed of appropriate representatives of providers (currently employed full-time, not as consultants, in their respective areas of expertise) who review clinical data and advise CMS about the clinical integrity of the APC groups and their payment weights. Since CY 2012, the Panel also is charged with advising the Secretary on the appropriate level of supervision for individual hospital outpatient therapeutic services. The Panel is technical in nature, and it is governed by the provisions of the Federal Advisory Committee Act (FACA). The current charter specifies, among other requirements, that the Panel—

- May advise on the clinical integrity of Ambulatory Payment Classification (APC) groups and their associated weights;
- May advise on the appropriate supervision level for hospital outpatient services;
- May advise on OPPS APC rates for ASC covered surgical procedures;
- Continues to be technical in nature;
- Is governed by the provisions of the FACA;
- Has a Designated Federal Official (DFO); and
- Is chaired by a Federal Official designated by the Secretary.

The Panel's charter was amended on November 15, 2011, renaming the Panel and expanding the Panel's authority to include supervision of hospital outpatient therapeutic services and to add critical access hospital (CAH) representation to its membership. The Panel's charter was also amended on November 6, 2014 (80 FR 23009), and the number of members was revised from up to 19 to up to 15 members. The Panel's current charter was approved on November 21, 2022, for a 2-year period.

The current Panel membership and other information pertaining to the Panel, including its charter, **Federal Register** notices, membership, meeting dates, agenda topics, and meeting reports, can be viewed on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html*.

3. Panel Meetings and Organizational Structure

The Panel has held many meetings, with the last meeting taking place on August 26, 2024. The recommendations of the Panel for the most recent meeting are available on the CMS website at: *https://www.cms.gov/medicare/regulations-guidance/advisory-committees/hospital-outpatient-payment*. Prior to each meeting, we publish a notice in the **Federal Register** to announce the meeting, new members, and any other changes of which the public should be aware. Beginning in CY 2017, we have transitioned to one meeting per year (81 FR 31941). In CY 2022, we published a **Federal Register** notice requesting nominations to fill vacancies on the Panel (87 FR 68499). CMS is currently accepting nominations at: *https://mearis.cms.gov*.

In addition, the Panel has established an administrative structure that, in part, currently includes the use of three subcommittee workgroups to provide preparatory meeting and subject support to the larger panel. The three current subcommittees include the following:

- APC Groups and Status Indicator Assignments Subcommittee, which advises and provides recommendations to the Panel on the appropriate status

indicators to be assigned to HCPCS codes, including but not limited to whether a HCPCS code or a category of codes should be packaged or separately paid, as well as the appropriate APC assignment of HCPCS codes regarding services for which separate payment is made;

- Data Subcommittee, which is responsible for studying the data issues confronting the Panel and for recommending options for resolving them; and

- Visits and Observation Subcommittee, which reviews and makes recommendations to the Panel on all technical issues pertaining to observation services and hospital outpatient visits paid under the OPPS.

Each of these workgroup subcommittees was established by a majority vote from the full Panel during a scheduled Panel meeting, and the Panel recommended at the August 21, 2023, meeting that the subcommittees continue. We accepted this recommendation.

For discussions of earlier Panel meetings and recommendations, we refer readers to previously published OPPS/ASC proposed and final rules, the CMS website mentioned earlier in this section, and the FACA database at *https://facadatabase.gov*.

F. Public Comments Received on the CY 2025 Proposed Rule

We received approximately 3,500 timely pieces of correspondence on the CY 2025 OPPS/ASC proposed rule that appeared in the **Federal Register** on July 22, 2024 (89 FR 59186). We received comments from elected officials, providers and suppliers, practitioners, and advocacy groups. We provide summaries of the public comments, and our responses are set forth in the various sections of this final rule with comment period under the appropriate headings. We note that we received some public comments that were outside the scope of the CY 2025 OPPS/ASC proposed rule. Out-of-scope-public comments are not addressed in this CY 2025 OPPS/ASC final rule with comment period.

G. Public Comments Received on the CY 2024 OPPS/ASC Final Rule With Comment Period

We received approximately 180 timely pieces of correspondence on the CY 2024 OPPS/ASC final rule with comment period that appeared in the **Federal Register** on November 22, 2023 (88 FR 81540).

II. Updates Affecting OPPS Payments

A. Recalibration of APC Relative Payment Weights

1. Database Construction

a. Database Source and Methodology

Section 1833(t)(9)(A) of the Act requires that the Secretary review not less often than annually and revise the relative payment weights for Ambulatory Payment Classifications (APCs). In the April 7, 2000, OPPS final rule with comment period (65 FR 18482), we explained in detail how we calculated the relative payment weights that were implemented on August 1, 2000, for each APC group.

For the CY 2025 OPPS, we proposed to recalibrate the APC relative payment weights for services furnished on or after January 1, 2025, and before January 1, 2026 (CY 2025), using the same basic methodology that we described in the CY 2024 OPPS/ASC final rule with comment period (88 FR 81549 through 81552), using CY 2023 claims data. That is, we proposed to recalibrate the relative payment weights for each APC based on claims and cost report data for hospital outpatient department (HOPD) services to construct a database for calculating APC group weights.

For the purpose of recalibrating the proposed APC relative payment weights for CY 2025, we began with approximately 145 million final action claims (claims for which all disputes and adjustments have been resolved and payment has been made) for HOPD services furnished on or after January 1, 2023, and before January 1, 2024, before applying our exclusionary criteria and other methodological adjustments. After the application of those data processing changes, we used approximately 73 million final action claims to develop the proposed CY 2025 OPPS payment weights. For exact numbers of claims used and additional details on the claims accounting process, we refer readers to the claims accounting narrative under supporting documentation for the CY 2025 OPPS/ASC proposed rule on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient*.

Addendum N to the CY 2025 OPPS/ASC proposed rule (which is available via the internet on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*) includes the proposed list of bypass codes for CY 2025. The proposed list of bypass codes contains codes that are reported on claims for services in CY 2023 and, therefore, includes codes that were in effect in CY 2023 and used for billing. We proposed to retain these deleted bypass codes on the proposed CY 2025 bypass list because these codes existed in CY 2023 and were covered OPD services in that period, and CY 2023 claims data were used to calculate proposed CY 2025 payment rates. Keeping these deleted bypass codes on the bypass list potentially allows us to create more ''pseudo'' single procedure claims for ratesetting purposes. ''Overlap bypass codes'' that are members of the proposed multiple imaging composite APCs are identified by asterisks (*) in the third column of Addendum N to the CY 2025 OPPS/ASC proposed rule. HCPCS codes that we proposed to add for CY 2025 are identified by asterisks (*) in the fourth column of Addendum N.

We did not receive any public comments on our general proposal to recalibrate the relative payment weights for each APC based on claims and cost report data for HOPD services or on our proposed bypass code process. We are finalizing as proposed the ''pseudo'' single claims process and the final CY 2025 list of bypass codes, as displayed in Addendum N to this final rule with comment period (which is available via the internet on the CMS website). For this final rule with comment period, for the purpose of recalibrating the final APC relative payment weights for CY 2025, we used approximately 78 million final action claims (claims for which all disputes and adjustments have been resolved and payment has been made) for HOPD services furnished on or after January 1, 2023, and before January 1, 2024. For the exact numbers of claims used and additional details on the claims accounting process, we refer readers to the claims accounting narrative under supporting documentation for this final rule with comment period on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient*.

b. Calculation and Use of Cost-to-Charge Ratios (CCRs)

For CY 2025, we proposed to continue to use the hospital-specific overall ancillary and departmental cost-to-charge ratios (CCRs) to convert charges to estimated costs through application of a revenue code-to-cost center crosswalk. To calculate the APC costs on which the proposed CY 2025 APC payment rates are based, we calculated hospital-specific departmental CCRs for each hospital for which we had CY 2023 claims data by comparing these claims data to the most recently available hospital cost reports, which, in most

cases, are from CY 2022. For the proposed CY 2025 OPPS payment rates, we used the set of claims processed during CY 2023. We applied the hospital-specific CCR to the hospital's charges at the most detailed level possible, based on a revenue code-to-cost center crosswalk that contains a hierarchy of CCRs used to estimate costs from charges for each revenue code. To ensure the completeness of the revenue code-to-cost center crosswalk, we reviewed changes to the list of revenue codes for CY 2023 (the year of claims data we used to calculate the proposed CY 2025 OPPS payment rates) and updates to the National Uniform Billing Committee (NUBC) 2023 Data specifications Manual. That crosswalk is available for review and continuous comment on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient*.

In accordance with our longstanding policy, similar to our finalized policy for CY 2024 OPPS ratesetting, we proposed to calculate CCRs for the standard cost centers—cost centers with a predefined label—and nonstandard cost centers—cost centers defined by a hospital—accepted by the electronic cost report database. In general, the most detailed level at which we calculate CCRs is the hospital-specific departmental level.

While we generally view the use of additional cost data as improving our OPPS ratesetting process, we have historically not included cost report lines for certain nonstandard cost centers in the OPPS ratesetting database construction when hospitals have reported these nonstandard cost centers on cost report lines that do not correspond to the cost center number. We believe it is important to further investigate the accuracy of these cost report data before including such data in the ratesetting process. Further, we believe it is appropriate to gather additional information from the public as well before including them in OPPS ratesetting. For CY 2025, we proposed not to include the nonstandard cost centers reported in this way in the OPPS ratesetting database construction.

We did not receive any public comments on the general CCR process and therefore, we are finalizing our proposal for CY 2025 to use the hospital-specific overall ancillary and departmental CRs to convert charges to estimated costs through application of a revenue code-to-cost center crosswalk and the proposed methodology.

2. Final Data Development and Calculation of Costs Used for Ratesetting

In this section of this final rule with comment period, we discuss the use of claims to calculate the OPPS payment rates for CY 2025. The Hospital OPPS page on the CMS website on which this final rule with comment period is posted (*https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient*) provides an accounting of claims used in the development of the proposed payment rates. That accounting provides additional detail regarding the number of claims derived at each stage of the process. In addition, later in this section we discuss the file of claims that comprises the data set that is available upon payment of an administrative fee under a CMS data use agreement. The CMS website, *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient*, includes information about obtaining the ''OPPS Limited Data Set,'' which now includes the additional variables previously available only in the OPPS Identifiable Data Set, including International Classification of Diseases, Tenth Revision, Clinical Modification (ICD–10–CM) diagnosis codes and revenue code payment amounts. This file is derived from the CY 2023 claims that are used to calculate the proposed payment rates for the CY 2025 OPPS/ASC proposed rule.

Previously, the OPPS established the scaled relative weights on which payments are based using APC median costs, a process described in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74188). However, as discussed in more detail in section II.A.2.f of the CY 2013 OPPS/ASC final rule with comment period (77 FR 68259 through 68271), we finalized the use of geometric mean costs to calculate the relative weights on which the CY 2013 OPPS payment rates were based. While this policy changed the cost metric on which the relative payments are based, the data process in general remained the same under the methodologies that we used to obtain appropriate claims data and accurate cost information in determining estimated service cost.

We used the methodology described in sections II.A.2.a through II.A.2.c of this final rule with comment period to calculate the costs we used to establish the proposed relative payment weights used in calculating the OPPS payment rates for CY 2025 shown in Addenda A and B to this final rule with comment period (which are available via the internet on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*). We refer readers to section II.A.4 of this final rule with comment period for a discussion of the conversion of APC costs to scaled payment weights.

We note that under the OPPS, CY 2019 was the first year in which the claims data used for setting payment rates (CY 2017 data) contained lines with the modifier ''PN,'' which indicates nonexcepted items and services furnished and billed by off-campus provider-based departments (PBDs) of hospitals. Because nonexcepted items and services are not paid under the OPPS, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58832), we finalized a policy to remove those claim lines reported with modifier ''PN'' from the claims data used in ratesetting for the CY 2019 OPPS and subsequent years. For the CY 2025 OPPS, we proposed to continue to remove claim lines with modifier ''PN'' from the ratesetting process.

We did not receive any public comments on our proposal and are finalizing our proposal to continue to remove claim lines reported with modifier ''PN'' from the ratesetting process.

For details of the claims accounting process used in this CY 2025 OPPS/ASC final rule with comment period, we refer readers to the claims accounting narrative under supporting documentation for this final rule with comment period on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient*.

a. Calculation of Single Procedure APC Criteria-Based Costs

(1) Blood and Blood Products

(a) Methodology

Since the implementation of the OPPS in August 2000, we have made separate payments for blood and blood products through APCs rather than packaging payment for them into payments for the procedures with which they are administered. Hospital payments for the costs of blood and blood products, as well as for the costs of collecting, processing, and storing blood and blood products, are made through the OPPS payments for specific blood product APCs.

In the CY 2025 OPPS/ASC proposed rule, we proposed to continue to establish payment rates for blood and blood products using our blood-specific CCR methodology (88 FR 49562), which utilizes actual or simulated CCRs from

the most recently available hospital cost reports to convert hospital charges for blood and blood products to costs. This methodology has been our standard ratesetting methodology for blood and blood products since CY 2005. It was developed in response to data analysis indicating that there was a significant difference in CCRs for those hospitals with and without blood-specific cost centers and past public comments indicating that the former OPPS policy of defaulting to the overall hospital CCR for hospitals not reporting a blood-specific cost center often resulted in an underestimation of the true hospital costs for blood and blood products. To address the differences in CCRs and to better reflect hospitals' costs, our methodology simulates blood CCRs for each hospital that does not report a blood cost center by calculating the ratio of the blood-specific CCRs to hospitals' overall CCRs for those hospitals that do report costs and charges for blood cost centers and applies this mean ratio to the overall CCRs of hospitals not reporting costs and charges for blood cost centers on their cost reports. We propose to calculate the costs upon which the proposed payment rates for blood and blood products are based using the actual blood-specific CCR for hospitals that reported costs and charges for a blood cost center and a hospital-specific, simulated, blood-specific CCR for hospitals that did not report costs and charges for a blood cost center.

We stated in the CY 2025 OPPS/ASC proposed rule that we continue to believe that the hospital-specific, simulated, blood-specific CCR methodology takes into account the unique charging and cost accounting structure of each hospital, as it better responds to the absence of a blood-specific CCR for a hospital than alternative methodologies, such as defaulting to the overall hospital CCR or applying an average blood-specific CCR across hospitals. This methodology also yields more accurate estimated costs for these products and results in payment rates for blood and blood products that appropriately reflect the relative estimated costs of these products for hospitals without blood cost centers and for these blood products in general.

We refer readers to Addendum B to this final rule with comment period (which is available via the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*) for the final CY 2025 payment rates for blood and blood products (which are generally identified with status indicator ''R'').

For a more detailed discussion of payments for blood and blood products through APCs, we refer readers to:

- the CY 2005 OPPS proposed rule (69 FR 50524 and 50525) for a more comprehensive discussion of the blood-specific CCR methodology;
- the CY 2008 OPPS/ASC final rule with comment period (72 FR 66807 through 66810) for a detailed history of the OPPS payment for blood and blood products; and
- the CY 2015 OPPS/ASC final rule with comment period (79 FR 66795 and 66796) for additional discussion of our policy not to make separate payments for blood and blood products when they appear on the same claims as services assigned to a C–APC.

Comment: We received one comment regarding the cost calculations for blood and blood products. The commenter stated that current payment rates do not always cover the cost to process, store, and transport the unit of blood. The commenter recommended that CMS utilize the average wholesale price (AWP) as the payment rate for blood products, in addition to basing payment rates on the hospital CCRs, as they believed using AWP would help eliminate outliers and produce more accurate payment calculations. The commenter explained that cost reporting methodologies may vary among hospitals. For example, some cost centers may combine blood products with blood bank testing which could skew the CCRs for that cost center, which would then impact the payment rates.

Response: We thank the commenter for their input and will keep it in mind for future rulemaking. However, we note that reflecting the range and variation of billing patterns across hospitals, as reflected in their claims, is part of establishing prospective payment rates. Additionally, we do not believe at this time that using AWP to set the payment rate for blood products would necessarily result in more accurate payment calculations, because AWP does not factor in volume discounts or rebates and, therefore, may not reflect the true cost of the product.

Comment: One commenter supported our proposal to continue to pay separately for blood and blood products.

Response: We thank the commenter for their support.

After consideration of the public comments we received, we are finalizing our proposals for blood and blood products using our blood-specific CCR methodology without modification. Please refer to Addendum B to this final rule with comment period, which is available on the CMS website, for the final CY 2025 payment rates for blood and blood products.

(b) New HCPCS Code for Red Blood Cell Product (HCPCS Code P9027)

Effective October 1, 2024, the HCPCS workgroup created HCPCS code P9027 (Red blood cells, leukocytes reduced, oxygen/carbon dioxide reduced, each unit). HCPCS code P9027 may be used to bill for a blood product that utilizes a two-stage process to remove oxygen and maintain a deoxygenated state throughout its storage period, thereby preventing oxidative damage to red blood cells. We note that because HCPCS code P9027 was created after the CY 2025 OPPS/ASC proposed rule was issued, we did not include a proposal regarding the APC assignment for HCPCS code P9027 in the CY 2025 OPPS/ASC proposed rule. Due to its effective date, we assigned HCPCS code P9027 to APC 9541 with an SI = R (Blood and Blood Products) in Change Request 13784. The payment rate for HCPCS code P9027, effective October 1, 2024, is $252.48.

While we usually calculate payment rates for blood and blood products using our blood-specific CCR methodology, when there is no claims data on the charges and costs for blood products upon which to apply our blood-specific CCR methodology, we establish a payment rate for the new blood product based on a crosswalk to an existing blood product HCPCS code that we believe provides the best proxy for the costs of the new blood product. Because we did not have any claims data on HCPCS code P9027 ahead of its October 1, 2024, effective date, we used a crosswalk code to assign a payment rate for HCPCS code P9027. Specifically, we found that HCPCS code P9040 (Red blood cells, leukocytes reduced, irradiated, each unit) with a CY 2024 payment rate of $252.48 was sufficiently similar to P9027 to serve as a crosswalk for purposes of a payment rate assignment.

Comment: We received a comment from the manufacturer of the blood product described by P9027. HCPCS code P9027 may be used to bill for the blood product involving the Hemanext ONE System. The commenter provided estimated cost information regarding the blood product, including an expected average per-unit anticipated hospital cost of $510. The manufacturer provided the estimated costs based on total blood establishment manufacturing costs, including the costs to manufacture a single unit of the starting materials, the sales price for the Hemanext ONE System, and the blood establishment labor, overhead,

administrative, and shipping costs. The commenter noted that they believe their red blood cell product is potentially transformative and would provide improved health outcomes. The commenter stated that they believe the product whose CY 2024 Medicare payment rate reasonably approximates the projected average hospital acquisition cost for HCPCS P9027 is HCPCS code P9057 (Red blood cells, frozen/deglycerolized/washed/leukocytes reduced, irradiated, each unit), with a CY 2024 payment rate of $493.21 per unit. As such, the commenter recommends that CMS crosswalk the payment rate for HCPCS P9057 to HCPCS P9027. The commenter believes that a crosswalk to any other red blood cell product will result in a payment rate that does not cover the acquisition cost for HCPCS P9027 and creates patient access barriers.

Response: We thank the commenter for their comment. Based on the additional cost information provided by the manufacturer, we believe that HCPCS code P9040 is not the best proxy for the costs of the blood product described by HCPCS code P9027. However, we disagree with the commenter that HCPCS code P9057 is the most appropriate crosswalk for new HCPCS code P9027 because the payment rate for HCPCS code P9057 reflects additional processes that are not reflected in the code descriptor for HCPCS code P9027. Given this difference in process, and the associated differences in estimated costs, we believe HCPCS code P9035 is a more appropriate proxy for the costs associated with HCPCS code P9027. Therefore, we are establishing an interim payment rate for HCPCS code P9027 based on a crosswalk to existing blood product HCPCS code P9035. Table 1 lists the new HCPCS code P9027 and its payment crosswalk.

TABLE 1: NEW HCPCS CODE P9027 PAYMENT RATE AND CROSSWALK FOR CY 2025

New HCPCS P-Code	New HCPCS P-code long descriptor	Crosswalked HCPCS P-code	Crosswalked HCPCS P-code long descriptor	Final CY 2025 OPPS payment amount
P9027	Red blood cells, leukocytes reduced, oxygen/carbon dioxide reduced, each unit	P9035	Platelets, pheresis, leukocytes reduced, each unit	$493.01

The interim payment rate for HCPCS code P9027 is open for public comment in this CY 2025 final rule with comment period. Specifically, HCPCS code P9027 is flagged with comment indicator ''NI'' in Addendum B to this final rule with comment period to indicate that we have assigned the codes an interim OPPS payment status for CY 2025 and are seeking public comments on the APC and status indicator assignments. Once we have claims data for this new HCPCS P-code, we will calculate a payment rate using the claims data that should be available for these new codes beginning in CY 2027, which is our practice for other blood products for which claims data have been available for 2 years.

(2) Brachytherapy Sources

Section 1833(t)(2)(H) of the Act mandates the creation of additional groups of covered OPD services that classify devices of brachytherapy—cancer treatment through solid source radioactive implants—consisting of a seed or seeds (or radioactive source) (''brachytherapy sources'') separately from other services or groups of services. The statute provides certain criteria for the additional groups. For the history of OPPS payment for brachytherapy sources, we refer readers to prior OPPS final rules, such as the CY 2012 OPPS/ASC final rule with comment period (77 FR 68240 and 68241). As we have stated in prior OPPS updates, we believe that adopting the general OPPS prospective payment methodology for brachytherapy sources is appropriate for a number of reasons (77 FR 68240). The general OPPS methodology uses costs based on claims data to set the relative payment weights for hospital outpatient services. This payment methodology results in more consistent, predictable, and equitable payment amounts per source across hospitals by averaging the extremely high and low values, in contrast to payment based on hospitals' charges adjusted to costs. We believe that the OPPS methodology, as opposed to payment based on hospitals' charges adjusted to cost, also would provide hospitals with incentives for efficiency in the provision of brachytherapy services to Medicare beneficiaries. Moreover, this approach is consistent with our payment methodology for the vast majority of items and services paid under the OPPS. We refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70323 through 70325) for further discussion of the history of OPPS payment for brachytherapy sources.

For CY 2025, except where otherwise indicated, we proposed to continue our policy and use the costs derived from CY 2023 claims data to set the proposed CY 2025 payment rates for brachytherapy sources because CY 2023 is the year of data we proposed to use to set the proposed payment rates for most other items and services that would be paid under the CY 2025 OPPS. With the exception of the proposed payment rate for brachytherapy source C2645 (Brachytherapy planar source, palladium-103, per square millimeter) and the proposed payment rates for low-volume brachytherapy APCs discussed in section III.D of the CY 2025 OPPS/ASC proposed rule, we proposed to base the payment rates for brachytherapy sources on the geometric mean unit costs for each source, consistent with the methodology that we proposed for other items and services paid under the OPPS, as discussed in section II.A.2 of the CY 2025 OPPS/ASC proposed rule. We also proposed for CY 2025 and subsequent years to continue the other payment policies for brachytherapy sources that we finalized and first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR

60537). For CY 2025 and subsequent years, we proposed to pay for the stranded and nonstranded not otherwise specified (NOS) codes, HCPCS codes C2698 (Brachytherapy source, stranded, not otherwise specified, per source) and C2699 (Brachytherapy source, non-stranded, not otherwise specified, per source), at a rate equal to the lowest stranded or nonstranded prospective payment rate for such sources, respectively, on a per-source basis (as opposed to, for example, per mCi), which is based on the policy we established in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66785). For CY 2025 and subsequent years, we also proposed to continue the policy we first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537) regarding payment for new brachytherapy sources for which we have no claims data, based on the same reasons we discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66786; which was delayed until January 1, 2010, by section 142 of Pub. L. 110–275). Specifically, this policy is intended to enable us to assign new HCPCS codes for new brachytherapy sources to their own APCs, with prospective payment rates set based on our consideration of external data and other relevant information regarding the expected costs of the sources to hospitals. The proposed CY 2025 payment rates for brachytherapy sources are included on Addendum B to the CY 2025 OPPS/ASC proposed rule (which is available via the internet on the CMS website) and identified with status indicator ''U.''

For CY 2018, we assigned status indicator ''U'' (Brachytherapy Sources, Paid under OPPS; separate APC payment) to HCPCS code C2645 (Brachytherapy planar source, palladium-103, per square millimeter) in the absence of claims data and established a payment rate using external data (invoice price) at $4.69 per mm^2 for the brachytherapy source's APC–APC 2648 (Brachytx planar, p-103). For CY 2019, in the absence of sufficient claims data, we continued to establish a payment rate for C2645 at $4.69 per mm^2 for APC 2648 (Brachytx planar, p103). Our CY 2018 claims data available for the CY 2020 OPPS/ASC final rule with comment period (84 FR 61142) included two claims with a geometric mean cost for HCPCS code C2645 of $1.02 per mm^2. In response to comments from interested parties, we agreed that, given the limited claims data available and a new outpatient indication for C2645, a payment rate for HCPCS code C2645 based on the geometric mean cost of $1.02 per mm^2 may not adequately reflect the cost of HCPCS code C2645. In the CY 2020 OPPS/ASC final rule with comment period, we finalized our policy to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act, which states that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments, to maintain the CY 2019 payment rate of $4.69 per mm^2 for HCPCS code C2645 for CY 2020. Similarly, in the absence of sufficient claims data to establish an APC payment rate, in the CY 2021, CY 2022, CY 2023, and CY 2024 OPPS/ASC final rules with comment period (85 FR 85879 through 85880, 86 FR 63469, 87 FR 71760–71761, and 88 FR 81553), we finalized our policy to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the CY 2019 payment rate of $4.69 per mm^2 for HCPCS code C2645 for CYs 2021 through 2024.

There were no CY 2023 claims available that reported HCPCS code C2645 for the CY 2025 OPPS/ASC proposed rule. Therefore, in the absence of claims data, we proposed to continue to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the CY 2024 payment rate of $4.69 per mm^2 for HCPCS code C2645, which we proposed to be assigned to APC 2648 (Brachytx planar, p-103), for CY 2025.

Additionally, for CY 2022 and subsequent calendar years, we adopted a Universal Low Volume APC policy for clinical and brachytherapy APCs. As discussed in further detail in section X.C of the CY 2022 OPPS/ASC final rule with comment period (86 FR 63743 through 63747), we adopted this policy to mitigate wide variation in payment rates that occur from year to year for APCs with low utilization. Such volatility in payment rates from year to year can result in even lower utilization and potential barriers to access. Brachytherapy APCs that have fewer than 100 single claims used for ratesetting purposes are designated as Low Volume APCs unless an alternative payment rate is applied, such as the use of our equitable adjustment authority under section 1833(t)(2)(E) of the Act in the case of APC 2648 (Brachytx planar, p-103), for which HCPCS code C2645 (Brachytherapy planar source, palladium-103, per square millimeter) is the only code assigned as discussed previously in this section.

For CY 2025, we proposed to designate six brachytherapy APCs as Low Volume APCs as these APCs meet our criteria to be designated as Low Volume APCs. For more information on the brachytherapy APCs we proposed to designate as Low Volume APCs, see section III.D of the CY 2025 OPPS/ASC proposed rule.

Comment: We received support from commenters for our proposal to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the CY 2024 payment rate of $4.69 per mm^2 for HCPCS code C2645, which we proposed to assign to APC 2648 (Brachytx planar, p-103) for CY 2025.

Response: We thank the commenters for their support.

After consideration of the public comment we received, we are finalizing, without modification, that we will use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the CY 2024 payment rate of $4.69 per mm^2 for HCPCS code C2645, which we are assigning to APC 2648 (Brachytx planar, p-103), for CY 2025.

The final CY 2025 payment rates for brachytherapy sources are included in Addendum B to this final rule with comment period (which is available via the internet on the CMS website) and are identified with status indicator ''U.'' We continue to invite interested parties to submit recommendations for new codes to describe new brachytherapy sources. Such recommendations should be directed via email to *outpatientpps@cms.hhs.gov* or by mail to the Division of Outpatient Care, Mail Stop C4–01–26, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244. We will continue to add new brachytherapy source codes and descriptors to our systems for payment on a quarterly basis.

b. Comprehensive APCs (C–APCs) for CY 2025

(1) Background

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74861 through 74910), we finalized a comprehensive payment policy that packages payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure under the OPPS at the claim level. The policy was finalized in CY 2014, but the effective date was delayed until January 1, 2015, to allow additional time for further analysis, opportunity for public comment, and systems preparation. The comprehensive APC (C–APC) policy was implemented effective January 1, 2015, with modifications and clarifications in response to public

comments received regarding specific provisions of the C–APC policy (79 FR 66798 through 66810).

A C–APC is defined as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. We established C–APCs as a category broadly for OPPS payment and implemented 25 C–APCs beginning in CY 2015 (79 FR 66809 and 66810). We have gradually added new C–APCs since the policy was implemented beginning in CY 2015, with the number of C–APCs now totaling 72 (80 FR 70332; 81 FR 79584 and 79585; 83 FR 58844 through 58846; 84 FR 61158 through 61166; 85 FR 85885; 86 FR 63474; 87 FR 71769; and 88 FR 81562).

Under our C–APC policy, we designate a service described by a HCPCS code assigned to a C–APC as the primary service when the service is identified by OPPS status indicator ''J1.'' When such a primary service is reported on a hospital outpatient claim, taking into consideration the few exceptions that are discussed below, we make payment for all other items and services reported on the hospital outpatient claim as being integral, ancillary, supportive, dependent, and adjunctive to the primary service (hereinafter collectively referred to as ''adjunctive services'') and representing components of a complete comprehensive service (78 FR 74865 and 79 FR 66799). Payments for adjunctive services are packaged into the payments for the primary services. This results in a single prospective payment for each of the primary, comprehensive services based on the costs of all reported services at the claim level. One example of a primary service would be a partial mastectomy and an example of a secondary service packaged into that primary service would be a radiation therapy procedure.

Services excluded from the C–APC policy under the OPPS include services that are not covered OPD services, services that cannot by statute be paid for under the OPPS, and services that are required by statute to be separately paid. This includes certain mammography and ambulance services that are not covered OPD services in accordance with section 1833(t)(1)(B)(iv) of the Act; brachytherapy seeds, which also are required by statute to receive separate payment under section 1833(t)(2)(H) of the Act; pass-through payment drugs and devices, which also require separate payment under section 1833(t)(6) of the Act; self-administered drugs (SADs) that are not otherwise packaged as supplies because they are not covered under Medicare Part B under section 1861(s)(2)(B) of the Act; and certain preventive services (78 FR 74865 and 79 FR 66800 and 66801). A list of services excluded from the C–APC policy is included in Addendum J to this final rule (which is available via the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*). If a service does not appear on this list of excluded services, payment for it will be packaged into the payment for the primary C–APC service when it appears on an outpatient claim with a primary C–APC service.

The C–APC policy payment methodology set forth in the CY 2014 OPPS/ASC final rule with comment period and modified and implemented beginning in CY 2015 is summarized as follows (78 FR 74887 and 79 FR 66800):

Basic Methodology. As stated in the CY 2015 OPPS/ASC final rule with comment period, we define the C–APC payment policy as including all covered OPD services on a hospital outpatient claim reporting a primary service that is assigned to status indicator ''J1,'' [2] excluding services that are not covered OPD services or that cannot by statute be paid for under the OPPS. Services and procedures described by HCPCS codes assigned to status indicator ''J1'' are assigned to C–APCs based on our usual APC assignment methodology by evaluating the geometric mean costs of the primary service claims to establish resource similarity and the clinical characteristics of each procedure to establish clinical similarity within each APC.

In the CY 2016 OPPS/ASC final rule with comment period, we expanded the C–APC payment methodology to qualifying extended assessment and management encounters through the ''Comprehensive Observation Services'' C–APC (C–APC 8011). Services within this APC are assigned status indicator ''J2.'' [3] Specifically, we make a payment through C–APC 8011 for a claim that:

- Does not contain a procedure described by a HCPCS code to which we have assigned status indicator ''T;''
- Contains 8 or more units of services described by HCPCS code G0378 (Hospital observation services, per hour);
- Contains services provided on the same date of service or one day before the date of service for HCPCS code G0378 that are described by one of the following codes: HCPCS code G0379 (Direct admission of patient for hospital observation care) on the same date of service as HCPCS code G0378; CPT code 99281 (Emergency department visit for the evaluation and management of a patient (Level 1)); CPT code 99282 (Emergency department visit for the evaluation and management of a patient (Level 2)); CPT code 99283 (Emergency department visit for the evaluation and management of a patient (Level 3)); CPT code 99284 (Emergency department visit for the evaluation and management of a patient (Level 4)); CPT code 99285 (Emergency department visit for the evaluation and management of a patient (Level 5)) or HCPCS code G0380 (Type B emergency department visit (Level 1)); HCPCS code G0381 (Type B emergency department visit (Level 2)); HCPCS code G0382 (Type B emergency department visit (Level 3)); HCPCS code G0383 (Type B emergency department visit (Level 4)); HCPCS code G0384 (Type B emergency department visit (Level 5)); CPT code 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes); or HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient); and
- Does not contain services described by a HCPCS code to which we have assigned status indicator ''J1.''

The assignment of status indicator ''J2'' to a specific set of services performed in combination with each other allows for all other OPPS payable services and items reported on the claim (excluding services that are not covered OPD services or that cannot by statute be paid for under the OPPS) to be deemed adjunctive services representing components of a comprehensive service and resulting in a single prospective payment for the comprehensive service based on the costs of all reported services on the claim (80 FR 70333 through 70336).

Services included under the C–APC payment packaging policy, that is, services that are typically adjunctive to the primary service and provided during the delivery of the comprehensive service, include diagnostic procedures, laboratory tests, and other diagnostic tests and treatments that assist in the delivery of the primary procedure; visits and evaluations performed in association with the procedure; uncoded services and supplies used during the service; durable medical equipment as well as prosthetic and

[2] Status indicator ''J1'' denotes Hospital Part B Services Paid Through a Comprehensive APC. Further information can be found in CY 2025 Addendum D1.

[3] Status indicator ''J2'' denotes Hospital Part B Services That May Be Paid Through a Comprehensive APC. Further information can be found in CY 2025 Addendum D1.

orthotic items and supplies when provided as part of the outpatient service; and any other components reported by HCPCS codes that represent services that are provided during the complete comprehensive service (78 FR 74865 and 79 FR 66800).

In addition, payment for hospital outpatient department services that are similar to therapy services, such as speech language pathology, and delivered either by therapists or nontherapists is included as part of the payment for the packaged complete comprehensive service. These services that are provided during the perioperative period are adjunctive services and are deemed not to be therapy services as described in section 1834(k) of the Act, regardless of whether the services are delivered by therapists or other nontherapist health care workers. We have previously noted that therapy services are those provided by therapists under a plan of care in accordance with section 1835(a)(2)(C) and section 1835(a)(2)(D) of the Act and are paid for under section 1834(k) of the Act, subject to annual therapy caps as applicable (78 FR 74867 and 79 FR 66800). However, certain other services similar to therapy services are considered and paid for as hospital outpatient department services. Payment for these nontherapy outpatient department services that are reported with therapy codes and provided with a comprehensive service is included in the payment for the packaged complete comprehensive service. We note that these services, even though they are reported with therapy codes, are hospital outpatient department services and not therapy services. We refer readers to the July 2016 OPPS Change Request 9658 (Transmittal 3523) for further instructions on reporting these services in the context of a C–APC service.

Items included in the packaged payment provided in conjunction with the primary service also include all drugs, biologicals, and radiopharmaceuticals, regardless of cost, except those drugs with pass-through payment status and SADs, unless they function as packaged supplies (78 FR 74868, 74869, and 74909 and 79 FR 66800). We refer readers to Section 50.2M, Chapter 15, of the Medicare Benefit Policy Manual for a description of our policy on SADs treated as hospital outpatient supplies, including lists of SADs that function as supplies and those that do not function as supplies.[4]

We define each hospital outpatient claim reporting a single unit of a single primary service assigned to status indicator ''J1'' as a single ''J1'' unit procedure claim (78 FR 74871 and 79 FR 66801). Line-item charges for services included on the C–APC claim are converted to line-item costs, which are then summed to develop the estimated APC costs. These claims are then assigned one unit of the service with status indicator ''J1'' and later used to develop the geometric mean costs for the C–APC relative payment weights. (We note that we use the term ''comprehensive'' to describe the geometric mean cost of a claim reporting ''J1'' service(s) or the geometric mean cost of a C–APC, inclusive of all the items and services included in the C–APC service payment bundle.) Charges for services that would otherwise be separately payable are added to the charges for the primary service. This process differs from our traditional cost accounting methodology only in that all such services on the claim are packaged (except certain services as described above). We apply our standard data trims, which exclude claims with extremely high primary units or extreme costs.

The comprehensive geometric mean costs are used to establish resource similarity and, along with clinical similarity, dictate the assignment of the primary services to the C–APCs. We establish a ranking of each primary service (single unit only) to be assigned to status indicator ''J1'' according to its comprehensive geometric mean costs. For the minority of claims reporting more than one primary service assigned to status indicator ''J1'' or units thereof, we identify one ''J1'' service as the primary service for the claim based on our cost-based ranking of primary services. We then assign these multiple ''J1'' procedure claims to the C–APC to which the service designated as the primary service is assigned. If the reported ''J1'' services on a claim map to different C–APCs, we designate the ''J1'' service assigned to the C–APC with the highest comprehensive geometric mean cost as the primary service for that claim. If the reported multiple ''J1'' services on a claim map to the same C–APC, we designate the most costly service (at the HCPCS code level) as the primary service for that claim. This process results in initial assignments of claims for the primary services assigned to status indicator ''J1'' to the most appropriate C–APCs based on both single and multiple procedure claims reporting these services and clinical and resource homogeneity.

Complexity Adjustments. We use complexity adjustments to provide increased payment for certain comprehensive services. We apply a complexity adjustment by promoting qualifying paired ''J1'' service code combinations or paired code combinations of ''J1'' services and certain add-on codes (as described further below) from the originating C–APC (the C–APC to which the designated primary service is first assigned) to the next higher paying C–APC in the same clinical family of C–APCs. We apply this type of complexity adjustment when the paired code combination represents a complex, costly form or version of the primary service according to the following criteria:

- Frequency of 25 or more claims reporting the code combination (frequency threshold); and
- Violation of the 2 times rule, as stated in section 1833(t)(2) of the Act and section III.B.2 of this final rule with comment period, in the originating C–APC (cost threshold).

These criteria identify paired code combinations that occur commonly and exhibit materially greater resource requirements than the primary service. The CY 2017 OPPS/ASC final rule with comment period (81 FR 79582) included a revision to the complexity adjustment eligibility criteria. Specifically, we finalized a policy to discontinue the requirement that a code combination (that qualifies for a complexity adjustment by satisfying the frequency and cost criteria thresholds described above) also not create a 2 times rule violation in the higher level or receiving APC.

After designating a single primary service for a claim, we evaluate that service in combination with each of the other procedure codes reported on the claim assigned to status indicator ''J1'' (or certain add-on codes) to determine if there are paired code combinations that meet the complexity adjustment criteria. For a new HCPCS code, we determine initial C–APC assignment and qualification for a complexity adjustment using the best available information, crosswalking the new HCPCS code to a predecessor code(s) when appropriate.

Once we have determined that a particular code combination of ''J1'' services (or combinations of ''J1'' services reported in conjunction with certain add-on codes) represents a

[4] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.*

complex version of the primary service because it is sufficiently costly, frequent, and a subset of the primary comprehensive service overall according to the criteria described above, we promote the claim including the complex version of the primary service as described by the code combination to the next higher cost C–APC within the clinical family, unless the primary service is already assigned to the highest cost APC within the C–APC clinical family or assigned to the only C–APC in a clinical family. We do not create new APCs with a comprehensive geometric mean cost that is higher than the highest geometric mean cost (or only) C–APC in a clinical family just to accommodate potential complexity adjustments. Therefore, the highest payment for any claim including a code combination for services assigned to a C–APC would be the highest paying C–APC in the clinical family (79 FR 66802).

We package payment for all add-on codes into the payment for the C–APC. However, certain primary service add-on combinations may qualify for a complexity adjustment. As noted in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70331), all add-on codes that can be appropriately reported in combination with a base code that describes a primary ''J1'' service are evaluated for a complexity adjustment.

To determine which combinations of primary service codes reported in conjunction with an add-on code may qualify for a complexity adjustment for CY 2025, we apply the frequency and cost criteria thresholds discussed above, testing claims reporting one unit of a single primary service assigned to status indicator ''J1'' and any number of units of a single add-on code for the primary ''J1'' service. If the frequency and cost criteria thresholds for a complexity adjustment are met and reassignment to the next higher cost APC in the clinical family is appropriate (based on meeting the criteria outlined above), we make a complexity adjustment for the code combination; that is, we reassign the primary service code reported in conjunction with the add-on code to the next higher cost C–APC within the same clinical family of C–APCs. As previously stated, we package payment for add-on codes into the C–APC payment rate. If any add-on code reported in conjunction with the ''J1'' primary service code does not qualify for a complexity adjustment, payment for the add-on service continues to be packaged into the payment for the primary service and is not reassigned to the next higher cost C–APC. We list the complexity adjustments for ''J1'' and add-on code combinations for CY 2025, along with all the other final complexity adjustments, in Addendum J to this final rule with comment period (which is available via the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*).

Addendum J to this final rule with comment period includes the cost statistics for each code combination that would qualify for a complexity adjustment (including primary code and add-on code combinations). Addendum J to this final rule with comment period also contains summary cost statistics for each of the paired code combinations that describe a complex code combination that would qualify for a complexity adjustment and be reassigned to the next higher cost C–APC within the clinical family. The combined statistics for all proposed reassigned complex code combinations are represented by an alphanumeric code with the first four digits of the designated primary service followed by a letter. For example, the proposed geometric mean cost listed in Addendum J for the code combination described by complexity adjustment assignment 3320R, which is assigned to C–APC 5224 (Level 4 Pacemaker and Similar Procedures), includes all paired code combinations that will be reassigned to C–APC 5224 when CPT code 33208 is the primary code. Providing the information contained in Addendum J to this final rule with comment period allows interested parties the opportunity to better assess the impact associated with the assignment of claims with each of the paired code combinations eligible for a complexity adjustment.

Comment: We received support from commenters for a variety of existing and proposed complexity adjustments.

Response: We thank the commenters for their support.

Comment: Multiple commenters requested that CMS apply a complexity adjustment to additional code combinations. The specific C–APC complexity adjustment code combinations requested by the commenters for CY 2025 are listed in Table 2.

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TABLE 2: C-APC COMPLEXITY ADJUSTMENTS REQUESTED BY COMMENTERS FOR CY 2025

Primary "J1" HCPCS/CPT Code	Secondary "J1" HCPCS/CPT code	Primary C-APC Assignment	Requested complexity adjusted C-APC assignment
28292 (Correction, hallux valgus with bunionectomy, with sesamoidectomy when performed; with resection of proximal phalanx base, when performed, any method)	**28270** (Capsulotomy; metatarsophalangeal joint, with or without tenorrhaphy, each joint (separate procedure))	5113	5115
28296 (Correction, hallux valgus with bunionectomy, with sesamoidectomy when performed; with distal metatarsal osteotomy, any method)	**28270** (Capsulotomy; metatarsophalangeal joint, with or without tenorrhaphy, each joint (separate procedure))	5113	5115
28750 (Arthrodesis, great toe; metatarsophalangeal joint)	**20902** (Bone graft, any donor area; major or large)	5114	5115
	27691 (Transfer or transplant of single tendon (with muscle redirection or rerouting); deep (eg, anterior tibial or posterior tibial through interosseous space, flexor digitorum longus, flexor hallucis longus, or peroneal tendon to midfoot or hindfoot)	5114	5115
	28309 (Osteotomy, with or without lengthening, shortening or angular correction, metatarsal; multiple (eg, swanson type cavus foot procedure)	5114	5115
28740 (Arthrodesis, midtarsal or tarsometatarsal, single joint)	**27687** (Gastrocnemius recession (eg, strayer procedure))	5114	5115
	27691 (Transfer or transplant of single tendon (with muscle redirection or rerouting); deep (eg, anterior tibial or posterior tibial through interosseous space, flexor digitorum longus, flexor hallucis longus, or peroneal tendon to midfoot or hindfoot))	5114	5115
	28270 (Capsulotomy; metatarsophalangeal joint, with or without tenorrhaphy, each joint (separate procedure))	5114	5115
	28740 (Arthrodesis, midtarsal or tarsometatarsal, single joint)	5114	5115
22514 (Percutaneous vertebral augmentation, including cavity	**22515** (Percutaneous vertebral augmentation, including cavity	5115	5115

creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; lumbar)	creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; each additional thoracic or lumbar vertebral body (list separately in addition to code for primary procedure))		
C9600 (Percutaneous transcatheter placement of drug eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch)	**92972** (Percutaneous transluminal coronary lithotripsy (list separately in addition to code for primary procedure))	5193	5194
C9604 (Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including distal protection when performed; single vessel)		5193	5194
92920 (Percutaneous transluminal coronary angioplasty; single major coronary artery or branch)		5192	5193
92928 (Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch)		5193	5194
92924 (Percutaneous transluminal coronary atherectomy, with coronary angioplasty when performed; single major coronary artery or branch)		5193	5194
92943 Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; single vessel)		5193	5194

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Response: We reviewed each of the requested code combinations suggested by commenters, listed in Table 2, against our complexity adjustment

criteria. The code combination for primary HCPCS code 28296 with secondary HCPCS code 28270 meets our cost and frequency criteria, qualifying for a complexity adjustment for CY 2025. All the remaining code combinations listed failed to meet our cost or frequency criteria and do not qualify for complexity adjustments for CY 2025. Addendum J to this final rule with comment period includes the cost statistics for each code combination that was evaluated for a complexity adjustment.

Comment: Commenters requested that CMS modify, waive, or eliminate the established C–APC complexity adjustment eligibility criteria of 25 or more claims reporting the code combination (frequency) and a violation of the 2 times rule in the originating C–APC (cost) to allow additional code combinations to qualify for complexity adjustments. These commenters were concerned that C–APC packaging and a lack of complexity adjustment would limit access to procedures. Specifically, some commenters expressed concern that CMS's methodology for determining complexity adjustments is unnecessarily restrictive, particularly the 25-claim threshold, and suggested that CMS eliminate the 25-claim threshold and implement a complexity adjustment whenever a code pair exceeds the cost threshold.

Some commenters were concerned that when multiple ''J1'' primary services are reported on a claim, along with an add-on service, the add-on service is not evaluated for a complexity adjustment. Commenters cited examples where significant claims volume from add-on services may not be incorporated into the complexity adjustment evaluation. Commenters also reiterated requests to broaden the complexity adjustment policy and allow clusters of procedures, consisting of a ''J1'' code pair and multiple other associated add-on codes used in combination with that ''J1'' code pair, to qualify for complexity adjustments. Commenters stated that there are certain complex procedures that include numerous add-on codes and this approach would allow more accurate reflection of the cost of medical practice when multiple procedures are performed together. They noted that lack of additional payment for these code combinations can present a financial challenge for the providers who perform these more resource intensive services.

Response: We appreciate these comments. At this time, we do not believe changes to the C–APC complexity adjustment criteria are necessary or that we should make exceptions to the criteria to allow claims with the code combinations suggested by the commenters to receive complexity adjustments. As we stated in the CY 2017 OPPS/ASC final rule (81 FR 79582), we believe that the complexity adjustment criteria, which require a frequency of 25 or more claims reporting a code combination and a violation of the 2 times rule in the originating C–APC, are appropriate to determine if a combination of procedures represents a complex, costly subset of the primary service that should qualify for the adjustment and be paid at the next higher paying C–APC in the clinical family. As we also previously stated in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61161), a minimum of 25 claims is already a very low threshold for a national payment system. Lowering the minimum of 25 claims further could lead to unnecessary complexity adjustments for service combinations that are rarely performed.

Comment: A few commenters suggested that to help maintain better stability and predictability of payments associated with complex procedures, CMS should revise the complexity adjustment policy by allowing qualifying codes to maintain the complexity adjusted payment for three calendar years before they are required to go through the eligibility review. For codes that do not qualify in a given year, they could be evaluated in the next calendar year. Commenters asserted that the updated cadence would allow more time for providers and coders to be educated on new code pairs that qualify for complexity adjustments and it would help promote payment stability and predictability for these complex procedures.

Response: For the OPPS ratesetting process, our goal is to use the best available data for ratesetting to accurately estimate the costs associated with furnishing outpatient services and to set appropriate payment rates. We evaluate code combinations each year against our complexity adjustment criteria using the latest available data. Potentially maintaining complexity adjustments that are not supported by the latest data could undermine our goals for the ratesetting process.

Comment: A few commenters requested that CMS provide additional information on the rationale for not counting claims that reflect code combinations of services that would otherwise meet the frequency criteria needed to receive a complexity adjustment. Commenters conducted their own data modeling using data reflecting all code combinations that met the frequency criteria needed to receive a complexity adjustment. Commenters asked for greater transparency on the methodology CMS used to evaluate the complexity adjustment frequency criteria for code combinations.

Response: We refer commenters to the claims accounting narrative under supporting documentation for this CY 2025 OPPS/ASC final rule on the CMS website at: *https://www.cms.gov/files/document/2025-nprm-opps-claims-accounting.pdf*. The claims accounting narrative provides a detailed overview of how CMS processes the CY 2023 claims data to produce the proposed prospective CY 2025 OPPS payment rates. We are updating the section on Comprehensive APCs in order to provide additional clarity on the claims accounting process used for determining complexity adjustments.

After consideration of the public comments we received, we are finalizing the C–APC complexity adjustment policy for CY 2025 as proposed. We are also finalizing the proposed complexity adjustments, with the addition of one new code combination (*i.e.,* primary HCPCS code 28296 with secondary HCPCS code 28270) suggested by commenters that meets our complexity adjustment criteria.

(2) Exclusion of Procedures Assigned to New Technology APCs From the C–APC Policy

Services that are assigned to New Technology APCs are typically new procedures that do not have sufficient claims history to establish an accurate payment for them. Beginning in CY 2002, we retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to an appropriate clinical APC. This policy allows us to move a service from a New Technology APC in less than 2 years if sufficient data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient data upon which to base a decision for reassignment have not been collected (82 FR 59277).

The C–APC payment policy packages payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure under the OPPS at the claim level. Prior to CY 2019, when a procedure assigned to a New Technology APC was included on the claim with a primary procedure, identified by OPPS status indicator ''J1,'' payment for the new technology service was typically packaged into the payment for the primary procedure.

Because the new technology service was not separately paid in this scenario, the overall number of single claims available to determine an appropriate clinical APC for the new service was reduced. This was contrary to the objective of the New Technology APC payment policy, which is to gather sufficient claims data to enable us to assign the service to an appropriate clinical APC.

To address this issue and ensure that there are sufficient claims data for services assigned to New Technology APCs, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58847), we finalized excluding payment for any procedure that is assigned to a New Technology APC (APCs 1491 through 1599 and APCs 1901 through 1908) from being packaged when included on a claim with a ''J1'' service assigned to a C–APC. In the CY 2020 OPPS/ASC final rule with comment period, we finalized that beginning in CY 2020, payment for services assigned to a New Technology APC would be excluded from being packaged into the payment for comprehensive observation services assigned status indicator ''J2'' when they are included on a claim with a ''J2'' service (84 FR 61167).

(3) Exclusion of Drugs and Biologicals Described by HCPCS Code C9399 (Unclassified Drugs or Biologicals) From the C–APC Policy

Section 1833(t)(15) of the Act, as added by section 621(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173), provides for payment under the OPPS for new drugs and biologicals until HCPCS codes are assigned. Under this provision, we are required to make payment for a covered outpatient drug or biological that is furnished as part of covered outpatient department services but for which a HCPCS code has not yet been assigned in an amount equal to 95 percent of average wholesale price (AWP) for the drug or biological.

In the CY 2005 OPPS/ASC final rule with comment period (69 FR 65805), we implemented section 1833(t)(15) of the Act by instructing hospitals to bill for a drug or biological that is newly approved by the Food and Drug Administration (FDA) and that does not yet have a HCPCS code by reporting the National Drug Code (NDC) for the product along with the newly created HCPCS code C9399 (Unclassified drugs or biologicals). We explained that when HCPCS code C9399 appears on a claim, the Outpatient Code Editor (OCE) suspends the claim for manual pricing by the Medicare Administrative Contractor (MAC). The MAC prices the claim at 95 percent of the drug or biological's AWP, using Red Book or an equivalent recognized compendium, and processes the claim for payment. We emphasized that this approach enables hospitals to bill and receive payment for a new drug or biological concurrent with its approval by the FDA. The hospital does not have to wait for the next quarterly release or for approval of a product specific HCPCS code to receive payment for a newly approved drug or biological or to resubmit claims for adjustment. We instructed that hospitals would discontinue billing HCPCS code C9399 and the NDC upon implementation of a product specific HCPCS code, status indicator, and appropriate payment amount with the next quarterly update. We also note that HCPCS code C9399 is paid in a similar manner in the ASC setting, as 42 CFR 416.171(b) outlines that certain drugs and biologicals for which separate payment is allowed under the OPPS are considered covered ancillary services for which the OPPS payment rate, which is 95 percent of AWP for HCPCS code C9399, applies. Since the implementation of the C–APC policy in 2015, payment for drugs and biologicals described by HCPCS code C9399 had been included in the C–APC payment when these products appear on a claim with a primary C–APC service. Packaging payment for these drugs and biologicals that appear on a hospital outpatient claim with a primary C–APC service is consistent with our C–APC packaging policy under which we make payment for all items and services, including all non-pass-through drugs, reported on the hospital outpatient claim as being integral, ancillary, supportive, dependent, and adjunctive to the primary service and representing components of a complete comprehensive service, with certain limited exceptions (78 FR 74869). It was our position that the total payment for the C–APC with which payment for a drug or biological described by HCPCS code C9399 is packaged includes payment for the drug or biological at 95 percent of its AWP.

However, we determined that in certain instances, drugs and biologicals described by HCPCS code C9399 are not being paid at 95 percent of their AWPs when payment for them is packaged with payment for a primary C–APC service. In order to ensure payment for new drugs, biologicals, and radiopharmaceuticals described by HCPCS code C9399 at 95 percent of their AWP, for CY 2023 and subsequent years, we finalized our proposal to exclude any drug, biological, or radiopharmaceutical described by HCPCS code C9399 from packaging when the drug, biological, or radiopharmaceutical is included on a claim with a ''J1'' service, which is the status indicator assigned to a C–APC, and a claim with a ''J2'' service, which is the status indicator assigned to comprehensive observation services. See Addendum J for the CY 2025 C–APC payment policy exclusions.

In the CY 2023 OPPS/ASC final rule with comment period, we finalized the proposal in section XI ''CY 2023 OPPS Payment Status and Comment Indicators'' to add a new definition to status indicator ''A'' to include unclassified drugs and biologicals that are reportable with HCPCS code C9399 (87 FR 72051). The definition, found in Addendum D1, would ensure the MAC prices claims for drugs, biologicals, or radiopharmaceuticals billed with HCPCS code C9399 at 95 percent of the drug or biological's AWP and pays separately for the drug, biological, or radiopharmaceutical under the OPPS when it appears on the same claim as a primary C–APC service.

(4) Exclusion of Cell and Gene Therapies From the C–APC Policy

As previously discussed in this section, and in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74865), the C–APC policy packages payment for items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to the primary service and provided during the delivery of the comprehensive service, including diagnostic procedures, laboratory tests and other diagnostic tests and treatments that assist in the delivery of the primary procedure. In the CY 2014 OPPS/ASC final rule (78 FR 74861), we finalized defining a comprehensive APC as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. Because a comprehensive APC treats all individually reported codes as representing components of the comprehensive service, we make a single prospective payment based on the cost of all individually reported codes that represent the provision of a primary service and all adjunctive services provided to support that delivery of the primary service.

As discussed in the CY 2025 OPPS/ASC proposed rule (89 FR 59201 through 59204), we generally treat all items and services reported on a C–APC claim as integral, ancillary, supportive, dependent, and adjunctive to the primary service and representing

components of a comprehensive service. Historically, items packaged for payment provided in conjunction with the primary C–APC service also include all drugs, biologicals, and radiopharmaceuticals, regardless of cost, except those drugs with pass-through payment status and those drugs that are usually self-administered (SADs), unless they function as supplies (78 FR 74868 through 74869 and 74909).

Our intent has been to make a single prospective payment based on the cost of all individually reported codes that appear on a claim with the primary C–APC service, which we believe represent the provision of a primary service and all adjunctive services provided to support that delivery of the primary service. We discussed in the CY 2025 OPPS/ASC proposed rule (89 FR 59201 through 59204), there are rare instances where the cell and gene therapies listed in Table 3, which are usually separately payable under the OPPS, appear on the same claim as a primary C–APC service and therefore, have their payment packaged with payment for the primary C–APC service. The therapies in Table 3 are usually separately paid and priced using the ASP methodology when not on a C–APC claim. Given the unique nature of these therapies, we do not believe they function as integral, ancillary, supportive, dependent, or adjunctive to any of the current C–APCs primary services. The cell therapies described in Table 3 are primarily for the treatment of specific cancers and are administered through an intravenous infusion. The gene therapies listed in Table 3 are generally for the treatment of certain rare ocular or spinal conditions caused by specific genetic mutations and are also either intravenously infused or administered through a subretinal injection. When these products are administered, they are the primary treatment being administered to a patient and thus, are not integral, ancillary, supportive, dependent, or adjunctive to any primary C–APC services. Additionally, the current primary C–APC services describe common surgical procedures, such as breast/lymphatic surgery and musculoskeletal procedures. The cell and gene therapies listed in Table 3 are intended to treat a specific condition and would not be used to support the outcome of any primary C–APC procedure. For example, HCPCS code J3399 (Injection, onasemnogene abeparvovec-xioi, per treatment, up to 5x10^15 vector genomes) may be used to describe the gene therapy Zolgensma. This product is FDA-approved as an adeno-associated virus (AAV) vector-based gene therapy indicated for the treatment of pediatric patients less than 2 years of age with spinal muscular atrophy (SMA) with bi-allelic mutations in the survival motor neuron 1 (SMN1) gene. The specified mechanism of onasemnogene abeparvovec is a recombinant AAV9-based gene therapy designed to deliver a copy of the gene encoding the human SMN protein.[5] The function of a product such as Zolgensma, is not intended to be integral, ancillary, supportive, dependent, and adjunctive to any C–APC as the gene therapy itself is an independent treatment.

Yescarta (HCPCS code Q2041) is an example of a cell therapy that functions as an independent treatment. Based on its FDA-approved indication,[6] this product's intended clinical use would not be integral, ancillary, supportive, dependent, or adjunctive to any current C–APC primary service. Yescarta is indicated as a CD19-directed genetically modified autologous T cell immunotherapy for the treatment of Adult patients with large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy and adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma. Yescarta is the primary treatment being performed when administered for these FDA-approved indications and should not be packaged as supportive of any C–APC primary service even if the two services appear on the same claim.

We explained in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74868) that intravenous drugs, for example, are OPPS services that are considered adjunctive to the primary procedure because the correct administration of the drug either promotes a beneficial outcome, such as the use of intravenous pain medications, or prevents possible complications, such as the use of intravenous blood pressure medications to temporarily replace oral blood pressure medications and reduce the risk of a sudden rise in blood pressure when a normal daily medication is stopped. In the case of the cell and gene therapies described in Table 3, however, we do not believe the therapies ''promote a beneficial outcome'' or ''prevent possible complications'' of any of the procedures currently designated as primary C–APC services. While the cell and gene therapies in Table 3 may ''promote a beneficial outcome'' for the patient in general, we do not believe the provision of cell and gene therapies are ''promoting a beneficial outcome'' for any of the primary C–APC services themselves, as the cell and gene therapies are serving as independent therapies. These are distinguishable from the previous examples of intravenous pain medications that are directly related to the primary C–APC service and promote a beneficial outcome for that procedure. Further, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74865), we stated that we proposed to package into C–APCs all of these integral, ancillary, supportive, dependent, and adjunctive services, hereinafter collectively referred to as ''adjunctive services,'' provided during the delivery of the comprehensive service. This includes the diagnostic procedures, laboratory tests and other diagnostic tests, and treatments that assist in the delivery of the primary procedure. In the CY 2025 OPPS/ASC proposed rule (89 FR 59201 through 59204), we stated we did not believe that the cell and gene therapies listed in Table 3 are assisting in the delivery of any primary procedure currently assigned to a C–APC.

Therefore, for CY 2025 only, we proposed not to package payment for the cell and gene therapies listed in Table 3 into the payment for the primary C–APC service when they appear on the same claim as primary C–APCs services. We proposed this policy for one year only in order to gather more information from interested parties as to whether the proposed policy appropriately captures all of the unique therapies, such as the cell and gene therapies listed in Table 3, that function as primary treatments and do not support C–APC primary services. As discussed later in this section, we welcomed comments from readers on the proposal and the potential need for a different, modified, expanded, or supplemental policy for future rulemaking. We stated we will assess whether to continue this policy, or a modified version of this policy, beyond one year in future rulemaking, taking into consideration the comments received.

We did not propose to include therapies that are on drug pass-through status for all of CY 2025 in Table 3

[5] Zolgensma. FDA Package Insert. October 2023. *https://www.fda.gov/media/126109/download?attachment.*

[6] FDA Package Insert. Yescarta. April 2024. *https://www.fda.gov/media/108377/download?attachment.*

because pass-through drugs are already excluded from C–APC packaging. We proposed that products for which pass-through status is expiring in CY 2025 would be excluded from C–APC packaging after their pass-through status expires. For example, the product described by HCPCS code Q2056 has pass-through status expiring June 30, 2025. Until its pass-through status expires, the product will be excluded from C–APC packaging due to the pass-through C–APC exclusion policy, but after its pass-through status expires, we propose that the therapy would continue to be excluded from C–APC packaging under our proposed exclusion for cell and gene therapies. For more information on drug pass-through status, including expiring and continuing pass-through status, please see section V.A of this final rule with comment period.

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TABLE 3: CELL AND GENE THERAPIES PROPOSED FOR EXCLUSION FROM C-APC PACKAGING FOR CY 2025

Trade Name	HCPCS Code	Long Descriptor
Yescarta	Q2041	Axicabtagene ciloleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Kymriah	Q2042	Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Provenge	Q2043	Sipuleucel-t, minimum of 50 million autologous cd54+ cells activated with pap-gm-csf, including leukapheresis and all other preparatory procedures, per infusion
Tecartus	Q2053	Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Breyanzi	Q2054	Lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Abecma	Q2055	Idecabtagene vicleucel, up to 510 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Carvytki	Q2056	Ciltacabtagene autoleucel, up to 100 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Luxturna	J3398	Injection, voretigene neparvovec-rzyl, 1 billion vector genomes
Zolgensma	J3399	Injection, onasemnogene abeparvovec-xioi, per treatment, up to 5x10^15 vector genomes

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We proposed to exclude the therapies listed in Table 3 from C–APC packaging. We invited comment on the proposal, and we invited comment on whether there are any additional cell and gene therapies that may be appropriate to exclude from C–APC packaging for CY 2025. We asked commenters to explain why any additional cell and gene therapies that they believe should be excluded from C–APC packaging were not integral, ancillary, supportive, dependent, or adjunctive to any C–APC primary service. We invited comment on whether the proposal should be extended beyond 1 year or if a different, expanded, or supplemental policy approach may be warranted in future rulemaking. For example, we were interested in comments on whether there are other classes of drugs, biologicals, or other products that are not clearly integral, ancillary, adjunctive, or supportive of a primary C–APC service but could appear on the same claim as the C–APC for that primary service and for which payment would be packaged into the C–APC payment under our current policy. We stated that we would expect clinical evidence supporting commenters' assertion that other identified classes of drugs, biologicals, medical devices, or other products are not clearly supportive of a primary C–APC service but may nonetheless appear on the same claim as a primary C–APC procedure. Similarly, we invited comment on whether interested parties believe it is appropriate for these other classes of drugs, biologicals, or medical devices to be excluded from packaging with all C–APCs or only specific C–APCs, such as the Comprehensive Observation Services C–APC (SI = ''J2'').

Finally, we invited comment on the following:

- Because the cell and gene therapies listed in Table 3 are not integral, ancillary, supportive, dependent, or adjunctive to any current C–APC procedure, how could CMS structure a new C–APC, or similar packaged payment policy, for the service to administer cell or gene therapies, such by creating as a Chimeric Antigen Receptor (CAR) T-cell therapy administration C–APC, with which the CAR–T or gene therapy would be integral, ancillary, supportive, dependent, or adjunctive to the primary C–APC service? What integral, ancillary, supportive, dependent, or adjunctive items and services are routinely provided as part of the administration of cell and gene therapies or in conjunction with cell and gene therapies generally?

We recognized that currently, for CY 2024, the following HCPCS codes are associated with CAR–T therapy: HCPCS code 0537T (Chimeric antigen receptor t-cell (car-t) therapy; harvesting of blood-derived t lymphocytes for development of genetically modified autologous car-t cells, per day), 0538T (Chimeric antigen receptor t-cell (car-t) therapy; preparation of blood-derived t lymphocytes for transportation (eg, cryopreservation, storage)), 0539T (Chimeric antigen receptor t-cell (car-t) therapy; receipt and preparation of car-t cells for administration), and 0540T (Chimeric antigen receptor t-cell (car-t) therapy; car-t cell administration, autologous) as discussed in previous OPPS rulemaking, including the CY 2022 OPPS/ASC final rule with comment period (86 FR 63550 through 63552).

Separately, we also invited comment on whether policy revisions to the C–APC policy may be appropriate in future rulemaking, such as a modified outlier payment policy specific to C–APCs to address related situations in the future. We listed all proposed C–APC exclusion categories for CY 2025 in Addendum J to the CY 2025 OPPS/ASC proposed rule (which is available via the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*).

Comment: Commenters were generally very supportive of the proposal and thought this agency action was a positive step forward to ensure access to these new classes of drugs. They agreed with CMS's assessment that the cell and gene therapies listed in the CY 2025 OPPS/ASC proposed rule did not function as integral, ancillary, supportive, dependent, or adjunctive to any of the current C–APCs primary services. Commenters noted that they agreed that these treatments acted as independent therapies and were the reason for a Medicare beneficiary's visit to a hospital outpatient department. Additionally, commenters believed that this policy was necessary and important given the large number of cell and gene therapy products currently being researched that may ultimately be approved and available to Medicare beneficiaries in the coming years.

Response: We thank commenters for their support of our proposal and rationale.

Comment: Many commenters recommended CMS make this policy permanent as soon as possible. They noted that they agreed with CMS's assessment that it would be inappropriate to package cell and gene therapies into C–APCs for CY 2025 only, but that the same reasons that C–APC packaging would be inappropriate for CY 2025 would also apply to subsequent years. Other commenters recommended that CMS make this policy effective for an extended period of time, such as three years, in order to better understand how the policy is working.

Response: We thank commenters for their feedback. Based on the comments received, we are persuaded that the reasoning for excluding these cell and gene therapy products from C–APC packaging in CY 2025 would also apply to subsequent years. As such, we will be finalizing our proposal as later discussed in this section for CY 2025 and subsequent years.

Comment: One commenter recommended that its cell therapy be added to the list of qualifying exceptions to C–APC packaging as their product received FDA approval on August 1, 2024, during the public comment period. A few commenters recommended CMS apply this packaging exception to other categories of drugs that they believed fell into a similar clinical category as cell and gene therapies. For example, one commenter suggested that its drug product is one of a growing number of innovative drugs that are administered using surgical procedures that are mapped to a C–APC, resulting in packaging of that product. The commenter stated that the product was the primary treatment being delivered to the patient, and not the C–APC procedure. Another commenter stated they have a product in the pipeline that, according to guidance from a specialty society, requires a procedure corresponding to CPT code 51720 (bladder instillation of anticarcinogenic agent), which is assigned to C–APC 5372, in order to insert the investigational product into the bladder. This commenter believed their product is the primary treatment being administered to a patient and is not supportive to any primary C–APC services. Therefore, they requested this product not be packaged into a C–APC and believed C–APC packaging would be inappropriate. This commenter also requested that in order to prevent C–APC packaging, one option would be for CMS to reassign the code used to describe the administration of its product to a drug administration APC rather than a C–APC. Specifically, they recommended CMS reassign CPT code 51720, which corresponds to the procedure used to administer the investigational product, to a non C–APC, such as a drug administration APC.

Some commenters recommended that CMS extend the proposed policy to cell and gene therapies assigned to status indicator ''G'', which correlates to pass-through status. Similarly, commenters recommend CMS exclude a variety of products from C–APC packaging, such as Casgevy, Lyfgenia, Amtagvi, Omisurge, Zynteglo, Obe-cel, Hemgenix, Beqvez, Roctavian, Spinraza and Elevidys. A few commenters suggested CMS should review and identify any other products that may be administered as independent therapies in the hospital outpatient setting and stated that such products should be separately paid.

Response: We greatly thank commenters for their detailed comments. For new cell and gene therapy products that are not integral, ancillary, supportive, dependent, or adjunctive to any C–APC primary service that were approved during CY 2024 and that continue to be approved, CMS will add their product specific HCPCS codes, when created, to the C–APC exclusion list. For example, HCPCS code J3392 (Injection, exagamglogene autotemcel, per treatment) effective October 1, 2024, which may be used to describe the product Casgevy, was added to the list of qualifying products. We also thank commenters for their suggestions to add additional drugs and classes of drugs to this C–APC exclusion policy as well as those drugs that are administered during a C–APC procedure. Additionally, we thank the commenter for its suggestion to move some codes that describe the administration of a product from a C–APC to a drug administration APC. We will take this feedback into consideration for future rulemaking. As we stated in the proposed rule, we welcomed comments from readers on the proposal and the potential need for a different, modified, expanded, or supplemental policy for future rulemaking. We believe that cell and gene therapies are a unique class of products, but we believe we need additional evidence and engagement from interested parties concerning whether other identified classes of drugs, biologicals, medical devices, or other products are not supportive of a primary C–APC service but may nonetheless appear on the same claim as a primary C–APC procedure. We strongly believe in the principles of our prospective payment system and the C–APC policy; therefore, we want to ensure than any potential future changes to our C–APC packaging policy maintain these principles.

Commenters suggested that we exclude several additional products from C–APC packaging, such as Lyfgenia, Zynteglo, Hemgenix, Beqvez, Roctavian, and Elevidys. We note that these products are currently on OPPS pass-through status for the duration of CY 2025, and therefore will be excluded from C–APC packaging under that policy. Similarly, in response to commenters suggestion that we apply this policy to cell and gene therapy products assigned to status indicator ''G'', we note that we specifically did not propose to include therapies that are on drug pass-through status, represented by status indicator ''G'' for all of CY 2025 because pass-through drugs are already excluded from C–APC packaging. Please see section V.A of this final rule with comment period for additional information on OPPS drug pass-through status.

Comment: Several commenters recommended that CMS unpackage all status indicator ''K'' drugs from C–APC packaging, which aligned with the 2024 Advisory Panel on Hospital Outpatient Payment recommendation to no longer package drugs with a status indicator of ''K'' into any C–APC and, instead, they recommended CMS provide separate payment for all drugs and biologicals above the drug packaging threshold. Commenters said these status indicator ''K'' drugs should be paid based on 1847A of the Social Security Act and reimbursed at Average Sales Price plus 6 percent rather than packaged. Similarly, a commenter suggested that since drugs on pass-through status are paid separately when billed with a C–APC, that CMS should continue that separately payable status after passthrough status expiration and the transition of that code's status indicator from ''G'' to ''K.''

Commenters suggested that the proportion of status indicator ''K'' drug charges relative to all other charges appearing on C–APCs claims was less than 2.5 percent across all C–APCs. Meaning, in commenters' views, that C–APCs do not inherently involve the provision of status indicator ''K'' drugs. Another commenter recommended that CMS exclude high-cost primary therapy drugs across drug classes and not only to cell and gene therapies, apply the C–APC exclusion to primary therapy drugs that clinically align to C–APCs, and they included specific examples they researched that serve as the primary therapy drugs similar to cell and gene therapies.

Response: We appreciate the information submitted by commenters, but respectfully disagree with their conclusions. The C–APC policy aims to package payment for items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to the primary service and provided during the delivery of the comprehensive service, including diagnostic procedures, laboratory tests and other diagnostic tests and treatments that assist in the delivery of the primary procedure. We believe it is appropriate for most drugs and biologicals to be packaged into C–APCs as we believe they function to ''promote a beneficial outcome'' or ''prevent possible complications'' of C–APC services. We explained in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74868) that intravenous drugs, for example, are OPPS services that are considered adjunctive to the primary procedure because the correct administration of the drug either promotes a beneficial outcome, such as the use of intravenous pain medications, or prevents possible complications, such as the use of intravenous blood pressure medications to temporarily replace oral blood pressure medications and reduce the risk of a sudden rise in blood pressure when a normal daily medication is stopped. We are therefore not excluding all status indicator ''K'' drugs above the drug packaging threshold from C–APC packaging. Our packaging policies are a fundamental component of the OPPS and they support our strategic goal of using larger payment bundles in the OPPS to maximize hospitals' incentives to provide care in the most efficient manner. Additionally, we do not believe at this time that cost alone is a reason to exclude a product from packaging.

Comment: Many commenters responded to several of our requests for comment associated with the proposal. Commenters recommended no significant overall changes to the general methodology CMS proposed to exclude products from all C–APC packaging and pay separately based on the individual product's average sales price plus 6 percent. Specifically, commenters strongly conveyed that they did not see an appropriate reason for CMS to structure a new C–APC, or similar packaged payment policy, for the service to administer cell or gene therapies, such as by creating a CAR T-cell therapy administration C–APC. Commenters believed that there is no accurate way to create a bundled payment for a whole group of cell and gene therapies as the costs and resources required are unique and novel between each of the therapies, which also makes it difficult to determine appropriate items and services associated with each therapy for inclusion in C–APC packaging. Commenters broadly believed no

different or supplemental policy was warranted given the numerous challenges providers face related to cell and gene therapies currently. They saw any additional change to move towards a packaged payment policy as an additional challenge for the hospitals providing the therapies.

Similarly, commenters cautioned CMS against creating C–APCs for cell and gene therapies as this may cause inadequate Medicare reimbursement to hospitals, which, in their view, has the potential to jeopardize beneficiary access to CAR T-cell therapy and other high-cost therapies as commenters communicated that institutions weigh reimbursement challenges with their ability to provide this costly care. Commenters were concerned that creating a new packaged payment policy could lead to a financial loss and decrease the number of facilities offering high-cost cell and gene therapies in the hospital outpatient department.

Commenters emphasized that these therapies involve highly specialized procedures, intensive monitoring, and multidisciplinary care teams, all of which contribute to their substantial costs. Commenters were concerned by the fact that the administration of cell and gene therapies are multi-step processes that can take weeks if not months and entail multiple services that would not appear on the same claim. Additional commenters reiterated that all of the various and distinct clinical services for CAR T-cell therapy are furnished over multiple encounters on different dates—making CAR T-cell therapy inappropriate for C–APCs, which are typically specific to a single encounter in their view. Commenters believed a CAR T-cell therapy C–APC, or similar packaged payment policy, would be unprecedented and a huge policy departure for CMS and recommended CMS not pursue the idea any further.

Many commenters believed that separate payment based on average sales price plus 6 percent is the most appropriate payment methodology for cell and gene therapies due to its transparency, uniformity and predictability. A few commenters pointed out that current hospital cost data is lower than ASP for CAR T-cell therapy products, potentially leaving products underpaid if paid based on C–APC principles. Commenters similarly took the position that there is no appropriate method in which CMS could modify its outlier payment policy with respect to C–APCs to better pay for these types of products.

Response: We appreciate the insights provided by commenters and will take them into consideration for future rulemaking. At this time, we are not considering the creation of a new C–APC, similar packaged payment policy, or modified outlier policy, for services to administer cell or gene therapies.

After consideration of the public comments we received, we are finalizing our policy proposal with a modification with respect to how long this policy will apply. For CY 2025 and subsequent years, we are finalizing a policy not to package payment for cell and gene therapies into C–APCs, when those cell and gene therapies are not functioning as integral, ancillary, supportive, dependent, or adjunctive to the primary C–APC service. For new cell and gene therapy products that are not integral, ancillary, supportive, dependent, or adjunctive to any C–APC primary service, we will continue to add their product specific HCPCS codes, when created, to the C–APC exclusion list. The current list of qualifying products can be found in Table 4. We are not adding any additional drug classes to this policy exclusion at this time, and we are not currently considering any additional modifications to our policy, but will continue to consider additional refinements for future rulemaking.

We list all final C–APC exclusion categories for CY 2025 in Addendum J to this final rule (which is available via the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*).

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TABLE 4: CELL AND GENE THERAPIES FINALIZED FOR EXCLUSION FROM C-APC PACKAGING FOR CY 2025

Trade Name	HCPCS Code	Long Descriptor
Yescarta	Q2041	Axicabtagene ciloleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Kymriah	Q2042	Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Provenge	Q2043	Sipuleucel-t, minimum of 50 million autologous cd54+ cells activated with pap-gm-csf, including leukapheresis and all other preparatory procedures, per infusion
Tecartus	Q2053	Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Breyanzi	Q2054	Lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Abecma	Q2055	Idecabtagene vicleucel, up to 510 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Carvytki	Q2056	Ciltacabtagene autoleucel, up to 100 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Luxturna	J3398	Injection, voretigene neparvovec-rzyl, 1 billion vector genomes
Zolgensma	J3399	Injection, onasemnogene abeparvovec-xioi, per treatment, up to 5x10^15 vector genomes
CASGEVY	J3392	Injection, exagamglogene autotemcel, per treatment

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(5) Exclusion of Non-Opioid Products for Pain Relief Under Section 4135 of the Consolidated Appropriations Act, 2023 From the C–APC Policy

The Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–328), was signed into law on December 29, 2022. Section 4135(a) and (b) of the CAA, 2023, titled ''Access to Non-Opioid Treatments for Pain Relief,'' amended section 1833(t)(16) and section 1833(i) of the Social Security Act, respectively, to provide for temporary additional payments for non-opioid treatments for pain relief (as that term is defined in section 1833(t)(16)(G)(i) of the Act). In particular, section 1833(t)(16)(G) provides that with respect to a non-opioid treatment for pain relief furnished on or after January 1, 2025,

and before January 1, 2028, the Secretary shall not package payment for the non-opioid treatment for pain relief into payment for a covered OPD service (or group of services) and shall make an additional payment for the non-opioid treatment for pain relief as specified in clause (ii) of that section. Clauses (ii) and (iii) of section 1833(t)(16)(G) of the Act provide for the amount of additional payment and set a limitation on that amount. As stated earlier in this section, our current policy is to exclude from the packaged C–APC payment those items and services that are required by statute to be separately paid.

Accordingly, we proposed to exclude the non-opioid treatments for pain relief identified as satisfying the required criteria for payment under section 4135 of the CAA, 2023 from the C–APC policy to ensure payment is not packaged into any C–APC and that separate payment is made in accordance with the statute.

Comment: Commenters were generally supportive of our proposal not to package payment and to pay separately for qualifying drugs, biologicals, and medical devices that met the criteria for payment under section 4135 of the CAA, 2023. A commenter mentioned its support of CMS packaging policies, and noted reservations about paying separately, and not packaging, non-opioid treatments for pain relief; however, they ultimately conceded that CMS must implement section 4135 of the CAA, 2023, which requires separately payable status, and supported CMS's implementation methodology.

Response: We thank commenters for their support.

After consideration of the public comments we received, we are finalizing our policy as proposed, and will exclude the non-opioid treatments for pain relief identified as satisfying the required criteria for payment under section 4135 of the CAA, 2023 from the C–APC policy to ensure payment is not packaged into any C–APC and that separate payment is made in accordance with the statute. Please see section XIII.F of this final rule with comment period for a list of the products that we are finalizing would qualify for payment under the new payment policy for non-opioid drugs, biologicals, and devices for pain relief.

(6) C–APCs for CY 2025

For CY 2025 and subsequent years, we proposed to continue to apply the C–APC payment policy methodology. We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79583) for a discussion of the C–APC payment policy methodology and revisions.

Each year, in accordance with section 1833(t)(9)(A) of the Act, we review and revise the services within each APC group and the APC assignments under the OPPS. As a result of our annual review of the services and the APC assignments under the OPPS, we did not propose to convert any standard APCs to C–APCs in CY 2025; thus, we proposed that the number of C–APCs for CY 2025 would be the same as the number for CY 2024, which is 72 C–APCs.

Comment: A few commenters requested that CMS reconsider our packaging policies for C–APC 8011 (Comprehensive Observation Services). They requested that CMS remove the rule that the presence of a SI ''T'' procedure on a claim excludes payment of C–APC 8011 and instead package the payment of the SI ''T'' procedure into C–APC 8011, as is already done with SI ''Q'' procedures. Commenters stated that this requirement violates the basic tenet of the packaging concept in that when observation services are ordered and furnished, the observation services become the primary service provided to such patients and the SI ''T'' procedure is provided ancillary to that primary service. Commenters cited scenarios in which hospitals provide significant, resource-intensive services to a patient but are paid significantly less than if a SI ''T'' procedure was not done.

Response: We thank the commenters for bringing this to our attention. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70334–70336), in response to commenters' concerns regarding packaging payment for potentially high-cost surgical procedures into the payment for an observation C–APC, we finalized a policy that claims reporting procedures assigned status indicator ''T'' do not qualify for payment through C–APC 8011, regardless of whether the procedure assigned status indicator ''T'' was furnished before or after observation services (described by HCPCS code G0378) were provided. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79562), we stated that services that would otherwise qualify for C–APC 8011 are not considered to be observation services when they are associated with a surgical procedure (assigned to status indicator ''T''). Instead, they are considered to be perioperative recovery, which is always packaged in with the surgical procedure. We will continue to review the impacts of this issue and may revisit it in future rulemaking.

Comment: Two commenters expressed concerns with the C–APC methodology for surgical insertion codes for brachytherapy treatment, stating that these concerns impact beneficiary access to brachytherapy in the HOPD setting. These commenters stated that the C–APC methodology lacks the appropriate charge capture mechanisms to accurately reflect the services associated with the C–APC, that there are significant variations in the clinical practice and billing patterns in the hospital claims data used for ratesetting, and that the C–APC rates do not accurately or fully reflect the services and costs associated with the primary procedure. Commenters urged the agency to explore alternatives, including that CMS discontinue the C–APC policy for all brachytherapy insertion codes. Alternatively, one commenter suggested that CMS could continue to pay for ''J1'' brachytherapy insertion codes under the C–APC payment methodology but exclude and make separate payment for designated preparation and planning services in addition to the C–APC payment. Another commenter called for education on whether services, like brachytherapy, that are assigned to a J1 indicators and delivered over multiple patient encounters may be reported per encounter.

Response: We appreciate the comments on the C–APC methodology. However, we believe that the current C–APC methodology is appropriately applied to surgical insertion for brachytherapy treatment procedures and is accurately capturing costs, particularly as the brachytherapy sources used for these procedures are excluded from C–APC packaging and are separately payable. We will evaluate if provider education may be appropriate in this circumstance. We will continue to examine these concerns and will determine if any modifications on this policy are warranted in future rulemaking.

After consideration of the public comments we received, we are finalizing the C–APCs as proposed. Table 5 lists the final C–APCs for CY 2025. All C–APCs are displayed in Addendum J to this CY 2025 OPPS/ASC final rule with comment period (which is available via the internet on the CMS website). Addendum J to this final rule with comment period also contains all of the data related to the C–APC payment policy methodology, including the list of complexity adjustments and other information for CY 2025.

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TABLE 5: FINAL CY 2025 C-APCs

C-APC	CY 2025 APC Group Title	Clinical Family	New C-APC
5072	Level 2 Excision/Biopsy/Incision and Drainage	EBIDX	
5073	Level 3 Excision/Biopsy/Incision and Drainage	EBIDX	
5091	Level 1 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5092	Level 2 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5093	Level 3 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5094	Level 4 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5112	Level 2 Musculoskeletal Procedures	ORTHO	
5113	Level 3 Musculoskeletal Procedures	ORTHO	
5114	Level 4 Musculoskeletal Procedures	ORTHO	
5115	Level 5 Musculoskeletal Procedures	ORTHO	
5116	Level 6 Musculoskeletal Procedures	ORTHO	
5153	Level 3 Airway Endoscopy	AENDO	
5154	Level 4 Airway Endoscopy	AENDO	
5155	Level 5 Airway Endoscopy	AENDO	
5163	Level 3 ENT Procedures	ENTXX	
5164	Level 4 ENT Procedures	ENTXX	
5165	Level 5 ENT Procedures	ENTXX	
5166	Cochlear Implant Procedure	COCHL	
5182	Level 2 Vascular Procedures	VASCX	
5183	Level 3 Vascular Procedures	VASCX	
5184	Level 4 Vascular Procedures	VASCX	
5191	Level 1 Endovascular Procedures	EVASC	
5192	Level 2 Endovascular Procedures	EVASC	
5193	Level 3 Endovascular Procedures	EVASC	
5194	Level 4 Endovascular Procedures	EVASC	
5200	Implantation Wireless PA Pressure Monitor	WPMXX	
5211	Level 1 Electrophysiologic Procedures	EPHYS	
5212	Level 2 Electrophysiologic Procedures	EPHYS	
5213	Level 3 Electrophysiologic Procedures	EPHYS	
5222	Level 2 Pacemaker and Similar Procedures	AICDP	
5223	Level 3 Pacemaker and Similar Procedures	AICDP	
5224	Level 4 Pacemaker and Similar Procedures	AICDP	
5231	Level 1 ICD and Similar Procedures	AICDP	
5232	Level 2 ICD and Similar Procedures	AICDP	
5244	Level 4 Blood Product Exchange and Related Services	SCTXX	
5302	Level 2 Upper GI Procedures	GIXXX	
5303	Level 3 Upper GI Procedures	GIXXX	

C-APC	CY 2025 APC Group Title	Clinical Family	New C-APC
5313	Level 3 Lower GI Procedures	GIXXX	
5331	Complex GI Procedures	GIXXX	
5341	Level 1 Abdominal/Peritoneal/Biliary and Related Procedures	GIXXX	
5342	Level 2 Abdominal/Peritoneal/Biliary and Related Procedures	GIXXX	
5361	Level 1 Laparoscopy and Related Services	LAPXX	
5362	Level 2 Laparoscopy and Related Services	LAPXX	
5372	Level 2 Urology and Related Services	UROXX	
5373	Level 3 Urology and Related Services	UROXX	
5374	Level 4 Urology and Related Services	UROXX	
5375	Level 5 Urology and Related Services	UROXX	
5376	Level 6 Urology and Related Services	UROXX	
5377	Level 7 Urology and Related Services	UROXX	
5378	Level 8 Urology and Related Services	UROXX	
5414	Level 4 Gynecologic Procedures	GYNXX	
5415	Level 5 Gynecologic Procedures	GYNXX	
5416	Level 6 Gynecologic Procedures	GYNXX	
5431	Level 1 Nerve Procedures	NERVE	
5432	Level 2 Nerve Procedures	NERVE	
5461	Level 1 Neurostimulator and Related Procedures	NSTIM	
5462	Level 2 Neurostimulator and Related Procedures	NSTIM	
5463	Level 3 Neurostimulator and Related Procedures	NSTIM	
5464	Level 4 Neurostimulator and Related Procedures	NSTIM	
5465	Level 5 Neurostimulator and Related Procedures	NSTIM	
5471	Implantation of Drug Infusion Device	PUMPS	
5491	Level 1 Intraocular Procedures	INEYE	
5492	Level 2 Intraocular Procedures	INEYE	
5493	Level 3 Intraocular Procedures	INEYE	
5494	Level 4 Intraocular Procedures	INEYE	
5495	Level 5 Intraocular Procedures	INEYE	
5496	Level 6 Intraocular Procedures	INEYE	
5503	Level 3 Extraocular, Repair, and Plastic Eye Procedures	EXEYE	
5504	Level 4 Extraocular, Repair, and Plastic Eye Procedures	EXEYE	
5627	Level 7 Radiation Therapy	RADTX	
5881	Ancillary Outpatient Services When Patient Dies	N/A	
8011	Comprehensive Observation Services	N/A	

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C–APC Clinical Family Descriptor Key:

AENDO = Airway Endoscopy
AICDP = Automatic Implantable Cardiac Defibrillators, Pacemakers, and Related Devices.
BREAS = Breast Surgery
COCHL = Cochlear Implant
EBIDX = Excision/Biopsy/Incision and Drainage
ENTXX = ENT Procedures
EPHYS = Cardiac Electrophysiology/
EVASC = Endovascular Procedures
EXEYE = Extraocular Ophthalmic Surgery
GIXXX = Gastrointestinal Procedures
GYNXX = Gynecologic Procedures
INEYE = Intraocular Surgery
LAPXX = Laparoscopic Procedures
NERVE = Nerve Procedures
NSTIM = Neurostimulators
ORTHO = Orthopedic Surgery
PUMPS = Implantable Drug Delivery Systems
RADTX = Radiation Oncology
SCTXX = Stem Cell Transplant

UROXX = Urologic Procedures
VASCX = Vascular Procedures
WPMXX = Wireless PA Pressure Monitor

c. Calculation of Composite APC Criteria-Based Costs

As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66613), we believe it is important that the OPPS enhance incentives for hospitals to provide necessary, high-quality care as efficiently as possible. For CY 2008, we developed composite APCs to provide a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service. Combining payment for multiple, independent services into a single OPPS payment in this way enables hospitals to manage their resources with maximum flexibility by monitoring and adjusting the volume and efficiency of services themselves. An additional advantage to the composite APC model is that we can use data from correctly coded multiple procedure claims to calculate payment rates for the specified combinations of services, rather than relying upon single procedure claims which may be low in volume and/or incorrectly coded. Under the OPPS, we currently have composite policies for mental health services and multiple imaging services. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66611 through 66614 and 66650 through 66652) for a full discussion of the development of the composite APC methodology, and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74163) and the CY 2018 OPPS/ASC final rule with comment period (82 FR 59241, 59242, and 59246 through 52950) for more recent background.

(1) Mental Health Services Composite APC

For CY 2025, we proposed to continue our longstanding policy of limiting the aggregate payment for specified less resource-intensive mental health services furnished on the same date to the payment for a day of partial hospitalization services provided by a hospital, which we consider to be the most resource-intensive of all outpatient mental health services (88 FR 49572). We refer readers to the April 7, 2000, OPPS final rule with comment period (65 FR 18452 through 18455) for the initial discussion of this longstanding policy and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74168) for more recent background.

In the CY 2018 OPPS/ASC proposed rule and final rule with comment period (82 FR 33580 and 33581 and 82 FR 59246 and 59247), we proposed and finalized the policy for CY 2018 and subsequent years that, when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on a single date of service, based on the payment rates associated with the APCs for the individual services, exceeds the maximum per diem payment rate for partial hospitalization services provided by a hospital, those specified mental health services will be paid through composite APC 8010 (Mental Health Services Composite). In addition, we set the payment rate for composite APC 8010 for CY 2018 at the same payment rate for APC 5863, which was the maximum partial hospitalization per diem payment rate for a hospital, and finalized a policy that the hospital would continue to be paid the payment rate for composite APC 8010. This policy applied in CYs 2018 through 2023.

In the CY 2024 OPPS/ASC proposed rule, we stated that APC 5863 was no longer the maximum partial hospitalization per diem payment rate for a hospital due to the creation of APC 5864, which is four or more hospital-based PHP services per day (88 FR 49572). We solicited comment on whether APC 5864 would be appropriate to use as the daily mental health cap, as we have historically set the daily mental health cap for composite APC 8010 at the maximum partial hospitalization per diem payment rate for a hospital (88 FR 49572). Based on public comments received and our longstanding policy, in CY 2024 OPPS/ASC final rule, we finalized APC 5864, four hospital-based PHP services per day, as the daily mental health cap (88 FR 81566).

We continue to believe that the costs associated with administering a partial hospitalization program represent the most resource intensive of all outpatient mental health services. For CY 2025 and subsequent years, we proposed to continue this policy that when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on a single date of service, based on the payment rates associated with the APCs for the individual services, exceeds the per diem payment rate for 4 partial hospitalization services provided in a day by a hospital (the payment amount for APC 5864), those specified mental health services would be paid through composite APC 8010. In addition, we proposed to continue to set the payment rate for composite APC 8010 at the same payment rate that we propose for APC 5864, which is a partial hospitalization per diem payment rate for 4 partial hospitalization services furnished in a day by a hospital.

Under the proposed policy, the Integrated OCE (I/OCE) would continue to determine whether to pay for these specified mental health services individually, or to make a single payment at the same payment rate established for APC 5864 for all the specified mental health services furnished by the hospital on that single date of service by paying for the services through composite APC 5863.

Comment: One commenter recommended that CMS change the status indicator for two neuropsychological testing codes (HCPCS codes 96133 and 96137) from SI = N to SI = Q3 to allow separate payment for additional hours of testing or increase the payment rate for the primary testing procedure codes. Noting the multiple day structure of neuropsychological testing, they requested a daily payment for each date of service. The commenters noted that the payment rate for Composite APC 8010, which is capped at the maximum per diem partial hospitalization rate, is lower than the individual HCPCS code APC payment rates and does not provide sufficient payment for these procedures.

Response: After reviewing this issue, we believe the Composite APC methodology is being appropriately applied in this case. Composite APCs provide a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service.

The words ''list separately in addition to code for primary procedure'' are included in the long descriptors for HCPCS codes 96133 and 96137 to indicate that that the codes are considered ''add-ons'' to another primary code that cannot be reported independently. Specifically, add-on codes must always be reported with another primary code on the same day. The AMA states in the CPT 2024 Professional Edition (page xviii) that ''add-on codes are always performed in addition to the primary service or procedure and must never be reported as a stand-alone code.'' In most cases, add-on codes are typically ancillary and supportive to a primary diagnostic or therapeutic modality and are an integral part of the primary service they support. As specified under 42 CFR 419.2(b)(18), certain services described by add-on codes are generally packaged under the OPPS, and payments for the codes are bundled with the primary codes.

Consequently, HCPCS codes 96133 and 96137 are not paid separately under the OPPS, but instead, their payment is packaged into the primary code.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59246 through 59247), we stated that the costs associated with administering a partial hospitalization program at a hospital represent the most resource intensive of all outpatient mental health services. We continue to believe that the Composite APC methodology, which limits the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on a single date of service, based on the payment rates associated with the APCs for the individual services, to the per diem payment rate for four partial hospitalization services provided in a day by a hospital (the payment amount for APC 5864), is appropriate.

We will continue to examine these concerns and will determine if any modifications to this policy are warranted in future rulemaking.

After consideration of the public comments we received, we are finalizing our proposal, without modification, that when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on a single date of service, based on the payment rates associated with the APCs for the individual services, exceeds the maximum per diem payment rate for four partial hospitalization services provided in a day by a hospital (the payment amount for APC 5864), those specified mental health services would be paid through composite APC 8010 for CY 2025. In addition, we are finalizing setting the payment rate for composite APC 8010 for CY 2025 at the same payment rate that we set for APC 5864, which is the maximum partial hospitalization per diem payment rate for a hospital.

(2) Multiple Imaging Composite APCs (APCs 8004, 8005, 8006, 8007, and 8008)

Effective January 1, 2009, we provide a single payment each time a hospital submits a claim for more than one imaging procedure within an imaging family on the same date of service, to reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session (73 FR 41448 through 41450). We utilize three imaging families based on imaging modality for purposes of this methodology: (1) ultrasound; (2) computed tomography (CT) and computed tomographic angiography (CTA); and (3) magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA). The HCPCS codes subject to the multiple imaging composite policy and their respective families are listed in Table 6.

While there are three imaging families, there are five multiple imaging composite APCs due to the statutory requirement under section 1833(t)(2)(G) of the Act that we differentiate payment for OPPS imaging services provided with and without contrast. While the ultrasound procedures included under the policy do not involve contrast, both CT/CTA and MRI/MRA scans can be provided either with or without contrast. The five multiple imaging composite APCs established in CY 2009 are:

- APC 8004 (Ultrasound Composite);
- APC 8005 (CT and CTA without Contrast Composite);
- APC 8006 (CT and CTA with Contrast Composite);
- APC 8007 (MRI and MRA without Contrast Composite); and
- APC 8008 (MRI and MRA with Contrast Composite).

We define the single imaging session for the ''with contrast'' composite APCs as having at least one or more imaging procedures from the same family performed with contrast on the same date of service. For example, if the hospital performs an MRI without contrast during the same session as at least one other MRI with contrast, the hospital will receive payment based on the payment rate for APC 8008, the ''with contrast'' composite APC.

We make a single payment for those imaging procedures that qualify for payment based on the composite APC payment rate, which includes any packaged services furnished on the same date of service. The standard (noncomposite) APC assignments continue to apply for single imaging procedures and multiple imaging procedures performed across families. For a full discussion of the development of the multiple imaging composite APC methodology, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68559 through 68569).

For CY 2025, we proposed to continue to pay for all multiple imaging procedures within an imaging family performed on the same date of service using the multiple imaging composite APC payment methodology. We continue to believe that this policy would reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session.

For CY 2025, except where otherwise indicated, we proposed to use the costs derived from CY 2023 claims data to set the proposed CY 2025 payment rates. Therefore, for CY 2025, the proposed payment rates for the five multiple imaging composite APCs (APCs 8004, 8005, 8006, 8007, and 8008) were based on proposed geometric mean costs calculated from CY 2023 claims available for the CY 2025 OPPS/ASC proposed rule that qualify for composite payment under the current policy (that is, those claims reporting more than one procedure within the same family on a single date of service). To calculate the proposed geometric mean costs, we used the same methodology that we used to calculate the geometric mean costs for these composite APCs since CY 2014, as described in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918). The imaging HCPCS codes referred to as ''overlap bypass codes'' that we removed from the bypass list for purposes of calculating the proposed multiple imaging composite APC geometric mean costs, in accordance with our established methodology as stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918), are identified by asterisks in Addendum N to this final rule with comment period (which is available via the internet on the CMS website) and are discussed in more detail in section II.A.1.a of the this final rule with comment period.

For this final rule with comment period, we were able to identify approximately 0.95 million ''single session'' claims out of an estimated 2.1 million potential claims for payment through composite APCs from our ratesetting claims data, which represents approximately 45.0 percent of all eligible claims, to calculate the final CY 2025 geometric mean costs for the multiple imaging composite APCs. Table 6 lists the final HCPCS codes that would be subject to the multiple imaging composite APC policy and their respective families and approximate composite APC final geometric mean costs for CY 2025.

We did not receive any public comments on this policy. We are finalizing without modification our proposal to continue the use of multiple imaging composite APCs to pay for the provision of more than one imaging procedure from the same imaging family on the same date. Table 6 lists the HCPCS codes that will be subject to the multiple imaging composite APC policy and their respective imaging families and approximate composite APC final geometric mean costs for CY 2025.

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TABLE 6: OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS

Family 1 – Ultrasound	
CY 2025 APC 8004 (Ultrasound Composite)	**CY 2025 Approximate APC Geometric Mean Cost = $310.21**
76700	Us exam, abdom, complete
76705	Echo exam of abdomen
76770	Us exam abdo back wall, comp
76776	Us exam k transpl w/Doppler
76831	Echo exam, uterus
76856	Us exam, pelvic, complete
76857	Us exam, pelvic, limited
76981	Us parenchyma
76982	Us 1st target lesion
Family 2 - CT and CTA with and without Contrast	
CY 2025 APC 8005 (CT and CTA without Contrast Composite) *	**CY 2025 Approximate APC Geometric Mean Cost = $227.27**
0633T	Ct breast w/3d uni c-
0636T	Ct breast w/3d bi c-
70450	Ct head/brain w/o dye
70480	Ct orbit/ear/fossa w/o dye
70486	Ct maxillofacial w/o dye
70490	Ct soft tissue neck w/o dye
71250	Ct thorax w/o dye
72125	Ct neck spine w/o dye
72128	Ct chest spine w/o dye
72131	Ct lumbar spine w/o dye
72192	Ct pelvis w/o dye
73200	Ct upper extremity w/o dye
73700	Ct lower extremity w/o dye
74150	Ct abdomen w/o dye
74176	Ct angio abd & pelvis
74261	Ct colonography, w/o dye
CY 2025 APC 8006 (CT and CTA with Contrast Composite)	**CY 2025 Approximate APC Geometric Mean Cost = $440.40**
0634T	Ct breast w/3d uni c+
0635T	Ct breast w/3d uni c-/c+
0637T	Ct breast w/3d bi c+
0638T	Ct breast w/3d bi c-/c+
70460	Ct head/brain w/dye
70470	Ct head/brain w/o & w/dye

70481	Ct orbit/ear/fossa w/dye
70482	Ct orbit/ear/fossa w/o & w/dye
70487	Ct maxillofacial w/dye
70488	Ct maxillofacial w/o & w/dye
70491	Ct soft tissue neck w/dye
70492	Ct sft tsue nck w/o & w/dye
70496	Ct angiography, head
70498	Ct angiography, neck
71260	Ct thorax w/dye
71270	Ct thorax w/o & w/dye
71275	Ct angiography, chest
72126	Ct neck spine w/dye
72127	Ct neck spine w/o & w/dye
72129	Ct chest spine w/dye
72130	Ct chest spine w/o & w/dye
72132	Ct lumbar spine w/dye
72133	Ct lumbar spine w/o & w/dye
72191	Ct angiograph pelv w/o & w/dye
72193	Ct pelvis w/dye
72194	Ct pelvis w/o & w/dye
73201	Ct upper extremity w/dye
73202	Ct uppr extremity w/o & w/dye
73206	Ct angio upr extrm w/o & w/dye
73701	Ct lower extremity w/dye
73702	Ct lwr extremity w/o & w/dye
73706	Ct angio lwr extr w/o & w/dye
74160	Ct abdomen w/dye
74170	Ct abdomen w/o & w/dye
74175	Ct angio abdom w/o & w/dye
74177	Ct angio abd & pelv w/contrast
74178	Ct angio abd & pelv 1+ regns
74262	Ct colonography, w/dye
75635	Ct angio abdominal arteries
* If a "without contrast" CT or CTA procedure is performed during the same session as a "with contrast" CT or CTA procedure, the I/OCE assigns the procedure to APC 8006 rather than APC 8005.	
Family 3 - MRI and MRA with and without Contrast	
CY 2025 APC 8007 (MRI and MRA without Contrast Composite) *	**CY 2025 Approximate APC Geometric Mean Cost = $546.82**
0609T	Mrs disc pain acquisj data
70336	Magnetic image, jaw joint
70540	Mri orbit/face/neck w/o dye

70544	Mr angiography head w/o dye
70547	Mr angiography neck w/o dye
70551	Mri brain w/o dye
70554	Fmri brain by tech
71550	Mri chest w/o dye
72141	Mri neck spine w/o dye
72146	Mri chest spine w/o dye
72148	Mri lumbar spine w/o dye
72195	Mri pelvis w/o dye
73218	Mri upper extremity w/o dye
73221	Mri joint upr extrem w/o dye
73718	Mri lower extremity w/o dye
73721	Mri jnt of lwr extre w/o dye
74181	Mri abdomen w/o dye
75557	Cardiac mri for morph
75559	Cardiac mri w/stress img
76391	Mr elastography
77046	Mri breast c- unilateral
77047	Mri breast c- bilateral
C8901	MRA w/o cont, abd
C8910	MRA w/o cont, chest
C8913	MRA w/o cont, lwr ext
C8919	MRA w/o cont, pelvis
C8932	MRA, w/o dye, spinal canal
C8935	MRA, w/o dye, upper extr
C9762	Cardiac MRI seg dys strain
C9763	Cardiac MRI seg dys stress
CY 2025 APC 8008 (MRI and MRA with Contrast Composite)	**CY 2025 Approximate APC Geometric Mean Cost = $865.19**
70542	Mri orbit/face/neck w/dye
70543	Mri orbt/fac/nck w/o & w/dye
70545	Mr angiography head w/dye
70546	Mr angiograph head w/o & w/dye
70547	Mr angiography neck w/o dye
70548	Mr angiography neck w/dye
70549	Mr angiograph neck w/o & w/dye
70552	Mri brain w/dye
70553	Mri brain w/o & w/dye
71551	Mri chest w/dye
71552	Mri chest w/o & w/dye
72142	Mri neck spine w/dye
72147	Mri chest spine w/dye

72149	Mri lumbar spine w/dye
72156	Mri neck spine w/o & w/dye
72157	Mri chest spine w/o & w/dye
72158	Mri lumbar spine w/o & w/dye
72196	Mri pelvis w/dye
72197	Mri pelvis w/o & w/dye
73219	Mri upper extremity w/dye
73220	Mri uppr extremity w/o & w/dye
73222	Mri joint upr extrem w/dye
73223	Mri joint upr extr w/o & w/dye
73719	Mri lower extremity w/dye
73720	Mri lwr extremity w/o & w/dye
73722	Mri joint of lwr extr w/dye
73723	Mri joint lwr extr w/o & w/dye
74182	Mri abdomen w/dye
74183	Mri abdomen w/o & w/dye
75561	Cardiac mri for morph w/dye
75563	Card mri w/stress img & dye
C8900	MRA w/cont, abd
C8902	MRA w/o fol w/cont, abd
C8903	MRI w/cont, breast, uni
C8905	MRI w/o fol w/cont, brst, un
C8906	MRI w/cont, breast, bi
C8908	MRI w/o fol w/cont, breast,
C8909	MRA w/cont, chest
C8911	MRA w/o fol w/cont, chest
C8912	MRA w/cont, lwr ext
C8914	MRA w/o fol w/cont, lwr ext
C8918	MRA w/cont, pelvis
C8920	MRA w/o fol w/cont, pelvis
C8931	MRA, w/dye, spinal canal
C8933	MRA, w/o&w/dye, spinal canal
C8934	MRA, w/dye, upper extremity
C8936	MRA, w/o&w/dye, upper extr
* If a “without contrast” MRI or MRA procedure is performed during the same session as a “with contrast” MRI or MRA procedure, the I/OCE assigns the procedure to APC 8008 rather than APC 8007.	

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3. Changes to Packaged Items and Services

a. Background and Rationale for Packaging in the OPPS

Like other prospective payment systems, the OPPS relies on the concept of averaging to establish a payment rate for services. The payment may be more or less than the estimated cost of providing a specific service or a bundle of specific services for a particular beneficiary. The OPPS packages payments for multiple interrelated items

and services into a single payment to create incentives for hospitals to furnish services most efficiently and to manage their resources with maximum flexibility. Our packaging policies support our strategic goal of using larger payment bundles in the OPPS to maximize hospitals' incentives to provide care in the most efficient manner. For example, where there are a variety of devices, drugs, items, and supplies that could be used to furnish a service, some of which are more costly than others, packaging encourages hospitals to use the most cost-efficient item that meets the patient's needs, rather than to routinely use a more expensive item, which may occur if separate payment is provided for the item.

Packaging also encourages hospitals to effectively negotiate with manufacturers and suppliers to reduce the purchase price of items and services or to explore alternative group purchasing arrangements, thereby encouraging the most economical health care delivery. Similarly, packaging encourages hospitals to establish protocols that ensure that necessary services are furnished, while scrutinizing the services ordered by practitioners to maximize the efficient use of hospital resources. Packaging payments into larger payment bundles promotes the predictability and accuracy of payment for services over time. Finally, packaging may reduce the importance of refining service-specific payments because packaged payments include costs associated with higher cost cases requiring many ancillary items and services and lower cost cases requiring fewer ancillary items and services. Packaging encourages efficiency and is an essential component of a prospective payment system, therefore packaging payments for items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service has been a fundamental part of the OPPS since its implementation in August 2000. As we continue to develop larger payment groups that more broadly reflect services provided in an encounter or episode of care, we have expanded the OPPS packaging policies. Most, but not necessarily all, categories of items and services currently packaged in the OPPS are listed in 42 CFR 419.2(b). Our overarching goal is to make payments for all services under the OPPS more consistent with those of a prospective payment system and less like those of a per-service fee schedule, which pays separately for each coded item. As a part of this effort, we have continued to examine the payment for items and services provided under the OPPS to determine which OPPS services can be packaged to further achieve the objective of advancing the OPPS toward a more prospective payment system.

b. Final CY 2025 Policy on Packaged Items and Services

For CY 2025, we examined the items and services currently provided under the OPPS, reviewing categories of integral, ancillary, supportive, dependent, or adjunctive items and services for which we believe payment would be appropriately packaged into payment for the primary service that they support. Specifically, we examined the HCPCS code definitions (including CPT code descriptors) and hospital outpatient department billing patterns to determine whether there were categories of codes for which packaging would be appropriate according to existing OPPS packaging policies or a logical expansion of those existing OPPS packaging policies.

For CY 2025, we did not propose any changes to the overall packaging policy discussed. We proposed to continue to conditionally package the costs of selected newly identified ancillary services into payment for a primary service where we believe that the packaged item or service is integral, ancillary, supportive, dependent, or adjunctive to the provision of care that was reported by the primary service HCPCS code.

While we did not propose any changes to the overall packaging policy, we proposed potential modifications to our packaging policy as described in the following sections.

We did not receive any public comments on our overall packaging policy proposal and therefore, we are finalizing our proposal to continue to conditionally package the costs of selected newly identified ancillary services into payment for a primary service where we believe that the packaged item or service is integral, ancillary, supportive, dependent, or adjunctive to the provision of care that was reported by the primary service HCPCS code, as proposed for CY 2025.

We did receive specific recommendations regarding C–APC packaging of Cell and Gene Therapies and associated products, which are addressed in section II.b.4 of this final rule with comment period, and the packaging of non-opioid treatments for pain relief, which are addressed in section XIII.E of this final rule with comment period. Additionally, commenters made recommendations on our packaging policies in the context of our diagnostic radiopharmaceutical proposal, which is discussed in the next section.

c. Payment for Diagnostic Radiopharmaceuticals

(1) Background on OPPS Packaging Policy for Diagnostic Radiopharmaceuticals

Under the OPPS, we package several categories of nonpass-through drugs, biologicals, and radiopharmaceuticals, regardless of the cost of the products. Because the products are packaged according to the policies in § 419.2(b), we refer to them as ''policy-packaged'' drugs, biologicals, and radiopharmaceuticals. In particular, under § 419.2(b)(15), payment for drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure is packaged with the payment for the related procedure or service. Packaging costs into a single aggregate payment for a service, encounter, or episode of care is a fundamental principle that distinguishes a prospective payment system from a fee schedule. In general, packaging the costs of supportive items and services into the payment for the primary procedure or service with which they are associated encourages hospital efficiencies and enables hospitals to manage their resources with maximum flexibility.

In the CY 2008 OPPS/ASC final rule with comment period we finalized the packaging status of diagnostic radiopharmaceuticals as part of our overall enhanced packaging approach for the CY 2008 OPPS and subsequent years (72 FR 66635 through 66641). Importantly, we believed diagnostic radiopharmaceuticals are always intended to be used with a diagnostic nuclear medicine procedure and function as supplies when used in a diagnostic test or procedure, making it appropriate to package the payment for the diagnostic radiopharmaceutical into the payment for the related nuclear medicine procedure. Diagnostic radiopharmaceuticals are one specific type of product that is policy packaged under the category described by § 419.2(b)(15). Since we implemented this policy in CY 2008, interested parties have raised concerns regarding policy packaging of diagnostic radiopharmaceuticals. In previous rulemaking (87 FR 71962 and 71963), commenters recommended that CMS always pay separately under the OPPS for diagnostic radiopharmaceuticals, not just when the products have pass-through payment status. Many of these commenters mentioned that pass-

through payment status helps the diffusion of new diagnostic radiopharmaceuticals into the market. However, commenters believe the packaged payment rate is often inadequate after pass-through status expires, especially in cases where the diagnostic radiopharmaceutical is high-cost and has low utilization.

We have heard from interested parties regarding alternative payment methodologies, such as subjecting diagnostic radiopharmaceuticals to the drug packaging threshold and creating separate APC payments for diagnostic radiopharmaceuticals with a per-day cost greater than $500. Interested parties have also recommended that we analyze our nuclear medicine APC structure and consider establishing additional nuclear medicine APCs to reflect the costs of diagnostic radiopharmaceuticals more accurately. Historically, commenters opposed incorporating the cost of diagnostic radiopharmaceuticals into the associated nuclear medicine APC as the nuclear medicine APCs are sometimes paid at a lower rate than the payment rate for the diagnostic radiopharmaceutical itself when it has pass-through payment status (87 FR 71962 and 71963).

Importantly, commenters historically have also been concerned that packaging payment for precision diagnostic radiopharmaceuticals in the outpatient hospital setting creates barriers to beneficiary access for safety net hospitals serving a high proportion of Medicare beneficiaries and hospitals serving underserved communities (87 FR 71962 and 71963). Commenters specified that certain populations, such as those with Alzheimer's disease, depend on the use of certain high-cost diagnostic radiopharmaceuticals. Commenters discussed difficulties enrolling hospitals in clinical studies due to OPPS packaging policies and suggested that we pay separately under the OPPS specifically for radiopharmaceuticals that are used for Alzheimer's disease. Additionally, commenters have recommended that CMS continue to apply radiolabeled product edits to the nuclear medicine procedures to ensure that all packaged costs are included on nuclear medicine claims to establish appropriate payment rates in the future. Beginning January 1, 2008, CMS implemented OPPS edits that require hospitals to include a HCPCS code for a radiolabeled product when a separately payable nuclear medicine procedure is present on a claim. This policy to require hospitals to include a HCPCS code for a radiolabeled product for a separately payable nuclear medicine procedure ended in CY 2014 (78 FR 75033 through 75034).

Many of these comments and our responses have been discussed in rulemaking since the policy to package diagnostic radiopharmaceuticals was adopted, and they prompted us to solicit comment on payment for diagnostic radiopharmaceuticals in the CY 2024 OPPS/ASC proposed rule (88 FR 49577). In that proposed rule, we stated we continue to believe that diagnostic radiopharmaceuticals are an integral component of many nuclear medicine and imaging procedures and charges associated with them should be reported on hospital claims to the extent they are used. Accordingly, we reiterated our belief that the payment for the diagnostic radiopharmaceutical should be reflected within the payment for the primary procedure with which it is used. We noted that ratesetting uses the geometric mean of reported procedure costs, which in the example of nuclear medicine procedures includes the costs of the reported diagnostic radiopharmaceutical, based on data submitted to CMS from all hospitals paid under the OPPS to set the payment rate for the service. The costs that are calculated by Medicare reflect the average costs of items and services that are packaged into a primary procedure and will not necessarily equal the sum of the cost of the primary procedure and the Average Sales Price (ASP) of the specific items and services used in the procedure in each case. Furthermore, we explained that the costs are based on the reported costs submitted to Medicare by the hospitals and not the list price established by the manufacturer. Claims data that include the diagnostic radiopharmaceutical packaged with the associated procedure should reflect the combined cost of the procedure and the radiopharmaceutical used in the procedure.

As we have reiterated over the years, we believe packaging policies are inherent principles of the OPPS and are essential to a prospective payment system. At the same time, we have explained that we are committed to ensuring beneficiary access to diagnostic radiopharmaceuticals while also ensuring the availability of new and innovative diagnostic tools for Medicare beneficiaries. Therefore, we sought public comments on potential modifications to our packaging policy for diagnostic radiopharmaceuticals to ensure equitable payment and continued beneficiary access.

As described in the CY 2024 OPPS/ASC proposed rule (88 FR 49578), we solicited comment on how the OPPS packaging policy for diagnostic radiopharmaceuticals has impacted beneficiary access, including whether there are specific patient populations or clinical disease states for whom this issue is especially critical.

In addition, we solicited comment on the following potential approaches that would enhance beneficiary access, while also maintaining the principles of the outpatient prospective payment system. These approaches included: (1) paying separately for diagnostic radiopharmaceuticals with per-day costs above the OPPS drug packaging threshold of $140; (2) establishing a specific per-day cost threshold that may be greater or less than the OPPS drug packaging threshold; (3) restructuring APCs, including by adding nuclear medicine APCs for services that utilize high-cost diagnostic radiopharmaceuticals; (4) creating specific payment policies for diagnostic radiopharmaceuticals used in clinical trials; and (5) adopting codes that incorporate the disease state being diagnosed or a diagnostic indication of a particular class of diagnostic radiopharmaceuticals.

Finally, we were interested in hearing from stakeholders how the suggested policy modifications might impact our overarching goal of utilizing packaging policies to better align OPPS policies with those of a prospective payment system rather than a fee schedule. We stated we would also like to know if making any of the suggested policy changes could have negative consequences for beneficiaries, such as unintentionally influencing clinical practice decisions, increasing beneficiary cost-sharing obligations, or inadvertently encouraging the use of higher-cost diagnostic radiopharmaceuticals over lower cost, but equally effective, diagnostic options.

We received a significant number of comments in response to the comment solicitation on potential issues caused by our current payment policy for diagnostic radiopharmaceuticals under the OPPS and on new approaches to payment for these products. Commenters expressed concerns regarding the CMS policy to package diagnostic radiopharmaceuticals and the financial implications this policy has for facilities. Commenters believe that, for newer, more innovative radiopharmaceuticals, the current OPPS packaging policy has led to a lack of patient access to the technologies after the radiopharmaceutical's pass-through status expires, especially if there is no clinical alternative to the radiopharmaceutical. Most commenters requested that CMS provide separate payment for diagnostic

radiopharmaceuticals. Some commenters believed paying separately for all diagnostic radiopharmaceuticals regardless of their per-day cost was the best methodology to avoid encouraging price inflation for diagnostic radiopharmaceuticals to reach a certain threshold. Other commenters thought that applying the existing OPPS per-day cost threshold ($135 for CY 2024) to the payment of diagnostic radiopharmaceuticals would be an adequate solution. Others supported a $500 threshold, and many cited the Facilitating Innovative Nuclear Diagnostics Act (FIND Act) of 2023 as their rationale for that number and recognized that the $500 threshold number may be a more targeted approach relative to the OPPS drug packaging threshold as the higher cost diagnostic radiopharmaceuticals are the most disadvantaged by the OPPS packaging policy in their view. For the full discussion on the comment solicitation summarized here, refer to the CY 2024 OPPS/ASC final rule with comment period (88 FR 81573 through 81577).

(2) Packaging Threshold for Diagnostic Radiopharmaceuticals

As stated in the CY 2024 OPPS final rule with comment period (88 FR 81577), we agree with commenters that payment for diagnostic radiopharmaceuticals is a complex and important issue. We explained that we intended to further consider these points and take them into consideration for future notice and comment rulemaking. As described in the CY 2025 OPPS/ASC proposed rule (89 FR 59213 through 59222), after significant consideration and ongoing engagement from interested parties, we proposed a change to our current policy that packages diagnostic radiopharmaceuticals regardless of their cost.

We continue to believe diagnostic radiopharmaceuticals are always intended to be used with a diagnostic nuclear medicine procedure and function as supplies when used in a diagnostic test or procedure, generally making it appropriate to package payment for them with payment for the related nuclear medicine procedure. In the CY 2025 OPPS/ASC proposed rule (89 FR 59213 through 59222), we stated that while we continue to believe that this should be the policy for most diagnostic radiopharmaceuticals, we believe there are certain situations in which the packaged payment amount attributed to the diagnostic radiopharmaceutical used in an imaging procedure assigned to a nuclear medicine APC may not adequately account for the cost of a diagnostic radiopharmaceutical that has a significantly higher cost, but lower utilization relative to the other diagnostic radiopharmaceuticals that may be used with the procedure. In situations where a hospital may have to pay significantly more to purchase a diagnostic radiopharmaceutical than Medicare pays, a hospital may decide not to provide that specific diagnostic radiopharmaceutical imaging agent to Medicare beneficiaries. This could potentially deny access to diagnostic tools for which there is no clinical alternative. To ensure Medicare payment policy is not providing a financial disincentive to using high cost, low utilization diagnostic radiopharmaceuticals, especially when those agents may be the most clinically appropriate, and to ensure appropriate beneficiary access, we believe a subset of diagnostic radiopharmaceuticals with higher per day costs should be paid separately and not packaged into the diagnostic procedure with which the diagnostic radiopharmaceutical is used.

To address these concerns, we proposed to pay separately for any diagnostic radiopharmaceutical with a per day cost greater than $630. Any diagnostic radiopharmaceutical with a per day cost below that threshold would continue to be policy packaged under the current policy at § 419.2(b)(15). We discuss our proposed methodology for determining the proposed per day cost threshold of $630 in further detail in this section.

To determine an appropriate threshold for our proposal, we estimated the approximate payment that would typically be attributable to diagnostic radiopharmaceutical payment within each nuclear medicine APC (APCs 5591, 5592, 5593, and 5594). We did this by assessing the offsets associated with these APCs that were directly attributable to ''policy packaged'' drugs. The offset amounts used are correlated with the approximate portion of APC payment associated with these ''policy packaged'' drugs. For nuclear medicine APCs, the primary ''policy packaged'' drugs are diagnostic radiopharmaceuticals. To calculate this threshold, we calculated a volume weighted average of the offset dollar amount of each nuclear medicine APC. This involved taking the offset percentage for ''policy packaged'' drugs, multiplying it by the APC geometric mean to get an offset dollar amount, and then multiplying that offset amount by the number of single claims to get the total offset amount for each nuclear medicine APC level. We then calculated the sum of the total offset amount for all 4 of the nuclear medicine APCs. We divided this number by the total number of single claims for all 4 nuclear medicine APCs, resulting in $314.28, which represents the volume weighted average policy packaged offset amount for the nuclear medicine APC series. We then took that number and multiplied it by 2, and rounded it to the nearest $5 increment, which resulted in $630. See Table 7 for the values used to calculate this threshold amount. We noted that the data values in Table 7 were collected without unpackaging the set of diagnostic radiopharmaceuticals listed in Table 8. We noted that if we finalized our proposal and those diagnostic radiopharmaceuticals were unpackaged, it would change the APC geometric mean unit costs (MUCs) as well as the offset percentages. This is why the APC geometric mean cost values listed below are not the same as in the addenda to this rule.

TABLE 7: CY 2025 COSTS STATISTICS FOR NUCLEAR MEDICINE APCS USED TO CALCULATE $630 THRESHOLD

APC	APC Title	Number of Single Claims	APC Geometric mean Cost	Portion of APC Payment Associated with "Policy Packaged" Drugs / Offset Percent for Packaged Drugs that are Always Packaged
5591	Level 1 Nuclear Medicine and Related Services	155,289	$416.50	0.152
5592	Level 2 Nuclear Medicine and Related Services	60,334	$556.84	0.2146
5593	Level 3 Nuclear Medicine and Related Services	496,758	$1,399.48	0.2387
5594	Level 4 Nuclear Medicine and Related Services	402,439	$1,738.01	0.2393

The offset percentages used were updated based on the available data for the CY 2025 proposed rule and these offset percentages are usually the offsets that are published in the final rule. However, we included the data in Table 7 to illustrate how we arrived at the proposed $630 threshold. Additionally, the file and corresponding offset percentages used for the $630 threshold are similar to and consistent with the ones that can be found in the CY 2024 NFRM APC Offset File. These files are available via the internet on the CMS OPPS website.[7]

We proposed to multiply by two the volume weighted average amount of the offset to establish the threshold triggering separate payment because this amount would ensure that separate payment would apply only to diagnostic radiopharmaceuticals whose costs significantly exceed the approximate amount of payment already attributed to the product in the nuclear medicine APC payment. This is consistent with the principles of a prospective payment system where some payments are lower than hospitals' costs while other payments are greater than a hospitals' costs. However, diagnostic radiopharmaceuticals with costs more than double the volume weighted average amount of the offset could present a hospital with a significant financial loss. This is why the OPPS has several payment provisions that rely on a multiplier of costs as a threshold for modifying payment.

Our proposed approach to multiply the average offset amount by two is consistent with the two-times rule the OPPS uses to determine Ambulatory Payment Classification (APC) levels, where a significant service that has a cost greater than two times the lowest cost significant service in an APC is generally moved to a higher level APC in the series. The two-times rule requires that the highest calculated cost of an individual procedure categorized to any given APC cannot exceed two times the calculated cost of the lowest cost procedure categorized to that same APC. We note that the two-times rule does not apply to diagnostic radiopharmaceuticals themselves, but only to the procedures in which they are used, which is why we are proposing a diagnostic radiopharmaceutical packaging threshold utilizing a similar two-times methodology.

As described in the CY 2025 OPPS/ASC proposed rule (89 FR 59213 through 59222), our proposed approach to multiply the average offset amount by two is also generally consistent with the OPPS outlier policy applicable to certain high-cost procedures, where costs greater than 1.75 times the APC payment trigger an additional outlier payment. The OPPS provides outlier payments to hospitals to help mitigate the financial risk associated with high-cost and complex procedures, where a very costly service could present a hospital with significant financial loss. Outlier payments are provided on a service basis when the cost of a service exceeds the APC payment amount multiplier threshold (1.75) as well as the APC payment amount plus a fixed-dollar amount threshold. The proposed diagnostic radiopharmaceutical packaging threshold would serve a similar purpose as the outlier policy, in that it would provide payments to hospitals to help mitigate the financial risk associated with high-cost diagnostic radiopharmaceuticals, where a very costly diagnostic radiopharmaceutical could present a hospital with significant financial loss.

We proposed a multiplier of two and explained that we believe two is the most appropriate number for the multiplier for the volume weighted average amount of the offset, but we sought comment on the alternatives of using 1.75 times the volume weighted average amount of the offset as the threshold amount for triggering separate payment, or another appropriate multiplier amount. We stated that, for example, an interested party could present data that a financial disincentive to use diagnostic radiopharmaceuticals exists when costs are 1.75 times, or three times or five times, the volume weighted average offset amount. Since the hospital outpatient outlier payment policy is a longstanding policy familiar to most hospitals, we sought comment on utilizing elements of that policy for purposes of our proposed diagnostic radiopharmaceutical packaging policy in order to help hospitals mitigate the financial risk that may be associated with furnishing high-cost and complex diagnostic radiopharmaceuticals. As previously mentioned, we sought comment on the use of 1.75 times as the multiplier threshold rather than 2. Although the outlier policy uses both a 1.75 multiplier threshold and a fixed-dollar threshold, we sought comment regarding the use of 1.75 as the multiplier to set a fixed dollar threshold for the volume weighted average amount of the offset as the goals of the

[7] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/annual-policy-files.*

outlier policy and the proposed diagnostic radiopharmaceutical policy are similar.

We also solicited comment on the alternative of using the standard drug packaging threshold, which was proposed to be $140 for CY 2025 and is being finalized as $140 for CY 2025 in section V.B of this final rule with comment period, as the threshold for separate payment for diagnostic radiopharmaceuticals. We believe that diagnostic radiopharmaceuticals are functioning as supplies to the nuclear medicine procedure in which they are used. Because diagnostic radiopharmaceuticals function as supplies in the diagnostic procedures in which they are used, they are serving as an item that is integral, ancillary, supportive, dependent, or adjunctive to the primary diagnostic service. This is in contrast to therapeutic drugs, biologicals, and therapeutic radiopharmaceuticals that are typically packaged under the standard drug packaging threshold. These products could be the only therapeutic modality provided to a patient during an encounter and may not serve as an item that is integral, ancillary, supportive, dependent, or adjunctive to the primary service. Due to this clinical difference, we did not believe that using the standard drug packaging threshold was appropriate for diagnostic radiopharmaceuticals, and therefore we proposed a threshold specific to diagnostic radiopharmaceuticals. As stated in the CY 2025 OPPS/ASC proposed rule (89 FR 59213 through 59222), we were interested to hear from commenters whether they agreed or disagreed with this assessment.

Comment: A significant portion of commenters provided broad support for CMS's overall proposal regarding payment for diagnostic radiopharmaceuticals, stating that this policy will ensure access for Medicare beneficiaries, empower clinicians to make the best treatment decisions, and encourage innovation from industry. Commenters frequently stated that this policy will ensure access for underrepresented populations, which often have higher rates of disease but lower rates of detection.

Response: We thank commenters for their support.

Comment: Many commenters were supportive of CMS's proposal regarding separate payment for diagnostic radiopharmaceuticals, including the packaging threshold of $630. Commenters appreciated that CMS was targeting those products with costs that significantly exceeded the amount of the current packaged payment. These commenters supported the overall methodology and rationale for the calculation of the threshold, which was based on the approximate payment that would typically be attributable to diagnostic radiopharmaceuticals within each nuclear medicine APC by assessing the offsets associated with these APCs that were directly attributable to ''policy packaged'' drugs. Commenters generally agreed with using two times this amount to establish the threshold as they agreed it correlated with the statutory OPPS two times rule.

Response: We thank commenters for their support of our proposal to create a $630 threshold and the associated methodology used to calculate that threshold.

Comment: While many commenters were supportive of CMS's proposed $630 using the two times threshold multiplier, several said they also would not be opposed to a 1.75 multiplier, which would result in a $550 threshold. Other commenters advocated solely for a 1.75 multiplier citing consistency with the OPPS outlier policy, which they believed is a more appropriate comparator policy than the OPPS two times rule.

Response: The OPPS provides outlier payments to hospitals to help mitigate the financial risk associated with high-cost and complex procedures, where a very costly service could present a hospital with significant financial loss. Outlier payments are provided on a service basis when the cost of a service exceeds the APC payment amount multiplier threshold (1.75) as well as the APC payment amount plus a fixed-dollar amount threshold. An outlier payment is triggered when the cost of a service exceeds two different thresholds, a fixed dollar threshold and a multiplier threshold. A 1.75 multiplier is appropriate for the outlier payment policy as it is combined with a secondary fixed-dollar threshold, which is appropriate for the broader OPPS outlier policy which can apply to a large number of services with vastly different costs and payment amounts. For the OPPS outlier policy, two separate thresholds must be surpassed in order for separate payment to be made. We believe the lower 1.75 multiplier is appropriate for the outlier policy as there is also a secondary threshold that must be met to trigger outlier payments. The single threshold for separate payment for diagnostic radiopharmaceuticals would apply to a much narrower range of products; therefore, we do not believe the same two-threshold system used for OPPS outlier payments is practical. This makes a single threshold more appropriate, and because we are using a single threshold, we believe the higher two times multiplier is more appropriate, as there is not a secondary threshold that must also be surpassed. We believe our proposed approach to multiply the average offset amount by two to set the threshold is the most appropriate approach to determining this threshold, as this results in only those products whose costs significantly exceed, by two-times, the approximate amount of payment already attributed to the product in the nuclear medicine APC payment. This multiplier is consistent with the two-times rule the OPPS uses to determine Ambulatory Payment Classification (APC) levels, which also uses a single two times multiplier, rather than a two-threshold system like the OPPS outlier policy. The OPPS two times rule instructs that a significant service that has a cost greater than two times the lowest cost significant service in an APC is generally moved to a higher-level APC in the series. The two-times rule requires that the highest calculated cost of an individual procedure categorized to any given APC cannot exceed two times the calculated cost of the lowest cost procedure assigned to that same APC. A two times multiplier ensures that separate payment would apply only to diagnostic radiopharmaceuticals whose costs significantly exceed the approximate amount of payment already attributed to the product in the nuclear medicine APC payment.

Comment: A few commenters suggested other thresholds, such as the OPPS drug packaging threshold, in order to treat diagnostic radiopharmaceuticals in a similar manner as other drugs, biologicals, and therapeutic radiopharmaceuticals paid under the OPPS. Commenters also believed that using a lower threshold actually decreased the likelihood that a provider would be financially incentivized to use a product above the threshold, as more products would be paid separately using a lower threshold. They believed a lower threshold decreased the likelihood of a non-clinical financial incentive to use a higher cost radiopharmaceutical. Other commenters believed using a $500 threshold would be appropriate as it coincided with the figure used for separate payment for diagnostic radiopharmaceuticals in draft legislation, titled the Facilitating Innovative Nuclear Diagnostics (FIND) Act. Commenters also suggested using an alternative threshold multiplier, such as 1.51, 1.50, or 1.25. These commenters thought these lower thresholds would

allow for more products to be paid separately and argued a cost for a diagnostic radiopharmaceutical even 25 percent higher than the average diagnostic radiopharmaceutical cost could be considered significant and warrant separate payment. Two commenters suggested reassessing the threshold based on the changing costs of products over time or assessing which products are driving the APC payments and then setting the threshold higher than the cost of those high-volume products.

Response: We thank commenters for their comments; however, we believe the commenters' suggested thresholds are inconsistent with our OPPS two-times rule as described, which we believe is a longstanding and reasonable proxy for determining when costs exceed payment to a degree that warrants payment modification. The two-times rule utilizes a two times multiplier to determine APC levels, where a significant service that has a cost greater than two times the lowest cost significant service in an APC is generally moved to a higher-level APC in the series. The lower thresholds suggested by commenters would not follow this principle, and therefore, would not exclusively identify diagnostic radiopharmaceuticals whose costs significantly exceed the approximate amount of payment already attributed to the product in the nuclear medicine APC payment. We believe diagnostic radiopharmaceuticals are unique and therefore warrant their own specific threshold that is distinct from the broader drug packaging threshold used for therapeutic drugs, biologicals, and radiopharmaceuticals. This is because diagnostic radiopharmaceuticals are functioning as supplies to the nuclear medicine procedure in which they are used and are serving as an item that is integral, ancillary, supportive, dependent, or adjunctive to the primary diagnostic service. This is in contrast to therapeutic drugs, biologicals, and therapeutic radiopharmaceuticals that are typically packaged under the standard drug packaging threshold. These products could be the only therapeutic modality provided to a patient during an encounter and may not serve as an item that is integral, ancillary, supportive, dependent, or adjunctive to the primary service. Due to these differences, we believe a threshold specific to diagnostic radiopharmaceuticals is appropriate.

Comment: Some commenters advocated that CMS use a threshold of at least $630. Several commenters believed that focusing separate payment on those radiopharmaceuticals whose costs significantly exceed the payment already attributable to the product will help concentrate the effects of unbundling on only those products that are most likely to create access issues for beneficiaries while reducing the broader effects on the nuclear medicine APCs. One commenter stated that unpackaging radiopharmaceuticals with per day costs greater than $630 would decrease the nuclear medicine APC procedure payment rates, but that decrease would be exacerbated if CMS used a lower threshold.

Response: We thank commenters for their support. We agree a $630 threshold would appropriately identify only those diagnostic radiopharmaceuticals whose costs significantly exceed the approximate amount of payment already attributed to the product in the nuclear medicine APC payment.

Comment: Several commenters requested that CMS clarify that the proposal does not alter the qualifications for pass-through payment status or the pass-through payment methodology for those diagnostic radiopharmaceuticals that apply for pass-through status under the OPPS.

Response: That is correct. This policy is distinct from the policies described in section V.A of this final rule with comment period, which describe the qualifications and payment methodology for those products that qualify for OPPS pass-through status.

Comment: A few commenters recommended CMS monitor the effects of this policy if finalized. For example, one commenter supported the proposal, but suggested CMS carefully monitor the affected nuclear medicine APCs and address any larger than expected alterations to their reimbursement or other unintended consequences. An additional commenter encouraged CMS to continue to evaluate this methodology as new products enter the market. This commenter recommended CMS ensure no unintended consequences of this policy occur, such as manufacturers purposefully pricing their products just above the payment threshold.

Response: We thank the commenter for their support. We will monitor the effects of this policy and will consider proposing modifications in future rulemaking if appropriate.

Comment: One commenter sought clarification from CMS that, if finalized, its proposal to provide separate payment for diagnostic radiopharmaceutical products would be implemented in a budget neutral manner.

Response: Yes. This policy will be implemented in a budget neutral manner.

After consideration of the public comments we received, we are finalizing this aspect of our proposal without modification and will pay separately for any diagnostic radiopharmaceutical with a per day cost greater than $630 for CY 2025. Any diagnostic radiopharmaceutical with a per day cost at or below that threshold will continue to be policy packaged under the current policy at § 419.2(b)(15).

(3) Calculating the Per Day Cost of Diagnostic Radiopharmaceuticals

We proposed to calculate the per day costs for diagnostic radiopharmaceuticals using a methodology similar to the one we use for determining the per day costs of drugs and biologicals for comparison to the OPPS drug packaging threshold, proposed to be $140 for CY 2025.

We proposed to calculate the per day cost based on the methodology described in section V.B.1.b of the CY 2025 OPPS/ASC proposed rule, which relies on the methodology in the CY 2006 OPPS/ASC proposed rule (70 FR 42723 and 42724) and finalized in the CY 2006 OPPS final rule with comment period (70 FR 68636 through 68638). Though the clinical use of the drugs, biologicals, and therapeutic radiopharmaceuticals differs from diagnostic radiopharmaceuticals, we believe the method of determining how much of that item is used per day should be similar. Therefore, we proposed to use a similar methodology for determining the per day costs of diagnostic radiopharmaceuticals, as we do drugs, biologicals, and therapeutic radiopharmaceuticals. This methodology consists of nine steps:

Step 1. After application of the CCRs, we aggregated all line-items for a single date of service on a single claim for each product. This resulted in creation of a single line-item with the total number of units and the total cost of a diagnostic radiopharmaceutical given to a patient in a single day.

Step 2. We then created a separate record for each diagnostic radiopharmaceutical by date of service, regardless of the number of lines on which the diagnostic radiopharmaceutical was billed on each claim. For example, ''diagnostic radiopharmaceutical X'' is billed on a claim with two different dates of service, and for each date of service, the diagnostic radiopharmaceutical is billed on two line-items with a cost of $10 and 5 units for each line-item. In this case,

the computer program would create two records for this diagnostic radiopharmaceutical, and each record would have a total cost of $20 and 10 units of the product.

Step 3. We trimmed records with unit counts per day greater or less than 3 standard deviations from the geometric mean.

Step 4. For each remaining record for a diagnostic radiopharmaceutical, we calculated the cost per unit of the diagnostic radiopharmaceutical. If the HCPCS descriptor for ''diagnostic radiopharmaceutical X'' is ''per 1 millicurie'' and one record was created for a total of 10 millicurie (as indicated by the total number of units for the diagnostic radiopharmaceutical on the claim for each unique date of service), the computer program divided the total cost for the record by 10 to give a per unit cost. We then weighted this unit cost by the total number of units in the record. We did this by generating a number of line-items equivalent to the number of units in that particular claim. Thus, a claim with 100 units of ''diagnostic radiopharmaceutical X'' and a total cost of $200 would be given 100 line-items, each with a cost of $2, while a claim of 50 units with a cost of $50 would be given 50 line items, each with a cost of $1.

Step 5. We trimmed the unit records with cost per unit greater or less than 3 standard deviations from the geometric mean.

Step 6. We aggregated the remaining unit records to determine the mean cost per unit of the diagnostic radiopharmaceutical.

Step 7. Using only the records that remained after records with unit counts per day greater or less than 3 standard deviations from the geometric mean were trimmed (step 3), we determined the total number of units billed for each item and the total number of unique per-day records for each item. We divided the count of the total number of units by the total number of unique per day records for each item to calculate an average number of units per day.

Step 8. We used the payment rate (the mean unit cost (MUC) derived from the CY 2023 hospital claims data) for each diagnostic radiopharmaceutical and multiplied the payment rate by the average number of units per day for each diagnostic radiopharmaceutical to arrive at its per day cost.

Step 9. We packaged the items with per day costs less than or equal to $630 and designated items with per day costs greater than $630 as separately payable.

As just described, to determine the proposed CY 2025 packaging status for all nonpass-through diagnostic radiopharmaceuticals, we proposed to use the per day cost, calculated on a HCPCS code-specific basis, of each diagnostic radiopharmaceutical that had a HCPCS code in CY 2023 and was paid (via packaged or separate payment) under the OPPS. We used data from CY 2023 claims processed through December 31, 2023, for this calculation.

We proposed to continue to package payment for diagnostic radiopharmaceuticals with per day costs less than or equal to $630 under our existing packaging policy for diagnostic radiopharmaceuticals that function as surgical supplies under § 419.2(b)(15). Similar to our policy for the drug packaging threshold, we proposed to use updated claims data to make final determinations of the packaging status of HCPCS codes for diagnostic radiopharmaceuticals for each OPPS/ASC final rule with comment period. We proposed to make an annual packaging determination for each diagnostic radiopharmaceutical HCPCS code only when we develop the OPPS/ASC final rule with comment period for the update year. We proposed that only diagnostic radiopharmaceutical HCPCS codes that are identified as separately payable in this final rule with comment period would be subject to quarterly updates.

Consequently, the packaging status of some HCPCS codes for diagnostic radiopharmaceuticals in the OPPS/ASC proposed rule may differ from the same HCPCS codes' packaging status determined based on the data used for the final rule with comment period. Under these circumstances, we proposed to follow the established policies for the OPPS drug packaging threshold, which were initially adopted for the CY 2005 OPPS (69 FR 65780), to more equitably pay for those diagnostic radiopharmaceuticals whose costs fluctuate relative to the proposed CY 2025 OPPS diagnostic radiopharmaceutical packaging threshold in a way that affects the product's payment status (packaged or separately payable). Our policy for the OPPS drug packaging threshold has not changed for many years and is the same as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70434). We believe these same policies should apply to diagnostic radiopharmaceuticals in order to ensure payment consistency for those diagnostic radiopharmaceuticals whose costs fluctuate relative to the proposed CY 2025 OPPS diagnostic radiopharmaceutical packaging threshold. For CY 2025, similar to our historical practice for the drug packaging threshold, we proposed to apply the following policies to those HCPCS codes for diagnostic radiopharmaceuticals whose relationship to the diagnostic radiopharmaceutical packaging threshold changes based on the final updated data: HCPCS codes for diagnostic radiopharmaceuticals that are proposed for separate payment in CY 2025, and that then have per day costs equal to or less than the CY 2025 final rule diagnostic radiopharmaceutical packaging threshold, based on the updated hospital claims data used for the CY 2025 final rule, would remain packaged in CY 2025. HCPCS codes for diagnostic radiopharmaceuticals for which we proposed packaged payment in CY 2025 but that then have per-day costs greater than the CY 2025 final rule drug packaging threshold, based on updated hospital claims data used for the CY 2025 final rule, would receive separate payment in CY 2025.

Comment: Most commenters were supportive of the methodology used to calculate the per day costs, and many commenters were able to analyze the cost data published with the proposed rule and calculate the same list of products with per day costs exceeding $630.

Response: We thank commenters for their support of our proposal, and for their agreement with our calculations of the per day costs.

Comment: A few commenters recommended CMS consider alternative methods of calculating per day costs and make refinements in the future as we gain more experience with this policy.

Response: We thank commenters for their input. Our methods for calculating per day cost are consistent with our longstanding policies for calculating per day costs for purposes of the OPPS drug packaging threshold and we believe they should be finalized for CY 2025 and subsequent years. We could address this methodology in future rulemaking if the need arises; however, this methodology has worked effectively for calculating per day costs of drugs, biologicals and radiopharmaceuticals for purposes of the OPPS drug packaging threshold, and we believe this well-known process will work equally well for diagnostic radiopharmaceuticals to create a trimmed data set from which from per day costs can be calculated.

Comment: Many commenters recommended that CMS not apply the proposed packaging rules in 2025 and pay separately for any product that was proposed for separate payment or that exceeds the cost threshold in the final rule data. Commenters stated that CMS

should only consider applying its proposed methodology after the separate payment threshold has been in effect for a reasonable period of time. Specifically, commenters recommended that HCPCS codes for diagnostic radiopharmaceuticals that are proposed for separate payment in CY 2025, and that then have per day costs equal to or less than the threshold for the final rule, be separately paid. Similarly, commenters believed HCPCS codes for diagnostic radiopharmaceuticals for which CMS proposed packaged payment in CY 2025 but that then have per-day costs greater than the CY 2025 final rule drug packaging threshold, based on updated hospital claims data used for the CY 2025 final rule, receive separate payment in CY 2025.

Commenters stated that the claims data and the cost report data are updated between the proposed and final rule. Specifically, commenters noted that the determination of whether a diagnostic radiopharmaceutical will qualify for separate payment uses both units and mean cost calculated from Medicare claims data to determine the per day cost. As the mean cost estimate relies on cost-to-charge ratios, in the commenter's view, the diagnostic radiopharmaceutical packaging determination is susceptible to fluctuations in the mean cost estimate and those fluctuations are not necessarily driven by variation in the actual price of the product. The commenter stated that this is in contrast to ASP based payment rates, as ASP is an external estimate of product cost.

Response: We thank commenters for their comments and understand their concerns about potential cost data fluctuations changing packaging determinations between the proposed and final rule. However, based on updated data for the final rule, the diagnostic radiopharmaceuticals that have per day costs that exceed $630 are the same 26 diagnostic radiopharmaceuticals that exceeded the $630 threshold using proposed rule data, meaning, for purposes of determining whether a product's per day cost exceeded $630, the updated data for the final rule did not change the list of qualifying products.

After consideration of the public comments we received, we are finalizing our proposal regarding the calculation of per day costs of diagnostic radiopharmaceuticals without modification. Specifically, we are finalizing a policy to calculate the per day costs for diagnostic radiopharmaceuticals for purposes of determining whether a diagnostic radiopharmaceutical qualifies for separate payment using a methodology similar to the one we use for determining the per day costs of drugs and biologicals for comparison to the OPPS drug packaging threshold. We calculated the per day cost based on the methodology described in section V.B.1.b of this final rule with comment period, which relies on the methodology in the CY 2006 OPPS/ASC proposed rule (70 FR 42723 and 42724) and finalized in the CY 2006 OPPS final rule with comment period (70 FR 68636 through 68638).

(4) Updating the Diagnostic Radiopharmaceutical Packaging Threshold in CY 2026

Starting in CY 2026 and subsequent years, we proposed to update the proposed threshold amount of $630 by the PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics series code WPUSI07003) from IHS Global, Inc (IGI). IGI is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the various price indexes including the Producer Price Index (PPI) Pharmaceuticals for Human Use (Prescription). This is the same as the update factor used for the OPPS drug packaging threshold, where we originally used the four-quarter moving average PPI levels for Pharmaceutical Preparations (Prescription) to trend the $50 threshold forward from the third quarter of CY 2005 (when the Pub. L. 108–173 mandated threshold became effective) to the third quarter of the applicable calendar year. We believe it is appropriate to use the same PPI for Pharmaceuticals for Human Use (Prescription) for the diagnostic radiopharmaceutical packaging threshold, as diagnostic radiopharmaceuticals are also prescription pharmaceuticals for human use. We proposed that starting for CY 2026, we would use the most recently available four quarter moving average PPI levels to trend the final CY 2025 threshold forward from the third quarter of CY 2024 to the third quarter of CY 2025 and round the resulting dollar amount to the nearest $5 increment. We explained that the proposal to update the diagnostic radiopharmaceutical packaging threshold would maintain consistency with our longstanding methodology for updating the OPPS drug packaging threshold, which is discussed in more detail in section V.B.1.a. of this final rule with comment period and also in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68085 and 68086).

Comment: The majority of commenters supported our proposal to update the final threshold by the PPI for Pharmaceuticals for Human Use (Prescription) in CY 2026 and future years. They stated this was appropriate to reflect the increasing cost of diagnostic radiopharmaceuticals annually.

Response: We thank commenters for their support.

Comment: A small number of commenters were not in favor of our proposal to update the threshold by the PPI for Pharmaceuticals for Human Use (Prescription). One commenter believed CMS should take a broader approach and comprehensively review the appropriateness of the threshold amount yearly based on data for that year.

Response: We thank commenters for their insights; however, we continue to believe it is appropriate to subject the diagnostic radiopharmaceutical packaging threshold to the same update factor that is used for the OPPS drug packaging threshold as supported by the majority of commenters. Updating the finalized threshold by the PPI for Pharmaceuticals for Human Use (Prescription) is consistent with our longstanding policy to update the OPPS drug packaging threshold annually. This PPI update factor provides aggregate changes in the selling prices of pharmaceuticals, which makes it an appropriate factor with which to update the diagnostic radiopharmaceutical packaging threshold to ensure that as diagnostic radiopharmaceuticals' costs change over time, the threshold continues to identify products with costs that significantly exceed the otherwise applicable APC payment amounts as determined in this rule and that therefore should be eligible for separate payment.

After consideration of the public comments we received, we are finalizing our proposal to update the finalized packaging threshold without modification. Specifically, starting in CY 2026 and for subsequent years, we will update the threshold amount of $630 by the PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics series code WPUSI07003) from IHS Global, Inc (IGI).

(5) Amount of Separate Payment for Diagnostic Radiopharmaceuticals Exceeding the Threshold

As discussed in the CY 2025 OPPS/ASC proposed rule (89 FR 59213 through 59222), once we determine that the per day cost of a nonpass-through diagnostic radiopharmaceutical exceeds the cost threshold of $630 per day for CY 2025, we then proposed to assign that radiopharmaceutical to an APC,

making it a specified covered outpatient drug (SCOD) per section 1833(t)(14)(B) of the Act. Accordingly, we proposed to pay for those nonpass-through, separately payable diagnostic radiopharmaceuticals based on our authority under section 1833(t)(14)(A)(iii)(II) of the Act. While under this authority we would ordinarily use the ASP methodology under section 1847A of the Act, we find that the ASP data we have is not usable for payment purposes. As previously mentioned, radiopharmaceuticals are not required to report ASP under section 1847A of the Act, and as such, there are very few manufacturers reporting ASP for their products currently. As discussed in the CY 2025 OPPS/ASC proposed rule (89 FR 59213 through 59222), of those few manufacturers reporting ASP, the ASP values that we do have generally do not align with the ASP we would expect based on the cost and Mean Unit Cost (MUC) data submitted to CMS by hospitals. For example, a frequently used diagnostic radiopharmaceutical had a reported ASP that is over 23,000 percent higher than the MUC derived from claims data. As manufacturers of diagnostic radiopharmaceuticals may be unaware of the correct reporting requirements, we explained that we believe it would be inappropriate to propose to pay for separately payable diagnostic radiopharmaceuticals based on their ASPs as currently reported, without giving manufacturers the opportunity to submit, certify, or restate the ASPs of their products. We believed MUC would be an appropriate proxy for the average price for a diagnostic radiopharmaceutical for a given year, as it is calculated based on the average costs for a particular year and is directly reflective of the actual cost data that hospitals submit to CMS.

In the CY 2025 OPPS/ASC proposed rule (89 FR 59213 through 59222), we stated that under our policy for therapeutic radiopharmaceuticals (74 FR 60520), there are several requirements for reporting ASP. For example, ASP data submitted would need to be provided for a patient-specific dose, or patient-ready form, of the radiopharmaceutical in order to properly calculate the ASP amount for a given HCPCS code if that HCPCS code dose descriptor was per study dose or similar. ASP data submitted should align with the code's dose descriptor and billing unit. We stated we would expect that the ASP data reported by a manufacturer would be representative of the item(s) sold by the manufacturer. We used the term ''patient-ready'' in that rule to ensure that ASP data submitted for OPPS payment purposes for separately payable radiopharmaceuticals reflect the costs of all the component materials of the finished radiopharmaceutical product. We expected that the ASP data would represent the sales price of all of the component materials of the finished radiopharmaceutical product sold by the manufacturer in terms that reflect the applicable HCPCS code descriptor such as ''per study dose'', ''per millicurie'' and ''up to XX millicuries.'' For the few manufacturers that reported ASP data for their diagnostic radiopharmaceuticals, we believed it may be possible that they are not aware of the reporting requirements or are unaware of how to properly report ASP for their product, as CMS has not used ASP as the basis of payment for nonpass-through diagnostic radiopharmaceuticals before. Therefore, we explained that we believe a reasonable alternative for CY 2025 for separate payment of diagnostic radiopharmaceuticals that exceed the per day cost threshold is to use of their mean unit cost from claims data. This is consistent with our current practice for therapeutic radiopharmaceuticals when ASP data is not available. For diagnostic radiopharmaceuticals, we believe that ASP data is effectively not available for purposes of determining a payment amount and, therefore, payment based on MUC is a reasonable alternative.

We previously acknowledged (74 FR 35335), and continue to acknowledge, the complexities associated with reporting ASP for radiopharmaceuticals. We encourage manufacturers to submit ASP information for diagnostic radiopharmaceuticals, if possible. While we proposed to use MUC to pay for separately payable diagnostic radiopharmaceuticals in CY 2025, manufacturers can begin, or continue, to report ASP data for potential future use in paying for diagnostic radiopharmaceuticals. For CY 2025, ASP reporting is voluntary for diagnostic radiopharmaceuticals paid under the OPPS. We encouraged interested parties to submit comments regarding potential issues that may arise that prevent appropriate ASP reporting for diagnostic radiopharmaceuticals. If manufacturers choose to report ASP data, the data must meet reporting requirements to be used for payment under the OPPS.

As discussed in the CY 2025 OPPS/ASC proposed rule (89 FR 59213 through 59222), manufacturers that choose to report ASP data for their diagnostic radiopharmaceuticals would need to provide comprehensive data for CMS to calculate an ASP amount for a given HCPCS code. In instances where there is more than one manufacturer of a particular diagnostic radiopharmaceutical, we proposed that all manufacturers would need to submit ASP information for payment to be made based on ASP. This is because it would be inappropriate for Medicare payment for a HCPCS code to be based on the payment information submitted by one manufacturer, if that payment is used for a product made by different manufacturers. This is because the ASP information reported by one manufacturer might not reflect the ASP of the same product made by other manufacturers.

We note that ASP submissions for radiopharmaceutical payment under the OPPS would need to meet all of the existing regulatory and subregulatory requirements of the ASP reporting process under sections 1847A and 1927(b)(3) of the Act.

Specifically, we reiterated our ASP reporting requirements outlined in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60520) for products for which we are encouraging the reporting of ASP, but for which reporting is not statutorily required. The ASP data submitted would need to be provided for a patient-specific dose, or patient-ready form, of the diagnostic radiopharmaceutical in order to properly calculate the ASP amount that aligns with the dose descriptor for a given HCPCS code. When reporting an ASP for a separately payable radiopharmaceutical, we expect that the ASP data reported by a manufacturer would be representative of the item(s) sold by the manufacturer. In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60520), we used the term ''patient-ready'' to ensure that ASP data submitted for OPPS payment purposes for separately payable radiopharmaceuticals reflect the costs of all the component materials of the finished radiopharmaceutical product. We expect that the ASP data would represent the sales price of all of the component materials of the finished radiopharmaceutical product sold by the manufacturer in terms that reflect the applicable HCPCS code descriptor, such as ''per study dose'' or ''millicurie.'' We defined a ''patient-ready'' dose for OPPS purposes as including all component materials of the radiopharmaceutical, at a minimum, and any other processing the manufacturer requires to produce the radiopharmaceutical that it sells that are reflected in the sales price, including radiolabeling, as long as any fees paid for such processing done on behalf of

the manufacturer meet the definition of ''bona fide service fees'' under § 414.802 (74 FR 60525).

As discussed in the CY 2025 OPPS/ASC proposed rule (89 FR 59213 through 59222), we understand that manufacturers of separately payable radiopharmaceuticals produce radiopharmaceuticals that require a variety of processing steps in order to prepare the product for administration to a beneficiary. To be used for separate OPPS radiopharmaceutical payment, the ASP data reported by a manufacturer must represent sales of all of the component materials associated with the radiopharmaceutical. For our full policy on which factors to incorporate into ASP pricing, please see the CY 2010 OPPS/ASC final rule with comment period (74 FR 60520 through 60521).

In order to be used for payment under the OPPS, all radiopharmaceutical ASP submissions should meet the existing regulatory and subregulatory requirements of the ASP submission process under sections 1847A and 1927(b)(3) of the Act. In particular, we explained that we believe the ''bona fide service fee'' test in the ASP regulations is instructive here, and we refer readers to the CY 2010 OPPS/ASC final rule with comment period for our discussion on radiopharmaceutical ASP reporting (74 FR 60521).

To summarize our CY 2010 policy for ASP reporting on radiopharmaceuticals for OPPS payment purposes (74 FR 60521), a patient-specific dose or patient-ready form in the context of OPPS ASP submission for radiopharmaceutical payment means that the ASP reflecting manufacturer sales must represent sales of all of the component materials for the radiopharmaceutical, including a minimum of a cold kit and a radioisotope, and be reported in terms that reflect the applicable HCPCS code descriptor, such as ''treatment dose'' or ''millicurie.'' The ASP would not necessarily take into account the preparation of the final form of the radiopharmaceutical for patient administration, including radiolabeling, which may be conducted by the manufacturer, freestanding radiopharmacy, hospital pharmacy, or other entity. With respect to the latter, fees paid by the manufacturer for these services would be excluded from the ASP calculation (that is, would not be considered price concessions that reduce the ASP) only if they are ''bona fide service fees'' as defined in the regulations governing ASP. Thus, if the manufacturer pays a ''bona fide service fee'' for the services of the freestanding radiopharmacy, hospital pharmacy, or other entity, and reflects that fee in its price for the radiopharmaceutical, the amount of the ''bona fide service fee'' would be taken into account in the reported ASP data. However, manufacturers are not required to pay for the preparation of a radiopharmaceutical (including radiolabeling) in a freestanding radiopharmacy, hospital pharmacy, or other entity after sale of all of the component materials, and in that case, the cost of those services would not be reflected in the ASP data submitted to CMS. Manufacturers should submit ASP data for a separately payable radiopharmaceutical that incorporates prices for sales of all of the component materials by the manufacturer. We sought comment on these ASP reporting requirements outlined in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60521) and previous CMS guidance on the guidelines for the Submission of OPPS ASP Data for Nonpass-Through Separately Payable Therapeutic Radiopharmaceuticals and Radiopharmaceuticals with Pass-Through Status.[8] We continue to believe that these ASP reporting practices should be applicable to radiopharmaceuticals, including both therapeutic and diagnostic radiopharmaceuticals, but sought comment from interested parties in this space to ensure that these reporting guidelines are clear and reflective of clinical practice today.

We mentioned in the CY 2025 OPPS/ASC proposed rule (89 FR 59213 through 59222) that we still see the potential value in the use of ASP data for payment purposes for diagnostic radiopharmaceuticals when reported correctly and by all manufacturers who manufacture a product that is described by a given HCPCS code. We stated that we believe that the use of ASP information for OPPS payment could provide an opportunity to improve payment accuracy for separately payable diagnostic radiopharmaceuticals by applying an established methodology that has already been successfully implemented under the OPPS for other separately payable drugs and biologicals, as well as therapeutic radiopharmaceuticals. Because the per day cost calculations determine whether a diagnostic radiopharmaceutical qualifies for separate payment, using the most accurate pricing information is paramount. The use of ASP information could provide an opportunity to further improve the accuracy of the per day cost calculations and the separate payment amounts for diagnostic radiopharmaceuticals. As previously mentioned, we do not believe that the limited amount of ASP information submitted currently is adequate for the purpose of determining separate payment for those few products that currently do report ASP, which is why we proposed to pay diagnostic radiopharmaceuticals with per day costs above the $630 threshold at each diagnostic radiopharmaceutical's mean unit cost. However, we were still interested in the potential to use ASP for the purpose of determining a diagnostic radiopharmaceutical's per day cost and payment amount in the future. Therefore, we wanted to engage with interested parties to learn about the unique aspects and challenges that may be associated with reporting ASP for diagnostic radiopharmaceuticals, and radiopharmaceuticals in general. We specifically sought comment as to whether interested parties believe CMS should require payment for diagnostic radiopharmaceuticals to be based on ASP in the future, such as in CY 2026 rulemaking, if interested parties are confident in their reporting ability.

We discussed in the CY 2025 OPPS/ASC proposed rule (89 FR 59213 through 59222) that we do believe that there could be situations in which it is appropriate to use ASP currently. For example, in section V.A.4 of the CY 2025 OPPS/ASC proposed rule (89 FR 59213 through 59222), we proposed to utilize ASP in payment for diagnostic radiopharmaceuticals on OPPS transitional pass-through status. In this situation, we believed the use of ASP is appropriate as the manufacturer of that diagnostic radiopharmaceutical is actively involved in the radiopharmaceutical's pass-through application, and CMS can ensure that pricing is reported appropriately for purposes of the drug pass-through cost significance tests and for purposes of payment if the pass-through status is approved. Typically, there is only one manufacturer for a diagnostic radiopharmaceutical applying for pass-through status, so CMS does not have to ensure all manufacturers are reporting ASP for that particular HCPCS code prior to establishing a separate payment amount based on ASP. Additionally, as discussed in section V.B.5 of the CY 2025 OPPS/ASC proposed rule (Proposed Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals with HCPCS Codes but Without OPPS Hospital

[8] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/opps_asp_radiopharm_guidance10302009.pdf.*

Claims Data), we proposed to base the initial payment for new diagnostic radiopharmaceuticals with HCPCS codes, but which do not have pass-through status and are without claims data, on ASP, and on WAC if ASP data for these diagnostic radiopharmaceuticals are not available. If the WAC also is unavailable, we proposed to make payment for new diagnostic radiopharmaceuticals at 95 percent of the products' most recent AWP. We believe the volume of products in this category will typically be very low; however, in these rare situations, we believe it would be appropriate to use ASP until a MUC is available. Similar to drugs applying for pass-through status, there is typically only one manufacturer for a diagnostic radiopharmaceutical that is new and described by a HCPCS code, but without claims data, so CMS does not have to ensure all manufacturers are reporting ASP for that particular HCPCS code prior to establishing a separate payment amount based on ASP. Additionally, although reporting of ASP is not a condition of CMS approving a HCPCS application, CMS has the opportunity to actively engage with the manufacturer, or sponsor of a HCPCS application, during the HCPCS application process. This allows for ongoing dialogue and education regarding the unique ASP reporting requirements that may be associated with a particular product, including how to ensure the reported ASP aligns with the dose descriptor for the newly assigned HCPCS code.

We sought comments on additional unique situations in which it still may be appropriate for CMS to use ASP information to assess per day costs and payment amounts for diagnostic radiopharmaceuticals for CY 2025. For example, we stated that one such unique situation could be continuing the use of ASP for a particular HCPCS code once its pass-through status has ended, if the HCPCS code was actively being paid based on ASP while on pass-through status. Under our proposal, payment for a diagnostic radiopharmaceutical would be based on MUC once its pass-through status ends. We sought comment on this potential unique situation, as well as others of which readers may be aware. We stated that we may finalize utilizing ASP in additional situations that commenters bring to our attention in the final rule as policies for CY 2025 depending on comments received.

As discussed, we proposed to base the payment rate for diagnostic radiopharmaceuticals on mean unit cost data derived from hospital claims. We did not propose to use ASP data for determining payment rates of nonpass-through diagnostic radiopharmaceuticals with claims data but are seeking comment on its use for determining the per day cost and setting the payment rate for diagnostic radiopharmaceuticals in the future. Additionally, we did not propose to use WAC or AWP as a basis for payment for diagnostic radiopharmaceuticals. Similar to our reasoning for payment of therapeutic radiopharmaceuticals in the CY 2012 OPPS/ASC final rule with comment period (77 FR 68390), we believe that paying for diagnostic radiopharmaceuticals using mean unit cost would appropriately pay for the average price of nonpass-through separately payable diagnostic radiopharmaceuticals for the applicable year. We believe MUC is an appropriate proxy for the average price for a diagnostic radiopharmaceutical for a given year, as it is calculated based on the average costs for a particular year and is directly reflective of the actual cost data that hospitals submit to CMS.

As we stated in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60523), we believe that WAC or AWP is not an appropriate proxy to provide OPPS payment for average therapeutic radiopharmaceutical acquisition cost and associated handling costs when manufacturers are not required to submit ASP data because payment based on WAC or AWP for separately payable drugs and biologicals is usually temporary for a calendar quarter until a manufacturer is able to submit the required ASP data in accordance with the quarterly ASP submission timeframes for reporting under section 1847A of the Act. However, WAC and AWP reported to compendia may not be reflective of a patient ready dose. We are additionally concerned about the use of WAC and AWP since ASP reporting for OPPS payment of separately payable diagnostic radiopharmaceuticals would not be required for CY 2025. The absence of appropriate ASP reporting could result in payment for a separately payable diagnostic radiopharmaceutical based on WAC or AWP indefinitely, a result which we believe would be inappropriate, as these pricing metrics do not capture all of the pricing discounts that may be reflected in the ASP. In the CY 2025 OPPS/ASC proposed rule (89 FR 59213 through 59222), we stated that given all of the concerns we had with other pricing methodologies for diagnostic radiopharmaceuticals, we proposed to rely on CY 2023 mean unit cost data derived from hospital claims data for payment rates for diagnostic radiopharmaceuticals for CY 2025.

Our proposed payment methodology for diagnostic radiopharmaceuticals that have costs above a $630 threshold would be similar, but not the same, as the methodology adopted for therapeutic radiopharmaceuticals as described in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60518). Although therapeutic radiopharmaceuticals are generally targeted at treating a certain disease or condition, and diagnostic radiopharmaceuticals are generally targeted at diagnosing a certain disease or condition, we believe they are clinically very similar products, manufactured in a similar manner, and should generally be paid using a similar payment methodology when paid separately. As such, we stated that we believe the same payment method as is used for therapeutic radiopharmaceuticals should apply to diagnostic radiopharmaceuticals above the cost threshold. However, as previously discussed, given our concerns with current ASP reporting patterns, we proposed to use MUC as the basis of payment for nonpass-through diagnostic radiopharmaceuticals for CY 2025. Therefore, we explained that we believe it is appropriate for the methodology to determine the proposed payment amounts to differ between diagnostic and therapeutic radiopharmaceuticals, at least for CY 2025. We stated that we will consider aligning the payment methodologies between therapeutic and diagnostic radiopharmaceuticals, either based on ASP or MUC, in future rulemaking.

We explained that we believe that mean unit cost data is an appropriate and adequate proxy for the average price for diagnostic radiopharmaceuticals and associated handling costs for these products. Mean unit cost data is reflective of the actual cost data that hospitals submit to CMS. The MUC payment methodology is consistent with our payment policy for therapeutic radiopharmaceuticals as stated in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60523) and is currently the basis of payment for many therapeutic radiopharmaceuticals when ASP is unavailable.

As previously discussed, we find that the ASP data we have is not usable for the purpose of paying for diagnostic radiopharmaceuticals and, therefore, we proposed to pay for qualifying nonpass-through diagnostic radiopharmaceuticals with claims data based on MUC. However, we also sought comment on how we could

potentially use our equitable adjustment authority at section 1833(t)(2)(E) of the Act to make an adjustment to the ASP data that has been reported in order to make it usable for the purpose of paying equitably for these products. For example, we sought comment as to whether CMS could use its equitable adjustment authority to adjust payment for diagnostic radiopharmaceuticals based on an adjusted ASP value when the ASP amounts reported to CMS deviate by a given threshold, such as two times the MUC calculated for the diagnostic radiopharmaceutical using claims data. Alternatively, the adjusted payment rate could be an average of the reported ASP and MUC, or other methodologies suggested by commenters. We broadly sought comment on this potential use of equitable adjustment authority to make the limited ASP data reported for diagnostic radiopharmaceuticals usable for purposes of setting payment rates for qualifying products.

We note, if readers do not believe it is appropriate for CMS to base the payment amount for diagnostic radiopharmaceuticals on MUC for CY 2025, we proposed in the alternative to maintain our current policy of unconditionally policy packaging all diagnostic radiopharmaceuticals regardless of their cost until an appropriate payment methodology can be established to determine a separate payment amount for diagnostic radiopharmaceuticals.

We stated that HCPCS codes that describe diagnostic radiopharmaceuticals with per day costs that meet or exceed the proposed diagnostic radiopharmaceutical packaging threshold would be assigned to a status indicator of ''K'', indicating separate payment. An APC and a payment rate would be assigned as shown in Addendum B to the proposed rule. HCPCS codes that describe diagnostic radiopharmaceuticals with per day costs that are at or below the proposed diagnostic radiopharmaceutical packaging threshold would continue to be assigned to a status indicator of ''N'', indicating packaged payment. We welcomed comment on these determinations. The proposed list of diagnostic radiopharmaceuticals that we calculated as having per day costs that exceed $630 and their proposed status indicators can be found in Table 8.

TABLE 8: Proposed Qualifying Diagnostic Radiopharmaceuticals with Per Day Costs Exceeding $630

HCPCS Code	Short Descriptor	Proposed CY 2025 Status Indicator Assignment
A9515	Choline c-11	K
A9521	Tc99m exametazime	K
A9542	In111 ibritumomab, dx	K
A9547	In111 oxyquinoline	K
A9548	In111 pentetate	K
A9557	Tc99m bicisate	K
A9568	Technetium tc99m arcitumomab	K
A9569	Technetium tc-99m auto wbc	K
A9570	Indium in-111 auto wbc	K
A9572	Indium in-111 pentetreotide	K
A9582	Iodine i-123 iobenguane	K
A9584	Iodine i-123 ioflupane	K
A9586	Florbetapir f18	K
A9587	Gallium ga-68	K
A9588	Fluciclovine f-18	K
A9591	Fluoroestradiol f 18	K
A9592	Copper cu 64 dotatate diag	K
A9593	Gallium ga-68 psma-11 ucsf	K
A9594	Gallium ga-68 psma-11, ucla	K
A9595	Piflu f-18, dia 1 millicurie	K
A9596	Gallium illuccix 1 millicure	K*
A9602	Fluorodopa f-18 diag per mci	K**
A9800	Gallium locametz 1 millicuri	K***
C9067	Gallium ga-68 dotatoc	K
Q9982	Flutemetamol f18 diagnostic	K
Q9983	Florbetaben f18 diagnostic	K

*HCPCS code A9596 will be assigned to status indicator "G" until its pass through expiration on 06/30/2025. For the remainder of CY 2025, we would propose to assign it to status indicator "K."

**HCPCS code A9602 will be assigned to status indicator "G" until its pass through expiration on 09/30/2025. For the remainder of CY 2025, we would propose to assign it to status indicator "K."

***HCPCS code A9800 will be assigned to status indicator "G" until its pass through expiration on 09/30/2025. For the remainder of CY 2025, we would propose to assign it to status indicator "K."

Proposed definitions of status indicators were included in Addendum D1 to the CY 2025 OPPS/ASC proposed rule (89 FR 59213 through 59222). Addenda to that proposed rule can be found on the CMS OPPS web page.

We proposed corresponding regulation text edits at § 419.2(b)(15) to only package diagnostic radiopharmaceuticals when their per day cost is at or below the per day diagnostic radiopharmaceutical packaging threshold for the applicable year. Specifically, we proposed to add the text ''at or below the per-day diagnostic radiopharmaceutical packaging threshold for the applicable year'' to qualify the packaging of diagnostic radiopharmaceuticals. We also proposed corresponding regulation text edits at § 419.41 (Calculation of national beneficiary copayment amounts and national Medicare program payment amounts) to codify our proposed payment policy for diagnostic radiopharmaceuticals and our existing policy for therapeutic radiopharmaceuticals.

Comment: Commenters were largely supportive of CMS's proposal to pay diagnostic radiopharmaceuticals based on their mean unit cost for CY 2025. Commenters applauded CMS for recognizing that the uniqueness of diagnostic radiopharmaceuticals could lead to some difficulty or uncertainty around reporting other pricing data, such as Average Sales Price (ASP), for these products. Additionally, commenters generally seemed to understand CMS's concerns with using ASP as a basis for payment broadly for CY 2025 given the limited information available.

Response: We thank commenters for their support of our proposal.

Comment: Although the majority of commenters were generally supportive of using mean unit cost as the basis for diagnostic radiopharmaceutical payment for CY 2025, many of these commenters saw the use of MUC as a transitional step, and recommended CMS consider Average Sales Price as the

methodology to determine the payment amount as soon as possible. Other commenters suggested specific unique situations in which they believed it would be appropriate for CMS to use ASP, such as when a product's OPPS pass-through status expires if the product was being paid based on ASP while on OPPS pass-through status. Similarly, some commenters expressed some drawbacks to using MUC as a payment amount rather than ASP, such as that mean unit cost depends on hospital cost to charge ratios and uses cost data from prior years, rather than from the current payment year. Similarly, a commenter communicated that the MUC methodology underestimates the actual costs to hospitals for higher priced technologies due to charge compression which, in their view, may result in an inaccurate payment rate for a product compared to the actual acquisition cost for a product by a given hospital.

Commenters stated that using ASP information was consistent with payment for drugs under the OPPS, and they also stated that ASP information was an established methodology that could provide an opportunity to improve payment accuracy.

Commenters believed there was value in using ASP as the basis of payment, and although they acknowledged CMS may not have access to ASP data for patient ready doses for all diagnostic radiopharmaceuticals, commenters recommended we transition to an ASP-based payment.

Some commenters stated their belief that separate payment will incentivize reporting of ASP data. CMS was urged to work with manufacturers to obtain ASP data and only consider basing payment on ASP when such data are determined to be reliable. Commenters also recommended that CMS provide at least one year notice of its intent to base payment on ASP to facilitate the most complete reporting and consistent payment methodologies across products.

Response: We thank commenters for their feedback and considerations on our proposal. Our concerns from the proposed rule remain for the final rule, in that there are very few manufacturers reporting ASP for their products currently, and of those few manufacturers reporting ASP, the ASP values that we do have generally do not align with the ASP we would expect based on the cost data submitted to CMS by hospitals. While a small number of manufacturers may be reporting ASP correctly, such as those recently on OPPS pass-through status, we believe a consistent payment methodology is most appropriate for nonpass-through diagnostic radiopharmaceuticals with per day costs above the threshold. We do agree that there could be some value in the use of ASP for determining a payment amount in the future; however, if we were to use the ASP methodology, we believe there must be more consistent, validated, and universal reporting in order for ASP to be a viable payment methodology. To maintain a consistent payment methodology for CY 2025, we believe it is appropriate to treat all nonpass-through diagnostic radiopharmaceuticals with claims data the same and pay using MUC without exception, such as for products with recent pass-through expiration.

Comment: Commenters expressed a broad interest in using ASP data and learning how to report that data appropriately to CMS, including regarding topics such as ''bona fide service fees.'' Commenters indicated a desire to learn more about how they could report ASP for their specific products. Many manufacturers expressed their intent to initiate discussions with CMS in order to potentially begin to report ASP data.

Response: We thank commenters for expressing their interest in use of ASP data and appropriate ASP reporting. As we have previously stated, and as commenters have noted, we recognize the complexities associated with reporting ASP for radiopharmaceuticals. We encourage ongoing engagement with CMS in order for manufacturers to provide information regarding their products' unique reporting complexities.

Comment: Some commenters recommended CMS continue to consider the appropriateness of other sources of cost data for future years, such as wholesale acquisition cost (WAC).

Response: We continue to believe that neither WAC nor AWP is an appropriate proxy to provide OPPS payment for average radiopharmaceutical acquisition costs and associated handling costs when manufacturers are not required to submit ASP data. This is because payment based on WAC or AWP for separately payable drugs and biologicals is usually temporary for a calendar quarter until a manufacturer is able to submit the required ASP data in accordance with the quarterly ASP submission timeframes for reporting under section 1847A of the Act. WAC and AWP reported to compendia may not be reflective of a patient ready dose. The absence of an ASP reporting requirement and inappropriate or no reporting of ASP could result in payment for a separately payable diagnostic radiopharmaceutical based on WAC or AWP indefinitely, a result which we believe would be inappropriate, as these pricing metrics do not capture all of the pricing discounts that may be reflected in the ASP.

Comment: Some commenters were concerned about potential fluctuations in MUC data and the effect on payment for separately payable diagnostic radiopharmaceuticals. Several commenters recommend CMS apply its low volume APC policy to diagnostic radiopharmaceutical APCs, stating that CMS's policy for setting payment rates for low volume APCs, defined as those with fewer than 100 claims, by using up to four years of claims data and basing the rate on the highest value among the arithmetic mean, geometric mean, or median improves payment rate stability for low volume APCs.

Response: We thank commenters for their recommendations. We did not propose to subject low volume diagnostic radiopharmaceutical APCs to the broader OPPS low volume policy, and we note that the low volume APC policy does not apply to APCs to which single drugs, biologicals, or radiopharmaceuticals are assigned, even if there is a low volume of claims for these items. We understand the commenter's concerns; however, we do not believe it would be appropriate to finalize this policy modification without further engagement from interested parties. While we agree this suggested policy modification could result in greater payment stability, we want to ensure that there are no unintended consequences of such a policy, such as an unintended decrease in the overall MUC payment rate as a result of using 4 years of cost data. We encourage additional engagement on this issue.

Comment: A commenter noted that we proposed that only diagnostic radiopharmaceutical HCPCS codes that are identified as separately payable in the final rule with a comment period would be subject to quarterly updates. The commenter was unsure why quarterly updates would be necessary for MUC-based payment, which they expect would be established annually as part of the rulemaking process and thus not be subject to quarterly updates.

Response: We thank the commenter for this comment and confirm that their understanding is correct. MUC will be calculated on an annual basis for the payment of nonpass-through diagnostic radiopharmaceuticals with per day costs exceeding $630. Because we are not adopting an ASP-based payment approach at this time, there is no need to update the payment amounts

quarterly as the MUC will be set in this final rule for the entire calendar year.

Comment: A few commenters believed that the product Magtrace, which may be described by HCPCS code A9697 (Injection, carboxydextran-coated superparamagnetic iron oxide, per study dose), was inappropriately assigned to a packaged payment status for the proposed rule and should be subject to this policy and designated for separate payment in the final rule. One commenter stated that the product is a magnetic tracer indicated to assist in localizing lymph nodes draining a tumor site, as part of a sentinel lymph node biopsy procedure in patients with breast cancer undergoing mastectomy or lumpectomy. The commenter stated that when HCPCS code A9697 was first incorporated in the October 2023 OPPS Update Transmittal, it was in a table titled ''Table 15.—Newly Established HCPCS Codes for Drugs, Biologicals, and Radiopharmaceuticals as of October 1, 2023'' and that Medicare Administrative Contractors (MACs) have indicated that HCPCS codes in the A9500–A9700 range, which the Magtrace code falls within, are for radiopharmaceuticals.

Response: We note that this product is not radioactive [9] [10] and is regulated by the FDA as a medical device under the product name ''Magtrace and Sentimag Magnetic Localization System'' with a premarket approval.[11] Accordingly, we do not believe that this product qualifies as a diagnostic radiopharmaceutical, and do not believe that it should be paid separately under this policy. We believe this product functions as a supply when used in a diagnostic test or procedure and should continue to be packaged under 42 CFR 419.2(b)(15). Please see section V.A. of this final rule with comment period for the payment status of HCPCS code A9697 for CY 2025.

Comment: Broadly, commenters suggested that CMS subject additional classes of drugs, such as contrast agents to this policy. For example, a commenter discussed one such product, Cysview, which may be described by HCPCS code A9589 (Instillation, hexaminolevulinate hydrochloride, 100 mg), and believed CMS's reasoning in the proposed rule for unpackaging and paying separately for diagnostic radiopharmaceuticals applies equally to their product. The commenter believed lack of separate payment was a barrier to beneficiary access and recommended CMS pay for products like theirs when the products' costs exceeded a certain threshold.

Response: We thank the commenters for their feedback. We continue to believe that our packaging policies are a fundamental principle that distinguishes a prospective payment system from a fee schedule. In general, packaging the costs of supportive items and services into the payment for the primary procedure or service with which they are associated encourages hospital efficiencies and enables hospitals to manage their resources with maximum flexibility. We will take the information commenters provided into consideration as appropriate for possible future rulemaking.

After consideration of the public comments we received, we are finalizing our proposal without modification. In summary, for CY 2025 we are paying separately for any diagnostic radiopharmaceutical with a per day cost greater than $630 using the methodology described. Any diagnostic radiopharmaceutical with a per day cost at or below that threshold would continue to be policy packaged under our longstanding policy at § 419.2(b)(15). We are finalizing our proposal regarding updating the selected packaging threshold without modification. Specifically, starting in CY 2026 and for subsequent years, we will update the threshold amount of $630 by the PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics series code WPUSI07003) from IHS Global, Inc (IGI). We are finalizing our proposal to pay for those nonpass-through, separately payable diagnostic radiopharmaceuticals based on our authority under section 1833(t)(14)(A)(iii)(II) of the Act, and as we find that the ASP data we have is not usable for the purpose of paying for diagnostic radiopharmaceuticals, we are paying for qualifying nonpass-through diagnostic radiopharmaceuticals with claims data based on mean unit cost data derived from hospital claims. We believe that paying for diagnostic radiopharmaceuticals using mean unit cost would appropriately pay for the average price of nonpass-through separately payable diagnostic radiopharmaceuticals for the applicable year. We believe MUC is an appropriate proxy for the average price for a diagnostic radiopharmaceutical for a given year, as it is calculated based on the average costs for a particular year and is directly reflective of the actual cost data that hospitals submit to CMS.

The finalized list of diagnostic radiopharmaceuticals that have calculated per day costs that exceed $630 and their status indicators can be found in Table 9.

[9] Per the manufacturer's website: ''Is Magtrace Radioactive? No. Magtrace is the world's first non-radioactive tracer to offer dual identification. This not only facilitates the eradication of radioactive products from the OR, but provides psychological benefits for the patient.'' *https://www.endomag.com/resources/faqs/magtrace/?product=magtrace.*

[10] Per the manufacturer's website: ''Magtrace® is a uniquely designed non-radioactive liquid tracer used to map the potential spread of cancer to the axilla in sentinel lymph node biopsy procedures. The liquid is made up of tiny particles of iron oxide, coated in sugar and suspended in saline.'' *https://www.endomag.com/resources/faqs/magtrace/.*

[11] *https://www.fda.gov/medical-devices/recently-approved-devices/magtrace-and-sentimag-magnetic-localization-system-p160053s002.*

TABLE 9: Finalized Qualifying Diagnostic Radiopharmaceuticals with Per Day Costs Exceeding $630

HCPCS Code	Short Descriptor	Final CY 2025 Status Indicator Assignment
A9515	Choline c-11	K
A9521	Tc99m exametazime	K
A9542	In111 ibritumomab, dx	K
A9547	In111 oxyquinoline	K
A9548	In111 pentetate	K
A9557	Tc99m bicisate	K
A9568	Technetium tc99m arcitumomab	K
A9569	Technetium tc-99m auto wbc	K
A9570	Indium in-111 auto wbc	K
A9572	Indium in-111 pentetreotide	K
A9582	Iodine i-123 iobenguane	K
A9584	Iodine i-123 ioflupane	K
A9586	Florbetapir f18	K
A9587	Gallium ga-68	K
A9588	Fluciclovine f-18	K
A9591	Fluoroestradiol f 18	K
A9592	Copper cu 64 dotatate diag	K
A9593	Gallium ga-68 psma-11 ucsf	K
A9594	Gallium ga-68 psma-11, ucla	K
A9595	Piflu f-18, dia 1 millicurie	K
A9596	Gallium illuccix 1 millicure	K*
A9602	Fluorodopa f-18 diag per mci	K**
A9800	Gallium locametz 1 millicuri	K***
C9067	Gallium ga-68 dotatoc	K
Q9982	Flutemetamol f18 diagnostic	K
Q9983	Florbetaben f18 diagnostic	K

*HCPCS code A9596 will be assigned to status indicator "G" until its pass through expiration on 06/30/2025. For the remainder of CY 2025, it will be assigned to status indicator "K."

**HCPCS code A9602 will be assigned to status indicator "G" until its pass through expiration on 09/30/2025. For the remainder of CY 2025, it will be assigned to status indicator "K."

***HCPCS code A9800 will be assigned to status indicator "G" until its pass through expiration on 09/30/2025. For the remainder of CY 2025, it will be assigned to status indicator "K."

Definitions of status indicators can be found in Addendum D1 to this final rule with comment period. Addenda to this final rule with comment period can be found on the CMS OPPS web page.

Additionally, we are finalizing with slight modification corresponding regulation text edits at § 419.2(b)(15) to only package diagnostic radiopharmaceuticals when their per day cost is at or below the per day diagnostic radiopharmaceutical packaging threshold for the applicable year. We are adding the language ''with per-day costs at or'' to the regulation text as a technical change to conform with our final policy as the prior text did not make it clear that the per day cost of a diagnostic radiopharmaceutical must be at or below the per-day diagnostic radiopharmaceutical packaging threshold in order for the product to be packaged. Overall, this regulation text is changed by adding the text ''with per-day costs at or below the per-day diagnostic radiopharmaceutical packaging threshold for the applicable year'' rather than only ''below the per-day diagnostic radiopharmaceutical packaging threshold for the applicable year'' to qualify the packaging of diagnostic radiopharmaceuticals. Aside from those changes described in V.B.5 of this CY 2025 OPPS/ASC final rule with comment period to conform with our payment policy for nonpass-through diagnostic radiopharmaceuticals in situations in which claims data are not available, we are finalizing without modification corresponding regulation text edits at § 419.41 (Calculation of national beneficiary copayment amounts and national Medicare program payment amounts) to codify our proposed payment policy for diagnostic radiopharmaceuticals and our existing policy for therapeutic radiopharmaceuticals.

4. Implementation of Section 4135 of the Consolidated Appropriations Act (CAA)

The Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–328), was signed into law on December 29, 2022. Section 4135(a) and (b) of the CAA, 2023, titled Access to Non-Opioid Treatments for Pain Relief, amended sections 1833(t)(16) and 1833(i) of the Act, respectively, to provide for temporary additional payments for non-opioid treatments for pain relief (as that term is defined in section 1833(t)(16)(G)(i) of the Act). In particular, section 1833(t)(16)(G) of the Act provides that with respect to a non-opioid treatment for pain relief furnished on or after January 1, 2025, and before January 1, 2028, the Secretary shall not package payment for the non-opioid treatment for pain relief into payment for a covered OPD service (or group of services) and shall make an additional payment for the non-opioid treatment for pain relief as specified in clause (ii) of that section. Clauses (ii) and (iii) of section 1833(t)(16)(G) of the Act provide for the amount of additional payment and set a limitation on that amount, respectively.

As the additional payments are required to begin on January 1, 2025, we proposed and are finalizing a policy to implement the CAA, 2023 section 4135 amendments in this final rule with comment period. Our finalized policy to implement section 4135 of CAA, 2023 can be found in section XIII.E of this final rule with comment period.

5. Calculation of OPPS Scaled Payment Weights

We established a policy in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68283) of using geometric mean-based APC costs to calculate relative payment weights under the OPPS. In the CY 2024 OPPS/ASC final rule with comment period (88 FR 81577 through 81578), we applied this policy and calculated the relative payment weights for each APC for CY 2024 that were shown in Addenda A and B of the CY 2024 OPPS/ASC final rule with comment period (which were made available via the internet on the CMS website) using the APC costs discussed in sections II.A.1 and II.A.2 of the CY 2024 OPPS/ASC final rule with comment period (88 FR 81549 through 81572). For CY 2025, as we did for CY 2024, we proposed to continue to apply the policy established in CY 2013 and calculate relative payment weights for each APC for CY 2025 using geometric mean-based APC costs.

For CY 2012 and CY 2013, outpatient clinic visits were assigned to one of five levels of clinic visit APCs, with APC 0606 representing a mid-level clinic visit. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75036 through 75043), we finalized a policy that created alphanumeric HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient), representing all clinic visits under the OPPS. HCPCS code G0463 was assigned to APC 0634 (Hospital Clinic Visits). We also finalized a policy to use CY 2012 claims data to develop the CY 2014 OPPS payment rates for HCPCS code G0463 based on the total geometric mean cost of the levels one through five CPT Evaluation or Assessment and Management (E/M) codes for clinic visits previously recognized under the OPPS (CPT codes 99201 through 99205 and 99211 through 99215). In addition, we finalized a policy to no longer recognize a distinction between new and established patient clinic visits.

For CY 2016, we deleted APC 0634 and reassigned the outpatient clinic visit HCPCS code G0463 to APC 5012 (Level 2 Examinations and Related Services) (80 FR 70372). For CY 2025, as we did for CY 2024, we proposed to continue to standardize all of the relative payment weights to APC 5012. We believe that standardizing relative payment weights to the geometric mean of the APC to which HCPCS code G0463 is assigned maintains consistency in calculating unscaled weights that represent the cost of some of the most frequently provided OPPS services. For CY 2025, as we did for CY 2024, we proposed to assign APC 5012 a relative payment weight of 1.00 and to divide the geometric mean cost of each APC by the geometric mean cost for APC 5012 to derive the unscaled relative payment weight for each APC. The choice of the APC on which to standardize the relative payment weights does not affect payments made under the OPPS because we scale the weights for budget neutrality.

Section 1833(t)(9)(B) of the Act requires that APC reclassification and recalibration changes, wage index changes, and other adjustments be made in a budget neutral manner. Budget neutrality ensures that the estimated aggregate weight under the OPPS for CY 2025 is neither greater than nor less than the estimated aggregate weight that would have been calculated without the changes. To comply with this requirement concerning the APC changes, we proposed to compare the estimated aggregate weight using the CY 2024 scaled relative payment weights to the estimated aggregate weight using the proposed CY 2025 unscaled relative payment weights.

For CY 2024, we multiplied the CY 2024 scaled APC relative payment weight applicable to a service paid under the OPPS by the volume of that service from CY 2023 claims to calculate the total relative payment weight for each service. We then added together the total relative payment weight for each of these services in order to calculate an estimated aggregate weight for the year. For CY 2025, we proposed to apply the same process using the estimated CY 2025 unscaled relative payment weights rather than scaled relative payment weights. We proposed to calculate the weight scalar by dividing the CY 2024 estimated aggregate weight by the unscaled CY 2025 estimated aggregate weight.

For a detailed discussion of the weight scalar calculation, we refer readers to the OPPS claims accounting document available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*. Click on the link labeled ''Hospital Outpatient Prospective Payment—Notice of Proposed Rulemaking with Comment Period (NPRM)'' for 2025, which can be found under the heading ''Hospital Outpatient Regulations and Notices'' and open the claims accounting document link, which is labeled ''2025 NPRM OPPS Claims Accounting (PDF).''

We proposed to compare the estimated unscaled relative payment weights in CY 2025 to the estimated total relative payment weights in CY 2024 using CY 2023 claims data, holding all other components of the payment system constant to isolate changes in total weight. Based on this comparison, we proposed to adjust the calculated CY 2025 unscaled relative payment weights for purposes of budget neutrality. We proposed to adjust the estimated CY 2025 unscaled relative payment weights by multiplying them by a proposed weight scalar of 1.4452 to ensure that the proposed CY 2025 relative payment weights are scaled to be budget neutral. The proposed CY 2025 relative payment weights listed in Addenda A and B to the proposed rule (which are available via the internet on the CMS website) are scaled and incorporate the recalibration adjustments discussed in sections II.A.1 and II.A.2 of this final rule with comment period.

Section 1833(t)(14) of the Act provides the payment rates for certain specified covered outpatient drugs (SCODs). Section 1833(t)(14)(H) of the

Act provides that additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion factor, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9) but shall be taken into account for subsequent years. Therefore, the cost of those SCODs (as discussed in section V.B.2 of this final rule with comment period) is included in the budget neutrality calculations for the CY 2025 OPPS.

We did not receive any public comments on the proposed weight scalar calculation, and we are finalizing our proposal to use the calculation process described in the CY 2025 OPPS/ASC proposed rule, without modification, for CY 2025. For CY 2025, as we did for CY 2024, we will continue to apply the policy established in CY 2013 and calculate relative payment weights for each APC for CY 2025 using geometric mean-based APC costs. For CY 2025, as we did for CY 2024, we will assign APC 5012 a relative payment weight of 1.00; and we will divide the geometric mean cost of each APC by the geometric mean cost for APC 5012 to derive the unscaled relative payment weight for each APC. To comply with this requirement concerning the APC changes, we will compare the estimated aggregate weight using the CY 2024 scaled relative payment weights to the estimated aggregate weight using the CY 2025 unscaled relative payment weights.

Using updated final rule claims data, we are updating the estimated CY 2025 unscaled relative payment weights by multiplying them by a weight scalar of 1.4452 to ensure that the final CY 2025 relative payment weights are scaled to be budget neutral. The final CY 2025 relative payments weights listed in Addenda A and B of this final rule with comment period (available via the internet on the CMS website) were scaled and incorporate the recalibration adjustments discussed in sections II.A.1 and II.A.2 of this final rule with comment period.

B. Conversion Factor Update

1. OPD Fee Schedule Increase Factor

Section 1833(t)(3)(C)(ii) of the Act requires the Secretary to update the conversion factor used to determine the payment rates under the OPPS on an annual basis by applying the OPD fee schedule increase factor. For purposes of section 1833(t)(3)(C)(iv) of the Act, subject to sections 1833(t)(17) and 1833(t)(3)(F) of the Act, the OPD fee schedule increase factor is equal to the hospital inpatient market basket percentage increase applicable to hospital discharges under section 1886(b)(3)(B)(iii) of the Act. In the FY 2025 IPPS/Long Term Care Hospital (LTCH) PPS proposed rule (89 FR 36204), consistent with current law, based on IHS Global, Inc.'s fourth quarter 2023 forecast, the proposed FY 2025 IPPS market basket percentage increase was 3.0 percent. In the CY 2025 OPPS/ASC proposed rule, we noted that under our regular process for the CY 2025 OPPS/ASC final rule with comment period, we would use the market basket update for the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986). We explained that if that forecast is different than the IPPS market basket percentage increase used for the proposed rule, the CY 2025 OPPS/ASC final rule with comment period OPD fee schedule increase factor would reflect that updated forecast of the market basket percentage increase.

For CY 2025, we proposed to use the estimate of the hospital inpatient market basket percentage increase of 3.0 percent as one component to calculate the OPD fee schedule increase factor.

Comment: Two commenters expressed their support for the proposed hospital inpatient market basket increase of 3.0 percent.

Response: We appreciate the support of the commenters.

Comment: Several commenters expressed concerns that the proposed CY 2025 market basket update does not adequately reflect the rising inflation and costs that hospitals have faced over the last few years. Commenters stated that economy-wide inflation grew by 12.4 percent from 2021 through 2023 (as measured by the Consumer Price Index (CPI)), more than two times faster than Medicare reimbursement for hospital outpatient services, which increased by 5.9 percent during the same time. A commenter noted that the US Health Care Inflation Rate (USHCIR) for June 2024 was 3.3 percent and long-term USHCIR was 5.1 percent. Another commenter noted that inflation for hospital services in July 2024 was 6.1 percent. The commenters observed these rates are substantially higher that the proposed market basket increase.

Many commenters stated that rapid and sustained growth in labor costs have put persistent cost pressure on hospitals. They also noted increases in drug prices, citing a recent study and a report by the Health and Human Services (HHS) Assistant Secretary for Planning and Evaluation which found that in 2022 and 2023, prices for nearly 2,000 drugs increased faster than the rate of general inflation, with an average price increase of 15.2 percent. Several commenters also stated that hospitals have seen significant growth in administrative costs due to what they described as inappropriate practices by large commercial health insurers, including Medicare Advantage and Medicaid managed care plans, such as automatic claim denials and onerous prior authorization requirements. Commenters also discussed the continued costs of addressing past and preventing future cyberattacks and a commenter stated they have seen significant increases in capital costs, particularly since the pandemic. Some commenters stated that hospitals will continue to face increased costs due to the Change Healthcare cyberattack, such as interest costs on loan payments for loans acquired during the cyberattack, expected denials that will require additional administrative costs, and manual processing of claims. Commenters also urged CMS to consider the changing health care environment, which they state is putting enormous financial strain on hospitals and health systems and is expected to continue through 2025.

Several commenters proposed CMS apply a payment increase of at least 4.1 percent which is aligned with MedPAC's March 2024 Report to Congress, which recommended a 1.5 percentage points increase over the FY 2025 payment update. These commenters noted that this was the second year that MedPAC made a recommendation of increasing the market basket update. Several commenters suggested various higher market basket increases, which they believe better reflects hospitals' input prices and the contract labor staffing challenge. A commenter encouraged CMS to consider, at a minimum, matching the 3.7 percent increase that the commenter stated Medicare Advantage will receive.

Several commenters recommended CMS look to alternative data sources that they asserted better reflect true labor and input cost increases in a timely manner. The commenters stated that the proposed payment update does not recognize these challenges, nor does it factor in the realities of inflation impacting operating costs. Commenters also stated CMS must use data that better reflects the input price inflation that hospitals have experienced and are projected to experience in CY 2025. Multiple commenters recommended CMS use more recent data to update adjustments to 2025 OPPS rates.

Many commenters noted their financial pressures due to the PHE, aging, more complex patients, negative Medicare margins of −12.7 percent as

estimated by MedPAC, and reliance on public payers. Several commenters urged CMS to consider and assess the financial position of hospitals, particularly those with low margins. Multiple commenters asked for CMS to increase rates to cover the cost of care for Medicaid patients. Many commenters noted financial hardships, particularly in 2022, with high inflation and workforce shortages. They noted that MedPAC found that all-payment operating and overall Medicare margins both fell to record lows, estimating Medicare hospital margins of negative 12.7 percent for FY 2022. MedPAC's FY 2024 recommendation was to increase the market basket update by one percentage point and, for FY 2025, that Congress increase the acute hospital market basket by 1.5 percentage points over current law.

Response: We acknowledge commenters' concerns, however, as we stated in the CY 2025 OPPS/ASC proposed rule, section 1833(t)(3)(C)(iv) of the Act requires the OPD fee schedule increase factor for a year to equal the IPPS market basket percentage increase factor applicable under section 1886(b)(3)(B)(iii) to hospital discharges in the fiscal year ending in such year. Accordingly, we are unable to adopt a final OPD fee schedule increase factor different than the IPPS market basket percentage increase factor finalized in the FY 2025 IPPS/LTCH PPS final rule. We refer commenters to that final rule for responses regarding the issues commenters raised (89 FR 69340).

Comment: Many commenters expressed concerns with the Employment Cost Index (ECI) used to measure changes in labor compensation in the market basket, which they state may no longer accurately capture the changing composition and cost structure of the hospital labor market given the large increases in short-term contract labor use and its growing costs. The commenters stated labor costs have increased by more than 18 percent from CY 2020 to CY 2023. They attributed this increase to expensive contract labor costs (as a result of higher utilization rates and higher costs per hour) and faster growth in salaries for employed workers (reflecting sign-on and retention bonuses). They further stated that while salaries for contract nurses have decreased some from a peak in certain geographical areas, they still remained nearly 60 percent higher at the end of FY 2023 compared to the start of FY 2020. They further stated that CMS recognizes that the ECI does not capture shifts in composition of labor, and the commenters stated that by design, the ECI is not capturing the shifts that have occurred as hospitals have had to turn to contract labor to meet patient demand. Several commenters recommended that CMS use its exceptions and adjustments authority to adopt new or supplemental data sources, to ensure labor costs are adequately reflected in the payment update in the final rule. They further requested CMS utilize supplemental data sources to evaluate the accuracy of the ECI proxy and to modify methodologies, including adopting new or supplemental data, to calculate the payment update if its analysis determines that the ECI is not adequately capturing labor costs.

Response: We refer commenters to the FY 2025 IPPS/LTCH PPS final rule, where we responded to similar comments regarding the use of the ECI and related issues raised by commenters (89 FR 69340 through 69341). We further note that, as we stated in the CY 2025 OPPS/ASC proposed rule, section 1833(t)(3)(C)(iv) of the Act requires the OPD fee schedule increase factor for a year to equal the IPPS market basket percentage increase factor applicable under section 1886(b)(3)(B)(iii) to hospital discharges in the fiscal year ending in such year. Accordingly, we are unable to adopt a final OPD fee schedule increase factor different than the IPPS market basket percentage increase factor finalized in the FY 2025 IPPS/LTCH PPS final rule, which would occur if we used a different methodology to measure changes in labor compensation in the OPPS market basket.

Comment: Several commenters recommended that CMS reevaluate the data sources it uses for rebasing its market basket and calculating the annual market basket update, including labor costs. They strongly encouraged CMS to adopt new or supplemental data sources in future rulemaking that more accurately reflect the costs to hospitals, such as through use of more real time data from the hospital community. They stated that they believe that the current market basket does not account for the higher costs of contract labor, which has become more common in hospitals in an era of clinical labor shortages. A commenter requested that CMS rebase the market baskets more frequently and at least every 3 years to ensure the market basket reflects the appropriate mix of services provided to Medicare beneficiaries.

Response: We refer commenters to the FY 2025 IPPS/LTCH PPS final rule, where we responded to similar comments (89 FR 69341). As we stated in the CY 2025 OPPS/ASC proposed rule, section 1833(t)(3)(C)(iv) of the Act requires the OPD fee schedule increase factor for a year to equal the IPPS market basket percentage increase factor applicable under section 1886(b)(3)(B)(iii) to hospital discharges in the fiscal year ending in such year. Accordingly, we are unable to adopt a final OPD fee schedule increase factor different than the IPPS market basket percentage increase factor finalized in the FY 2025 IPPS/LTCH PPS final rule.

Comment: Commenters stated that since the COVID–19 PHE, IHS Global, Inc (IGI) has shown a consistent 3-year trend of under-forecasting the market basket growth and expressed concern this may indicate a more systematic issue with IGI's forecasting. They stated that these missed forecasts are permanently established in the standard payment rate for IPPS and will continue to compound, which they estimate to be $4 billion. Several commenters, including many associations, urged CMS to use its special exceptions and adjustments authority under section 1886(d)(5)(i) of the Act to implement a retrospective one-time adjustment for CY 2025 to account for the underestimation of the market basket updates over the last several years. Commenters recommended that CMS implement various one-time adjustments to account for underpayments in one or more years between CY 2021 and CY 2023 as well as for forecasted underpayments for CY 2024. The commenters stated the underestimation is, in large part, because the market basket is a time-lagged estimate that cannot fully account for unexpected changes that occur, such as historic inflation and increased labor and supply costs. They stated this is exactly what occurred at the end of the CY 2021 into CY 2022, which resulted in a large forecast error in the CY 2022 market basket update.

Several commenters noted that CMS currently implements a capital IPPS market basket forecast error adjustment as well as SNF PPS market basket forecast error adjustment policy, which resulted in FY 2024 and FY 2025 SNF forecast error adjustments of 3.6 percentage points and 1.7 percentage points, respectively. They stated while CMS has not developed an analogous policy for the OPPS operating update, they believe such a forecast error adjustment to the CY 2025 OPPS operating update could be adopted under CMS' existing authority. They noted the forecast errors for CY 2021 through CY 2023 for OPPS exceeded the 0.5 percentage point threshold that is used for the SNF forecast error adjustment policy. A commenter recommended CMS establish a forecast

error threshold of 1.5 percentage points, and retroactively adjust payments for that year.

Response: We refer commenters to the FY 2025 IPPS/LTCH PPS final rule, where we responded to similar comments (89 FR 69342). As we stated in the CY 2025 OPPS/ASC proposed rule, section 1833(t)(3)(C)(iv) of the Act requires the OPD fee schedule increase factor for a year to equal the IPPS market basket percentage increase factor applicable under section 1886(b)(3)(B)(iii) to hospital discharges in the fiscal year ending in such year. Accordingly, we are unable to adopt a final OPD fee schedule increase factor different than the IPPS market basket percentage increase factor finalized in the FY 2025 IPPS/LTCH PPS final rule.

Comment: Multiple commenters supported the proposed 3.0 percent market basket increase believing the market basket increase would help rural hospitals. However, the commenters believe inflation for outpatient hospital services is substantially higher than the market basket increase, and they would prefer a higher market basket increase to help rural providers. The commenters stated that the operating margin for independent rural hospitals is -2.2 percent and that the operating margins for system-affiliated rural hospitals is 1.7 percent. Other commenters believe the low market basket increases lead to challenges for rural providers. Those commenters noted that the operating margins for rural hospitals are not sustainable, and they noted that eleven hospitals in rural and underserved areas have closed in the past two years even with the establishment of a new Medicare provider type that allows such hospitals to become rural emergency hospitals. The commenters believe a higher market basket increase would help rural hospitals stay open and provide access to quality care especially maternal care in the areas that they serve.

Response: We appreciate the support of the commenters of the proposed market basket increase, and we appreciate the commenters' raising their concerns regarding rural hospitals. As we stated in the CY 2025 OPPS/ASC proposed rule, section 1833(t)(3)(C)(iv) of the Act requires the OPD fee schedule increase factor for a year to equal the IPPS market basket percentage increase factor applicable under section 1886(b)(3)(B)(iii) to hospital discharges in the fiscal year ending in such year. Accordingly, we are unable to adopt a final OPD fee schedule increase factor different than the IPPS market basket percentage increase factor finalized in the FY 2025 IPPS/LTCH PPS final rule.

Comment: Multiple commenters claim that section 1833(t)(3)(C)(iv) of the Act, which defines the outpatient hospital department market basket increase factor, has provisions that give CMS flexibility to use a different market basket increase factor for outpatient hospital services than the market basket increase factor used for inpatient hospital services. The commenters requested that CMS take advantage of section 1833(t)(3)(C)(iv) to establish a market basket increase for CY 2025 for the OPPS that would be larger than the market basket increase that was finalized for FY 2025 for the IPPS.

Response: Section 1833(t)(3)(C)(iv) of the Act permits the Secretary to substitute for the market basket percentage increase an annual percentage increase that is computed and applied with respect to covered OPD services furnished in a year in the same manner as the market basket percentage increase is determined and applied to inpatient hospital services for discharges occurring in a fiscal year. We would only anticipate utilizing a specific outpatient hospital market basket factor if the rate of change in the cost of covered OPD services was substantially different than the rate of change in the cost of inpatient hospital services for the previous fiscal year. We did not find evidence that the rate of change for covered OPD services was substantially different that the rate of changes for inpatient hospital services. Therefore, we are adopting an OPD fee schedule increase factor for CY 2025 equal to the IPPS market basket percentage increase factor applicable under section 1886(b)(3)(B)(iii) to hospital discharges in the fiscal year ending in such year, as required by section 1833(t)(3)(C)(iv) of the Act. We decline to adopt a final OPD fee schedule increase factor different than the IPPS market basket percentage increase factor finalized in the FY 2025 IPPS/LTCH PPS final rule.

2. Productivity Adjustment

Section 1833(t)(3)(F)(i) of the Act requires that, for 2012 and subsequent years, the OPD fee schedule increase factor under subparagraph (C)(iv) be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period) (the ''productivity adjustment''). In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692), we finalized our methodology for calculating and applying the productivity adjustment. The U.S. Department of Labor's Bureau of Labor Statistics (BLS) publishes the official measures of private nonfarm business productivity for the U.S. economy. We note that previously the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act was published by BLS as private nonfarm business multifactor productivity. Beginning with the November 18, 2021, release of productivity data, BLS replaced the term multifactor productivity (MFP) with total factor productivity (TFP). BLS noted that this is a change in terminology only and will not affect the data or methodology. As a result of the BLS name change, the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act is now published by BLS as private nonfarm business total factor productivity. However, as mentioned, the data and methods are unchanged. Please see *www.bls.gov* for the BLS historical published TFP data. A complete description of IHS Global, Inc.'s (IGI) TFP projection methodology is available on the CMS website at *https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-research-and-information*. In addition, we note that beginning with the FY 2022 IPPS/LTCH PPS final rule, we refer to this adjustment as the productivity adjustment rather than the MFP adjustment to more closely track the statutory language in section 1886(b)(3)(B)(xi)(II) of the Act. We note that the adjustment continues to rely on the same underlying data and methodology. In the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 36204), the proposed productivity adjustment for FY 2025 was 0.4 percentage point.

Therefore, we proposed that the productivity adjustment for the CY 2025 OPPS/ASC would be 0.4 percentage point. We also proposed that if more recent data subsequently became available after the publication of the CY 2025 OPPS/ASC proposed rule (for example, a more recent estimate of the market basket percentage increase and/or the productivity adjustment), we would use such updated data, if appropriate, to determine the CY 2025 hospital inpatient market basket update and the productivity adjustment, which are components in calculating the OPD fee schedule increase factor under

sections 1833(t)(3)(C)(iv) and 1833(t)(3)(F) of the Act.

We note that section 1833(t)(3)(F) of the Act provides that application of this subparagraph may result in the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act being less than 0.0 percent for a year and may result in OPPS payment rates being less than rates for the preceding year. As described in further detail below, we proposed for CY 2025 an OPD fee schedule increase factor of 2.6 percent for the CY 2025 OPPS/ASC (which is the proposed estimate of the hospital inpatient market basket percentage increase of 3.0 percent, less the proposed 0.4 percentage point productivity adjustment).

Comment: Several commenters expressed concerns about the application of the productivity adjustment, particularly given the extreme pressures in which hospital and health systems operate. They stated the use of the private nonfarm business TFP is meant to capture gains from new technologies, economies of scale, business acumen, managerial skills and changes in productions. Thus, they stated this measure effectively assumes the hospital sector can mirror productivity gains from the private nonfarm business sector. They stated, however, in an economy marked by great uncertainty due to the PHE and labor and other productivity shocks, this assumption is significantly flawed. Other commenters requested that productivity adjustment be eliminated for CY 2025 without any additional reasons. A commenter also requested that CMS use its ''special exceptions and adjustments'' authority to reduce the productivity adjustment for CY 2025. Another commenter asked that the productivity adjustment not apply to small rural and sole community hospitals for CY 2025.

Response: Section 1833(t)(3)(F)(i) requires that after determining the OPD fee schedule increase factor under subparagraph (C)(iv), the Secretary shall reduce such increase factor by the productivity adjustment described in section 1886(b)(3)(B)(xi) of the Act. As required by statute, the FY 2025 productivity adjustment is derived based on the 10-year moving average growth in economy-wide productivity for the period ending FY 2025.

We thank the commenters for their comments. After consideration of the comments received and consistent with our proposal, we are finalizing an OPD fee schedule increase factor of 2.9 percent for CY 2025, which consists of the IPPS market basket increase factor of 3.4 percent less a 0.5 percentage point productivity adjustment.

3. Other Conversion Factor Adjustments

To set the OPPS conversion factor for 2025, we proposed to increase the CY 2024 conversion factor of $87.382 by 2.6 percent. In accordance with section 1833(t)(9)(B) of the Act, we proposed further to adjust the conversion factor for CY 2025 to ensure that any revisions made to the wage index and rural adjustment are made on a budget neutral basis. We proposed to calculate an overall budget neutrality factor of 1.0026 for wage index changes by comparing proposed total estimated payments from our simulation model using the proposed FY 2025 IPPS wage indexes to those payments using the FY 2024 IPPS wage indexes, as adopted on a calendar year basis for the OPPS. We further proposed to calculate an additional budget neutrality factor of 0.9982 to account for our proposed policy to cap wage index reductions for hospitals at 5 percent on an annual basis.

For CY 2025, we proposed to maintain the current rural adjustment policy, as discussed in section II.E of this final rule with comment period. Therefore, the proposed budget neutrality factor for the rural adjustment was 1.0000.

We proposed to calculate a CY 2025 budget neutrality adjustment factor for the cancer hospital payment adjustment by transitioning from the target PCR of 0.89 we finalized for CYs 2020 through 2023 (which included the 1.0 percentage point reduction as required by section 16002(b) of the 21st Century Cures Act) and incrementally reducing the target PCR by an additional 1.0 percentage point for each calendar year, beginning with CY 2024, until the target PCR equals the PCR of non-cancer hospitals calculated using the most recent data minus 1.0 percentage point as required by section 16002(b) of the 21st Century Cures Act. Therefore, we proposed to apply a budget neutrality adjustment factor of 1.0006 to the conversion factor for the cancer hospital payment adjustment. In accordance with section 1833(t)(18)(C) of the Act, as added by section 16002(b) of the 21st Century Cures Act (Pub. L. 114–255), we reduce the target PCR by 0.01, which brings the proposed target PCR to 0.87. This is 0.02 less than the target PCR of 0.89 from CY 2021 through CY 2023, which was held at the pre-PHE target.

For the CY 2025 OPPS/ASC proposed rule, we estimated that proposed pass-through spending for drugs, biologicals, and devices for CY 2025 would equal approximately $625 million, which represented 0.71 percent of total projected CY 2025 OPPS spending. Therefore, we stated that the proposed conversion factor would be adjusted by the difference between the 0.27 percent estimate of pass-through spending for CY 2024 and the 0.71 percent estimate of proposed pass-through spending for CY 2025, resulting in a proposed decrease to the conversion factor for CY 2025 of 0.44 percent.

We proposed that estimated payments for outliers would remain at 1.0 percent of total OPPS payments for CY 2025. We estimated for the proposed rule that outlier payments would be approximately 0.85 percent of total OPPS payments in CY 2024; the 1.00 percent for proposed outlier payments in CY 2025 would constitute a 0.15 percent increase in payment in CY 2025 relative to CY 2024.

For CY 2025, we proposed to use a conversion factor of $87.382 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs; that is, the proposed OPD fee schedule increase factor of 2.6 percent for CY 2025, the required proposed wage index budget neutrality adjustment of approximately 1.0026, the proposed 5 percent annual cap for individual hospital wage index reductions adjustment of approximately 0.9982, the proposed cancer hospital payment adjustment of 1.0006, and the proposed adjustment of a decrease of 0.44 percentage point of projected OPPS spending for the difference in pass-through spending, which resulted in a proposed conversion factor for CY 2025 of $89.379.

For CY 2025, we also proposed that hospitals that fail to meet the reporting requirements of the Hospital OQR Program would continue to be subject to a further reduction of 2.0 percentage points to the OPD fee schedule increase factor. For hospitals that fail to meet the requirements of the Hospital OQR Program, we proposed to make all other adjustments discussed above, but use a reduced OPD fee schedule update factor of 0.6 percent (that is, the proposed OPD fee schedule increase factor of 2.6 percent further reduced by 2.0 percentage points). This would result in a proposed reduced conversion factor for CY 2025 of $87.636 for hospitals that fail to meet the Hospital OQR Program requirements (a difference of −1.743 in the conversion factor relative to hospitals that met the requirements). For further discussion of the Hospital OQR Program, we refer readers to section XV of this final rule with comment period. For 2025, we proposed

to use a reduced conversion factor of $87.636 in the calculation of payments for hospitals that fail to meet the Hospital OQR Program requirements (a difference of −1.743 in the conversion factor relative to hospitals that met the requirements).

We received no comments on our proposed adjustments to the conversion factor for CY 2025. For this CY 2025 OPPS/ASC final rule with comment period, based on more recent data available, the OPD fee schedule increase factor for the CY 2025 OPPS is 2.9 percent (which reflects the 3.4 percent final estimate of the hospital inpatient market basket percentage increase reduced by a 0.5 percentage point productivity adjustment). For CY 2025, we are using a conversion factor of $89.169 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs; that is, the OPD fee schedule increase factor of 2.9 percent for CY 2025, the required wage index budget neutrality adjustment of 0.9927, the 5 percent annual cap for individual hospital wage index reductions of 0.9995, the cancer hospital payment adjustment of 1.0005, and the adjustment of 0.10 (or 0.37 less 0.27) percentage point of projected OPPS spending for the difference in pass-through spending that results in a conversion factor for CY 2024 of $89.169. We are also finalizing a reduced conversion factor of $87.439 in the calculation of payments for hospitals that fail to meet the Hospital OQR Program requirements (a difference of −1.730 in the conversion factor relative to hospitals that met the requirements).

The calculations we performed to determine the CY 2025 final conversion factor are shown in Table 10.

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TABLE 10: CALCULATION OF CY 2025 FINAL OPPS CONVERSION FACTOR

Start: CY 2024 Final OPPS Conversion Factor = **$87.382**
Step 1a: Adjust the conversion factor to temporarily account for additional drug and device pass-through spending and outlier spending in CY 2024. This action causes an increase in the conversion factor. So, the amount of both drug and device pass-through spending (0.0027) and the percentage of outlier spending (0.01) as a share of total OPPS outpatient hospital spending is subtracted from 1.0000, which represents total OPPS outpatient hospital spending for CY 2024. ➢ 1.0000– (0.0027+0.01) = 0.9873
Step 1b: Divide $87.382 by 0.9873 ➢ $87.382/0.9873 = **$88.506**
Step 2: Adjust the conversion factor by the required wage index budget neutrality adjustment of approximately 0.9927. This adjustment increases the amount of OPPS outpatient hospital spending and is multiplied with $88.506. ➢ $88.506* 0.9927 = **$87.860**
Step 3: Adjust the conversion factor by the 5 percent annual cap for individual hospital wage index reductions adjustment of approximately 0.9995. This adjustment reduces the amount of OPPS outpatient hospital spending and is multiplied with $87.860. ➢ $87.860* 0.9995 = **$87.816**
Step 4: Adjust the conversion factor by the cancer hospital payment adjustment of 1.0005. Because the PCR for cancer hospitals is declining between CY 2024 and CY 2025, it increases the amount of OPPS outpatient hospital spending for providers that are not cancer hospitals and is multiplied with $87.816. ➢ $87.816*1.0005 = **$87.860**
Step 5: Adjust the conversion factor by rural SCH adjustment policy of 1.0000. Since we are maintaining our current policy, there is no impact on the conversion by this policy.

➢ $87.860*1.0000 = **$87.860**
Step 6a: Adjust the conversion factor by the OPD fee schedule increase factor of 0.029 for CY 2025. The OPD fee schedule increase factor increases outpatient hospital spending in CY 2025 over CY 2024 and is added to 1.0000 which represents total outpatient hospital OPPS spending in CY 2024. ➢ 1.0000+0.029 = 1.0290
Step 6b: Multiply $87.860 by 1.0290. ➢ $87.860*1.0290 = **$90.408**
Step 7a: Adjust the conversion factor to remove additional drug and device pass-through spending and outlier spending for CY 2025. This action causes a decrease in the conversion factor. So, the amount of both drug and device pass-through spending (0.0037) and the percentage of outlier spending (0.01) as a share of total OPPS outpatient hospital spending is subtracted from 1.0000, which represents total OPPS outpatient hospital spending for CY 2025. ➢ 1.0000– (0.0037+0.01) = 0.9863
Step 7b: Multiply $90.408 by 0.9863 to get the CY 2025 final OPPS conversion factor. $90.408*0.9863 = **$89.169**
Finish: **CY 2025 OPPS Conversion Factor = $89.169**

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C. Wage Index Changes

Section 1833(t)(2)(D) of the Act requires the Secretary to determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner (codified at 42 CFR 419.43(a)). This portion of the OPPS payment rate is called the OPPS labor-related share. Budget neutrality is discussed in section II.A.5 of this final rule with comment period.

The OPPS labor-related share is 60 percent of the national OPPS payment. This labor-related share is based on a regression analysis that determined that, for all hospitals, approximately 60 percent of the costs of services paid under the OPPS were attributable to wage costs. We confirmed that this labor-related share for outpatient services is appropriate during- our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553). We proposed to continue this policy for the CY 2025 OPPS/ASC. We refer readers to section II.C of this final rule with comment period for a description and an example of how the wage index for a particular hospital is used to determine payment for the hospital.

We did not receive any public comments on our proposed labor-related share, and we are finalizing our proposal without modification.

As discussed in the claims accounting narrative included with the supporting documentation for this final rule with comment period (which is available via the internet on the CMS website (*https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*)), for estimating APC costs, we would standardize 60 percent of estimated claims costs for geographic area wage variation using the same FY 2025 pre-reclassified wage index that we use under the IPPS to standardize costs. This standardization process removes the effects of differences in area wage levels from the determination of a national unadjusted OPPS payment rate and copayment amount.

Under 42 CFR 419.41(c)(1) and 419.43(c) (published in the OPPS April 7, 2000, final rule with comment period (65 FR 18495 and 18545)), the OPPS adopted the final fiscal year IPPS post-reclassified wage index as the calendar year wage index for adjusting the OPPS standard payment amounts for labor market differences. Therefore, in general, the wage index that applies to a particular acute care, short-stay hospital under the IPPS has also applied to that hospital under the OPPS. As initially explained in the September 8, 1998, OPPS/ASC proposed rule (63 FR 47576), we believe that using the IPPS wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall. In accordance with section 1886(d)(3)(E) of

the Act, the IPPS wage index is updated annually.

The Affordable Care Act contained several provisions affecting the wage index. These provisions were discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74191). Section 10324 of the Affordable Care Act added section 1886(d)(3)(E)(iii)(II) to the Act, which defines a frontier State and amended section 1833(t) of the Act to add paragraph (19), which requires a frontier State wage index floor of 1.00 in certain cases, and states that the frontier State floor shall not be applied in a budget neutral manner. We codified these requirements at § 419.43(c)(2) and (3) of our regulations. For CY 2025 we proposed to implement this provision in the same manner as we have since CY 2011. Under this policy, the frontier State hospitals would receive a wage index of 1.00 if the otherwise applicable wage index (including reclassification, the rural floor, and rural floor budget neutrality) is less than 1.00. Because the HOPD receives a wage index based on the geographic location of the specific inpatient hospital with which it is associated, the frontier State wage index adjustment applicable for the inpatient hospital also would apply for any associated HOPD. We refer readers to the FY 2011 through FY 2024 IPPS/LTCH PPS final rules for discussions regarding this provision, including our methodology for identifying which areas meet the definition of ''frontier States'' as provided for in section 1886(d)(3)(E)(iii)(II) of the Act: for FY 2011, 75 FR 50160 through 50161; for FY 2012, 76 FR 51793, 51795, and 51825; for FY 2013, 77 FR 53369 and 53370; for FY 2014, 78 FR 50590 and 50591; for FY 2015, 79 FR 49971; for FY 2016, 80 FR 49498; for FY 2017, 81 FR 56922; for FY 2018, 82 FR 38142; for FY 2019, 83 FR 41380; for FY 2020, 84 FR 42312; for FY 2021, 85 FR 58765; for FY 2022, 86 FR 45178; FY 2023, 87 FR 49006; and for FY 2024, 88 FR 58977.

In addition to the changes required by the Affordable Care Act, we note that the proposed FY 2025 IPPS wage indexes continue to reflect a number of adjustments implemented in past years, including, but not limited to, reclassification of hospitals to different geographic areas, the rural floor provisions, the imputed floor wage index adjustment in all-urban states, an adjustment for occupational mix, an adjustment to the wage index based on commuting patterns of employees (the out-migration adjustment), and the permanent 5-percent cap on any decrease to a hospital's wage index from its wage index in a prior FY. Beginning with FY 2024, we include hospitals with § 412.103 reclassification along with geographically rural hospitals in all rural wage index calculations, and exclude ''dual reclass'' hospitals (hospitals with simultaneous § 412.103 and Medicare Geographic Classification Review Board (MGCRB) reclassifications) implicated by the hold harmless provision at section 1886(d)(8)(C)(ii) of the Act (88 FR 58971 through 58973). We also proposed to continue the low wage index hospital policy, under which we increase the wage index for hospitals with a wage index value below the 25th percentile wage index value for a fiscal year by half the difference between the otherwise applicable final wage index value for a year for that hospital and the 25th percentile wage index value for that year across all hospitals. We refer readers to the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 36181 through 36186) for a detailed discussion of all proposed changes to the FY 2025 IPPS wage indexes.

We note that in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49018 through 49021), we finalized a permanent approach to smooth year-to-year decreases in hospitals' wage indexes. Specifically, for FY 2023 and subsequent years, we apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline. That is, a hospital's wage index for FY 2025 would not be less than 95 percent of its final wage index for FY 2024. Except for newly opened hospitals, we apply the cap for a fiscal year using the final wage index applicable to the hospital on the last day of the prior fiscal year. A newly opened hospital would be paid the wage index for the area in which it is geographically located for its first full or partial fiscal year (subject to any reclassification), and it would not receive a cap for that first year, because it would not have been assigned a wage index in the prior year (in accordance with 42 CFR 419.41(c)(1) and 419.43(c), as noted previously).

We delineate hospital labor market areas based on Core-Based Statistical Areas (CBSAs) established by the Office of Management and Budget (OMB). As discussed in the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 36139 through 36174), OMB issued revisions to the current labor market area delineations on July 21, 2023, that included a number of significant changes such as new CBSAs, urban counties that become rural, rural counties that become urban, and existing CBSAs that are split apart (OMB Bulletin 23–01). This bulletin can be found at: *https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf*. The proposed changes to the IPPS wage index based on the newest CBSA delineations are available in the FY 2025 IPPS/LTCH PPS proposed rule. We proposed that corresponding changes would be adopted in the OPPS, which uses the IPPS wage index, based on the new OMB delineations in the CY 2025 OPPS/ASC proposed rule, consistent with any proposals in the FY 2025 IPPS/LTCH PPS proposed rule. We believe that using the revised delineations based on OMB Bulletin No. 23–01 will increase the integrity of the OPPS wage index system by creating a more accurate representation of current geographic variations in wage levels. We refer readers to proposed changes based on the new OMB delineations in the FY 2025 IPPS/LTCH PPS proposed rule at 89 FR 36139 through 36174, which includes a discussion of the effects of implementation of the proposal to adopt the revised OMB labor market area delineations on reclassified hospitals.

CBSAs are made up of one or more constituent counties. Each CBSA and constituent county has its own unique identifying codes. The FY 2018 IPPS/LTCH PPS final rule (82 FR 38130) discussed the two different lists of codes to identify counties: Social Security Administration (SSA) codes and Federal Information Processing Standard (FIPS) codes. Historically, CMS listed and used SSA and FIPS county codes to identify and crosswalk counties to CBSA codes for purposes of the IPPS and OPPS wage indexes. However, the SSA county codes are no longer being maintained and updated, although the FIPS codes continue to be maintained by the U.S. Census Bureau. The Census Bureau's most current statistical area information is derived from ongoing census data from 2020. The Census Bureau maintains a complete list of changes to counties or county equivalent entities on the website at: *https://www.census.gov/geo/reference/county-changes.html* (which, as of May 6, 2019, migrated to: *https://www.census.gov/programs-surveys/geography.html*). In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38130), for purposes of cross walking counties to CBSAs for the IPPS wage index, we finalized our proposal to discontinue the use of the SSA county codes and begin using only the FIPS county codes. Similarly, for the purposes of cross walking counties to CBSAs for the OPPS wage index, in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59260), we finalized our proposal to discontinue

the use of SSA county codes and begin using only the FIPS county codes. For CY 2025, under the OPPS, we are continuing to use only the FIPS county codes for purposes of cross walking counties to CBSAs.

We proposed to use the FY 2025 IPPS post-reclassified wage index for urban and rural areas as the wage index for the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment rate for CY 2025. We note that the proposed FY 2025 IPPS wage indexes reflect several proposed changes as a result of the revised OMB delineations, including proposed policies to accommodate changes in rural or urban status for existing counties, as well as addition or removal of certain individual CBSAs compared to the previous delineations. Therefore, policies and adjustments that were finalized for the FY 2025 IPPS post-reclassified wage index would be reflected in the final CY 2025 OPPS wage index beginning on January 1, 2025, if appropriate. We refer readers to the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 36181 through 36186) and the proposed FY 2025 hospital wage index files posted on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2025-ipps-proposed-rule-home-page*. Regarding budget neutrality for the CY 2025 OPPS wage index, we refer readers to section II.C of this final rule with comment period.

As a general matter, we continue to believe that using the IPPS post-reclassified wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall. We acknowledge, however, that an interim final action with comment period (IFC) entitled Changes to the Fiscal Year 2025 Hospital Inpatient Prospective Payment System (IPPS) Rates Due to Court Decision appeared in the October 3, 2024 **Federal Register** (89 FR 80405), which makes certain changes to the FY 2025 IPPS post-reclassified wage index for some hospitals that were not and could not have been anticipated or accounted for in the OPPS proposed rule. For reasons discussed in detail later in this section, we believe it is more appropriate and consistent with CMS' authority to use the post-reclassified wage index established in the FY 2025 IPPS final rule (89 FR 68986) as corrected in the FY 2025 IPPS final rule correction (89 FR 80098) for purposes of the CY 2025 OPPS wage index than it would be to incorporate the exceptional changes implemented by the IFC.

Hospitals that are paid under the OPPS, but not under the IPPS, do not have an assigned hospital wage index under the IPPS. Therefore, for non-IPPS hospitals paid under the OPPS, it is our longstanding policy to assign the wage index that would be applicable if the hospital was paid under the IPPS, based on its geographic location and any applicable wage index policies and adjustments. We proposed to continue this policy for CY 2025. We refer readers to the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 36181 through 36186) for a detailed discussion of the proposed changes to the FY 2025 IPPS wage indexes.

It has been our longstanding policy to allow non-IPPS hospitals paid under the OPPS to qualify for the out-migration adjustment if they are located in a section 505 out-migration county (section 505 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)) (Pub. L. 108–173). Applying this adjustment is consistent with our general approach to adopt IPPS wage index policies for hospitals paid under the OPPS. We note that, because non-IPPS hospitals cannot reclassify, they are eligible for the out-migration wage index adjustment if they are located in a section 505 out-migration county. This is the same out-migration adjustment policy that would apply if the hospital were paid under the IPPS. For CY 2025, we proposed to continue our policy of allowing non-IPPS hospitals paid under the OPPS to qualify for the outmigration adjustment if they are located in a section 505 out-migration county (section 505 of the MMA) (88 FR 49585 and 49586). Furthermore, we proposed that the wage index that would apply for CY 2025 to non-IPPS hospitals paid under the OPPS would continue to include the rural floor adjustment and any policies and adjustments applied to the IPPS wage index to address wage index disparities. In addition, we proposed that the wage index that would apply to non-IPPS hospitals paid under the OPPS would include the 5-percent cap on wage index decreases.

Comment: One commenter supported CMS's decision to utilize the updated OMB delineations and agreed with the CBSA assignments made in Connecticut based on the regional planning areas.

Response: We appreciate the commenter's support.

Comment: A commenter did not agree with CMS's adoption of OMB's CBSA delineation revisions. The commenter stated that OMB cautions that CBSAs are not intended for any non-statistical uses and should only be used for other purposes with full consideration of the effects of using the delineations for such purposes. Further, the commenter stated that the Metropolitan Areas Protection and Standardization Act (MAPS Act) bars the automatic propagation of OMB revisions in CBSA delineations to geographic area determinations in nonstatistical Federal programs, and stated that any change to the standards of CBSA delineations shall propagate for any non-statistical use by any domestic assistance program only if the relevant agency determines that such a propagation supports the purposes of the program, is in the public interest, and adopts the change through notice-and-comment rulemaking. The commenter contends that if CMS chooses to adopt new OMB delineations, CMS must fully explain why reliance on the updated CBSAs as set forth by OMB is appropriate for purposes of the FY 2025 hospital wage index adjustments. The commenter stated that CMS has not provided an appropriate rationale for relying on the updated CBSAs and proposed to adopt the revised CBSAs by default. The commenter contends that CMS must make a fact-specific determination of those CBSAs' suitability for Medicare reimbursement purposes, including whether it would be appropriate to use additional data to modify OMB's delineations to ensure that such changes are appropriate for purposes of defining regional labor markets for hospital workers.

Response: CMS acknowledges that the CBSA definitions and delineations were not specifically created for the purpose of determining a hospital wage index. However, based on the reasons stated in prior rulemaking, we continue to believe that these definitions and delineations, which are regularly reviewed and updated by OMB, are the best proxy for CMS to use to adjust hospital payment rates based on geographic variations in labor costs in accordance with the statute. We note that the OPPS wage index has historically adopted the IPPS wage index on a calendar year basis, and thus the same structure for organizing geographic areas applied to the IPPS through CBSAs has applied in the OPPS.

Section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals through the IPPS, the Secretary must adjust the standardized amounts ''for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the

geographic area of the hospital compared to the national average hospital wage level.'' Section 1833(t)(2)(D) of the Act provides that for the OPPS, ''the Secretary shall determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner.'' We refer readers to the FY 1985 IPPS final rule (50 FR 24375 through 24377) and the FY 1995 IPPS final rule (60 FR 29218 through 29220) for a history of the outreach, consultation, and discussion of the challenges faced in defining appropriate labor market areas for purposes of the wage index methodology. As with any classification system in which boundaries must be established, it is impossible to designate boundaries that will be completely satisfactory to all concerned. There was no consensus among the interested parties on a choice for new labor market areas, and CMS concluded the adoption and continuation of an MSA-based framework was the most prudent course of action. We also refer readers to the FY 2005 rule (69 FR 49027 through 49028) for further discussion regarding the process and outreach CMS undertook before initially adopting OMB CBSAs as the basis for the wage index methodology. We found that the CBSA framework offered a useful proxy for labor market area delineations and that none of the alternative labor market areas that were studied provided a distinct improvement over the use of MSAs.

As stated previously, CMS continued to evaluate other potential methods to calculate variations in geographic labor markets in a manner that maintains or improves consistency and equity in hospital payments in response to recommendations from MedPAC. However, as stated in the 2012 Report to Congress: Plan to Reform the Medicare Wage Index (on the web at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-IndexReform*), CMS has concluded that implementing any of the recommended revisions to wage index methodologies would require Congressional action. The commenter did not suggest any alternative method for defining geographic labor market areas and, given our decades long history of using OMB CBSA (and the prior Primary MSA) definitions and delineations for wage index purposes, we continue to believe adopting OMB revisions in a timely manner is essential to the wage index by creating a more accurate representation of geographic variations in wage levels. CMS is aware of the MAPS Act requirements for the adoption of CBSA definitions for nonstatistical use and believes that we have provided an adequate rationale to support our proposed adoption through notice and comment rulemaking. As we stated in the proposed rule (89 FR 36140), we believe that using the revised delineations based on OMB Bulletin No. 23–01 will increase the integrity of the wage index by creating a more accurate representation of current geographic variations in wage levels. While the adoption of the revised delineations will have both positive and negative impacts on specific hospitals and labor markets, we believe that periodically updating the labor market delineations using objective criteria and based on the most recently available commuting data will serve the public's interest in ensuring accurate Medicare payments to hospitals under the OPPS by more accurately reflecting current geographic variations in labor costs in the hospital payment methodology. While some CBSAs would be modified in significant ways, the criteria for MSA, Micropolitan Statistical Area, and Metropolitan Division definitions finalized by OMB are generally consistent with past updates, and we do not find that the adoption of these delineations will create extreme variations in payments to hospitals, especially when considering the impact of the policy to cap annual wage index reductions at 5 percent. On this basis, and for the reasons we stated in prior rulemaking, we have determined that their use supports the purpose of adjusting hospital payment rates based on geographic variations in labor costs in accordance with the statute. We have reviewed our findings and impacts relating to the new OMB delineations and find no compelling reason to delay implementation. Therefore, we are finalizing the proposed policies implementing the revised OMB delineations, including the policy for the treatment of Micropolitan Statistical areas, Metropolitan divisions, and the change to county-equivalent definitions for the State of Connecticut.

Comment: A commenter requested that in addition to the permanent cap policy, CMS implement a 3-year wage index transition period consistent with prior updates to the CBSA categorizations made due to OMB updates.

Response: We note that when we previously adopted revised OMB delineations, the majority of negatively impacted hospitals received a wage index adjustment for only one fiscal year via a 50/50 blend of wage index values using the then-current and newly adopted delineations (79 FR 66827). Hospitals that were reassigned from an urban to rural area as a result of our adoption of the revised OMB delineations received a 3-year transition period from their previous urban area wage index, as long as they did not obtain a new MGCRB reclassification during that time period. As discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49018 through 49021), the 5 percent cap on annual wage index reductions was intended to make unnecessary any future transitions in connection with wage index policy implementations, including the adoption of revised labor market area definitions. Based on our analysis of wage index differences between FY 2024 and FY 2025, we estimate that only 136 hospitals (less that 4 percent) will receive a wage index cap that did not receive the cap in FY 2024. This indicates any impact on overall wage index values that could be caused by the adoption of the revised delineations would be relatively small. Furthermore, given the iterative and interactive effects of different reclassification and wage index hold-harmless policies, it is difficult to isolate the effects on wage index values (both positive and negative) that are due solely to the adoption of the revised delineations. That is, hospitals may make different reclassification decisions based on the transition policy, rather than the actual impacts of the revised delineations. We believe that any attempt to tailor a transition policy specifically to the impacts of adopting revised labor market delineations is not likely to yield results that more accurately reflect current differences in area wages than the 5 percent cap policy. We believe the 5 percent cap policy ensures that hospitals will not experience large payment reductions as a result of annual changes in their wage index value, allows adequate time for hospitals to evaluate reclassification options, and provides consistency and predictability in wage index values. Largely due to the modification of the rural wage index calculation finalized in FY 2024 IPPS/LTCH PPS final rule (88 FR 58971 through 58977), a much larger number of urban and rural hospitals within the same state (nearly 60 percent) receive identical wage index values (prior to the application of other policies, such as the outmigration adjustment, 5 percent cap on annual wage index decreases, and low-wage index hospital policy). This

fact suggests that there is even less need for separate transition policies for urban and rural hospitals in response to changes in geographic delineations than there was previously. Furthermore, we did not receive a comment from any hospital (urban or rural) citing specific negative impacts due solely or primarily to the proposed adoption of the revised OMB delineations. For these reasons, we do not believe it is necessary to implement any additional or alternative transition policy to the 5 percent cap on wage index decrease policy.

Comment: A commenter supported our policy to treat urban hospitals reclassified as rural hospitals under § 412.103 as rural hospitals for purposes of the rural wage indexes and the rural floor.

Response: We appreciate the commenter's support of our policy.

Comment: Multiple commenters supported our proposed low-wage index policy, which, for hospitals with a wage index value below the 25th percentile, increases the hospital's wage index by half the difference between the otherwise applicable wage index value for that hospital and the 25th percentile wage index value for all hospitals. Some commenters stated that the policy helps to address unjustified disparities in Medicare reimbursement. One commenter supported the continuation of this policy and noted the court decision in *Bridgeport Hospital* v. *Becerra,* 108 F.4th 882 (D.C. Cir. 2024) that determined that CMS lacked the statutory authority to adopt this policy in the IPPS.

One commenter opposed the proposed low wage index hospital policy. They believe that it has the effect of harming hospitals in high wage areas while having unclear impacts on the hospitals in low wage areas that receive higher payments. The commenter further noted the recent court decision in *Bridgeport Hospital* v. *Becerra.* As a result, they urged CMS to discontinue the low wage index policy in the OPPS, but advocated that if CMS maintained the policy, it do so in a non-budget neutral manner.

Response: We appreciate these comments.

Since the establishment of the OPPS, we have adopted the IPPS wage index on a calendar year basis in the OPPS. As we have noted across the years and earlier in this section, using the IPPS wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall. In cases where CMS has had statutory authority to implement certain policies under the IPPS in a non-budget neutral manner, to apply the same wage index values in the OPPS we have budget neutralized those adjustments in accordance with section 1833(t)(2)(D) of the Act, such as with the outmigration adjustment (69 FR 65842 through 65844).

On July 23, 2024, the Court of Appeals for the D.C. Circuit held that the Secretary lacked authority under section 1886(d)(3)(E) of the Act or under the ''adjustments'' language of section 1886(d)(5)(I)(i) of the Act to adopt the low wage index hospital policy for FY 2020 for the IPPS, and that the policy and related budget neutrality adjustment in the IPPS must be vacated. *Bridgeport Hosp.* v. *Becerra,* 108 F.4th 882, 887–91 & n.6 (D.C. Cir. 2024). In consideration of the court decision, CMS subsequently issued the interim final action with comment period (IFC) entitled Changes to the Fiscal Year 2025 Hospital Inpatient Prospective Payment System (IPPS) Rates Due to Court Decision (CMS–1808–IFC) to remove the low wage index hospital policy for FY 2025 IPPS purposes. At the same time, the IFC included a payment exception under section 1886(d)(5)(I)(i) of the Act that corresponded mathematically to a 5 percent cap on wage index reductions from FY 2024 for certain low wage index hospitals most significantly impacted by the removal of the low wage index policy.

We note that we proposed to include the low wage index hospital policy as part of the CY 2025 OPPS wage index and believe that the statutory authority provided under section 1833(t)(2)(D) of the Act allows us to finalize a similar policy for the CY 2025 OPPS, as we have done each year beginning in CY 2020. Specifically, section 1886(d)(3)(E) of the Act requires that CMS base the IPPS wage index on a comparison of ''the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level,'' and on ''a survey conducted by the Secretary (and updated as appropriate) of the wages and wage–related costs of subsection (d) hospitals in the United States,'' whereas section 1833(t)(2)(D) contains no such prescriptions for the manner of determining the OPPS wage index. (We continue to effectuate relevant prescriptions, such as the requirement in sections 1833(t)(2)(D) and 1833(t)(9) of the Act that OPPS wage index policies are generally budget neutral.) In addition, CMS has authority to apply the low wage index hospital policy to the OPPS wage index under section 1833(t)(2)(E) of the Act, which allows the Secretary to ''establish, in budget neutral manner, . . . other adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals. We believe implementing the low wage index hospital policy is a valid exercise of the Secretary's authority to adopt ''adjustments'' to OPPS payments under the OPPS statute, where the provision regarding calculation of the OPPS wage adjustment factor does not contain the same language that the D.C. Circuit found to be prescriptive for the calculation of the IPPS wage index found at section 1886(d)(3)(E) of the Act. Additionally, section 1833(t)(2)(E) of the Act—unlike the adjustment authority at section 1886(d)(5)(I)—authorizes us to make adjustments to ''ensure equitable payments.'' In light of the unique circumstances presented by the timing of D.C. Circuit's decision, application of the low wage-index-hospital policy under the OPPS for CY 2025 avoids unexpected and arguably unfair payment consequences for hospitals that were not plaintiffs in the *Bridgeport* case and so falls within our equitable adjustment authority.

While this would create a divergence between the OPPS wage index values in CY 2025 and the ultimate, effective FY 2025 IPPS wage index values for some hospitals, we continue to believe that the concerns related to the wage index that led to the application of this policy to the OPPS wage index in previous years continue to apply, and that the OPPS authority for wage adjustment factors continues to give CMS the authority to implement a budget neutral low wage index hospital policy. Additionally, we believe that the same reasons underlying adoption of the IFC policies for the FY 2025 IPPS wage index weigh against incorporating those policies for purposes of the CY 2025 OPPS wage index. Specifically, we noted in the IFC that the intention of the policies implemented therein is to ''promote certainty regarding. . .payments'' and ''provide for payment stability and promote predictability,'' in light of the court's decision in the *Bridgeport Hospital* case (89 FR 80408). Given the differences noted in the previous paragraph between the IPPS and OPPS in CMS's statutory authorities related to the wage index, those interests are better served by finalizing the OPPS wage index methodology as proposed, including the low wage index hospital policy.

Finally, we acknowledge that in the IFC, we implemented under section 1886(d)(5)(I)(i) of the Act a transitional payment exception for hospitals that benefitted from the FY 2024 low wage

index hospital policy in the IPPS without budget neutralizing that exception. But that payment exception serves a different purpose from that of the low wage index hospital policy. And, in any event, unlike the statute authorizing the transitional payment exception, CMS's authority to implement a low wage index hospital policy in the OPPS requires it to budget neutralize that policy. That is, while section 1886(d)(5)(I)(i) contains no budget neutrality requirement, both section 1833(t)(2)(D) and (t)(2)(E) do. Thus, in the context of the OPPS, we will continue to budget neutralize the low wage index hospital policy. For these reasons, and those discussed above, we are finalizing in the CY 2025 OPPS the low wage index hospital policy as we had proposed in the CY 2025 OPPS/ASC proposed rule (89 FR 59227).

We recognize that creating different effective wage index values for a hospital under the OPPS than the wage index value for the hospital under the IPPS for CY 2025 differs in some respects from how we have implemented the OPPS wage index previously, where we have used the IPPS wage index value in effect throughout the FY as the OPPS wage index value for all hospitals. However, we believe this is the appropriate approach for the CY 2025 OPPS given the unusual circumstances wherein an appellate court ruled that CMS lacked authority under the IPPS statute for a policy under the FY 2020 IPPS wage index that the OPPS proposed rule had already proposed to include in the OPPS wage index. We further believe the approach in this final rule is consistent with § 419.43(c), which states: ''CMS uses the hospital inpatient prospective payment system wage index established in accordance with Part 412 of this chapter to make the adjustment specified under paragraph (a) of this section.'' The OPPS wage index values will match the IPPS wage index values in the FY 2025 IPPS final rule, as corrected in the FY 2025 IPPS final rule correction (89 FR 80098), which were ''established in accordance with Part 412''; we are merely declining to incorporate certain modifications to those values made in the IFC, which reflect extraordinary steps taken due to the timing of the court's decision in *Bridgeport Hospital.*

CMS will explore options for realigning the IPPS and OPPS wage index values through future rulemaking.

Comment: Multiple commenters supported our policy to apply a 5 percent cap on any decrease to a hospital's wage index from its wage index in the prior FY. Commenters also requested that the proposed 5-percent cap policy be applied in a non-budget neutral manner, which the commenter stated would allow the cap to be applied while avoiding decreases to the wage index in areas with high wage indexes.

Response: We appreciate the commenters' support of our policy to apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY. For the OPPS, section 1833(t)(2)(D) of the Act requires the Secretary to determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner, which is inconsistent with the commenters' request to exclude the wage index cap policy from budget neutrality.

After consideration of the public comments we received, we are finalizing our proposal without modification to use the FY 2025 IPPS post-reclassified wage index for urban and rural areas as finalized in the FY 2025 IPPS final rule and corrected in the FY 2025 IPPS final rule correction as the wage index for the OPPS, which includes the OPPS low wage index hospital policy, to determine the wage adjustments for both the OPPS payment rate and the copayment rate for CY 2025. In addition to the low wage index hospital policy, which will only apply in the OPPS in CY 2025, certain FY 2025 post-reclassified wage index policies will be reflected in the final CY 2025 OPPS wage index beginning on January 1, 2025, including, but not limited to, reclassification of hospitals to different geographic areas, the rural floor provisions, the imputed floor wage index adjustment in all-urban states, an adjustment for occupational mix, an adjustment to the wage index based on commuting patterns of employees (the out-migration adjustment), and a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY. We refer readers to the FY 2025 IPPS/LTCH PPS final rule (89 FR 69252 through 69310) and the FY 2025 hospital wage index files posted on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2025-ipps-final-rule-home-page*. Regarding budget neutrality for the CY 2025 OPPS wage index, we refer readers to section II.B. of this final rule with comment period.

For CMHCs, for CY 2025, we proposed to continue to calculate the wage index by using the post-reclassification IPPS wage index based on the CBSA where the CMHC is located. Furthermore, we proposed that the wage index that would apply to a CMHC for CY 2025 would continue to include the rural floor adjustment and any policies and adjustments applied to the IPPS wage index to address wage index disparities. In addition, the wage index that would apply to CMHCs would include the 5-percent cap on wage index decreases. Also, we proposed that the wage index that would apply to CMHCs would not include the outmigration adjustment because that adjustment only applies to hospitals.

We did not receive any public comments on our proposals, and we are finalizing our proposals regarding CMHC wage index calculations without modification.

Table 4A associated with the FY 2025 IPPS/LTCH PPS final rule (available via the internet on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2025-ipps-final-rule-home-page*) identifies counties that would be eligible for the out-migration adjustment. Table 2 associated with the FY 2025 IPPS/LTCH PPS final rule as corrected by the FY 2025 IPPS final rule correction identifies IPPS hospitals that would receive the out-migration adjustment for FY 2025. We are including the outmigration adjustment information from Table 2 associated with the FY 2025 IPPS/LTCH PPS final rule as Addendum L to this final rule with comment period, with the addition of non-IPPS hospitals that would receive the section 505 outmigration adjustment under this final rule. Addendum L is available via the internet on the CMS website. We refer readers to the CMS website for the OPPS at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*. At this link, readers will find a link to the FY 2025 IPPS final rule wage index tables and the CY 2025 OPPS final rule Addendum L.

D. Statewide Average Default Cost-to-Charge Ratios (CCRs)

In addition to using CCRs to estimate costs from charges on claims for ratesetting, we use overall hospital-specific CCRs calculated from the hospital's most recent cost report (OMB control number: 0938–0050 for Form CMS–2552–10) to determine outlier payments, payments for pass-through devices, and monthly interim transitional corridor payments under the OPPS during the PPS year. For certain hospitals, under the regulations at 42 CFR 419.43(d)(5)(iii), we use the

statewide average default CCRs to determine the payments mentioned earlier if it is not possible to determine an accurate CCR for a hospital in certain circumstances. This includes hospitals that are new, hospitals that have not accepted assignment of an existing hospital's provider agreement, and hospitals that have not yet submitted a cost report. We also use the statewide average default CCRs to determine payments for hospitals whose CCR falls outside the predetermined ceiling threshold for a valid CCR or for hospitals in which the most recent cost report reflects an all-inclusive rate status (Medicare Claims Processing Manual (Pub. L. 100–04), Chapter 4, Section 10.11).

We discussed our policy for using default CCRs, including setting the ceiling threshold for a valid CCR, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599) in the context of our adoption of an outlier reconciliation policy for cost reports beginning on or after January 1, 2009. For details on our process for calculating the statewide average CCRs, we refer readers to the Claims Accounting Narrative for this final rule with comment period, which is posted on our website. We proposed to calculate the default ratios for CY 2025 using the most recent cost report data.

We did not receive any public comments on our proposal, and we are finalizing our proposal without modification to calculate the default ratios for CY 2025 using the most recent cost report data, which are from a June 2024 HCRIS cost report extract.

We no longer publish a table in the **Federal Register** containing the statewide average CCRs in the annual OPPS/ASC proposed rule and final rule with comment period. These CCRs and the upper limit CCR value at which we would apply statewide CCRs will be available for download with each OPPS/ASC CY proposed rule and final rule on the CMS website. We refer readers to our website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices;* click on the link on the left of the page titled ''Annual Policy Files'' and then select the relevant year to download the statewide CCRs and upper limit in the ''Downloads'' section of the web page.

E. Adjustment for Rural Sole Community Hospitals (SCHs) and Essential Access Community Hospitals (EACHs) Under Section 1833(t)(13)(B) of the Act for CY 2025

In the CY 2006 OPPS final rule with comment period (70 FR 68556), we finalized a payment increase for rural sole community hospitals (SCHs) of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, items paid at charges reduced to costs, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act, as added by section 411 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173). Section 1833(t)(13) of the Act provides the Secretary the authority to make an adjustment to OPPS payments for rural hospitals, effective January 1, 2006, if justified by a study of the difference in costs by APC between hospitals in rural areas and hospitals in urban areas. Our analysis showed a difference in costs for rural SCHs. Therefore, for the CY 2006 OPPS, we finalized a payment adjustment for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, items paid at charges reduced to costs, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act.

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68010 and 68227), for purposes of receiving this rural adjustment, we revised our regulations at § 419.43(g) to clarify that essential access community hospitals (EACHs) are also eligible to receive the rural SCH adjustment, assuming these entities otherwise meet the rural adjustment criteria. Currently, two hospitals are classified as EACHs, and as of CY 1998, under section 4201(c) of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), a hospital can no longer become newly classified as an EACH.

This adjustment for rural SCHs is budget neutral and applied before calculating outlier payments and copayments. We stated in the CY 2006 OPPS final rule with comment period (70 FR 68560) that we would not reestablish the adjustment amount on an annual basis, but we may review the adjustment in the future and, if appropriate, would revise the adjustment. We provided the same 7.1 percent adjustment to rural SCHs, including EACHs, again in CYs 2008 through 2024.

For CY 2025, we proposed to continue the current policy of a 7.1 percent payment adjustment for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, items paid at charges reduced to costs, and devices paid under the pass-through payment policy, applied in a budget neutral manner.

Comment: Many commenters supported our policy to continue the 7.1 percent payment adjustment for rural SCHs and EACHs.

Response: We thank the commenters for their support of our policy.

Comment: Multiple commenters stated that the 7.1 percent payment adjustment should be extended to urban SCHs and Medicare dependent hospitals (MDHs). The commenters suggested CMS perform another study to look at the costs that MDHs incur and that CMS has the authority to extend the adjustment to MDHs and urban SCHs without legislation.

Response: We reiterate that our study of the cost difference by APC's between hospitals in rural areas and urban areas only showed a significant difference in costs for rural SCHs. CMS results did not identify significant cost differences between hospitals in urban areas and MDHs. In addition, our authority under section 1833(t)(13) of the Act only extends to rural hospitals. Therefore, we are not expanding the types of hospitals eligible for the 7.1 percent payment adjustment at this time.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to continue our current policy of utilizing a budget neutral 7.1 percent payment adjustment for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs.

F. Payment Adjustment for Certain Cancer Hospitals for CY 2025

1. Background

Since the inception of the OPPS, which was authorized by the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), Medicare has paid the 11 hospitals that meet the criteria for cancer hospitals identified in section 1886(d)(1)(B)(v) of the Act under the OPPS for covered outpatient department services. These cancer hospitals are exempted from payment under the IPPS. With the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999 (Pub. L. 106–113), the Congress added section 1833(t)(7), ''Transitional Adjustment to Limit Decline in Payment,'' to the Act, which requires the Secretary to determine OPPS payments to cancer and children's hospitals based on their pre-BBA

payment amount (these hospitals are often referred to under this policy as ''held harmless'' and their payments are often referred to as ''hold harmless'' payments).

As required under section 1833(t)(7)(D)(ii) of the Act, a cancer hospital receives the full amount of the difference between payments for covered outpatient department services under the OPPS and a ''pre-BBA amount.'' That is, cancer hospitals are permanently held harmless to their ''pre-BBA amount,'' and they receive transitional outpatient payments (TOPs) or hold harmless payments to ensure that they do not receive a payment that is lower in amount under the OPPS than the payment amount they would have received before implementation of the OPPS, as set forth in section 1833(t)(7)(F) of the Act. The ''pre-BBA amount'' is the product of the hospital's reasonable costs for covered outpatient department services occurring in the current year and the base payment-to-cost ratio (PCR) for the hospital defined in section 1833(t)(7)(F)(ii) of the Act. The ''pre-BBA amount'' and the determination of the base PCR are defined at § 419.70(f). TOPs are calculated on Worksheet E, Part B, of the Hospital Cost Report or the Hospital Health Care Complex Cost Report (Form CMS–2552–96 or Form CMS–2552–10 (OMB NO: 0938–0050), respectively), as applicable each year. Section 1833(t)(7)(I) of the Act exempts TOPs from budget neutrality calculations.

Section 3138 of the Affordable Care Act (Pub. L. 111–148) amended section 1833(t) of the Act by adding a new paragraph (18), which instructs the Secretary to conduct a study to determine if, under the OPPS, outpatient costs incurred by cancer hospitals described in section 1886(d)(1)(B)(v) of the Act with respect to APC groups exceed outpatient costs incurred by other hospitals furnishing services under section 1833(t) of the Act, as determined appropriate by the Secretary. Section 1833(t)(18)(A) of the Act requires the Secretary to take into consideration the cost of drugs and biologicals incurred by cancer hospitals and other hospitals. Section 1833(t)(18)(B) of the Act provides that, if the Secretary determines that cancer hospitals' costs are higher than those of other hospitals, the Secretary shall provide an appropriate adjustment under section 1833(t)(2)(E) of the Act to reflect these higher costs. In 2011, after conducting the study required by section 1833(t)(18)(A) of the Act, we determined that outpatient costs incurred by the 11 specified cancer hospitals were greater than the costs incurred by other OPPS hospitals. For a complete discussion regarding the cancer hospital cost study, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74200 and 74201).

Based on these findings, we finalized a policy to provide a payment adjustment to the 11 specified cancer hospitals that reflects their higher outpatient costs, as discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74202 through 74206). Specifically, we adopted a policy to provide additional payments to the cancer hospitals so that each cancer hospital's final PCR for services provided in a given calendar year is equal to the weighted average PCR (which we refer to as the ''target PCR'') for other hospitals paid under the OPPS. The target PCR is set in advance of the calendar year and is calculated using the most recently submitted or settled cost report data that are available at the time of final rulemaking for the calendar year. The amount of the payment adjustment is made on an aggregate basis at cost report settlement. We note that the changes made by section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs are assessed, as usual, after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period. Table 11 displays the target PCR for purposes of the cancer hospital adjustment for CY 2012 through CY 2024.

TABLE 11: CANCER HOSPITAL ADJUSTMENT TARGET PAYMENT-TO-COST RATIOS (PCRS), CY 2012 THROUGH CY 2024

Calendar Year	Target PCR
2012	0.91
2013	0.91
2014	0.90
2015	0.90
2016	0.92
2017	0.91
2018	0.88
2019	0.88
2020	0.89
2021	0.89
2022	0.89
2023	0.89
2024	0.88

2. Policy for CY 2025

Section 16002(b) of the 21st Century Cures Act (Pub. L. 114–255) amended section 1833(t)(18) of the Act by adding subparagraph (C), which requires that in applying § 419.43(i) (that is, the payment adjustment for certain cancer hospitals) for services furnished on or after January 1, 2018, the target PCR adjustment be reduced by 1.0 percentage point less than what would

otherwise apply. Section 16002(b) also provides that, in addition to the percentage reduction, the Secretary may consider making an additional percentage point reduction to the target PCR that takes into account payment rates for applicable items and services described under section 1833(t)(21)(C) of the Act for hospitals that are not cancer hospitals described under section 1886(d)(1)(B)(v) of the Act. Further, in making any budget neutrality adjustment under section 1833(t) of the Act, the Secretary shall not take into account the reduced expenditures that result from application of section 1833(t)(18)(C) of the Act.

We proposed to provide additional payments to the 11 specified cancer hospitals so that each cancer hospital's proposed PCR is equal to the weighted average PCR (or ''target PCR'') for the other OPPS hospitals, generally using the most recent submitted or settled cost report data that are available, reduced by 1.0 percentage point, to comply with section 16002(b) of the 21st Century Cures Act, and adjusted by the proposed post-Public Health Emergency (PHE) transition as described later in this section. We are not proposing an additional reduction beyond the 1.0 percentage point reduction required by section 16002(b) of the 21st Century Cures Act for CY 2025.

To calculate the proposed CY 2025 target PCR, we proposed to use the same extract of cost report data from HCRIS used to estimate costs for the CY 2025 OPPS which, in most cases, would be the most recently available hospital cost reports. Using these cost report data, we included data from Worksheet E, Part B, for each hospital, using data from each hospital's most recent cost report, whether as submitted or settled.

We then limited the dataset to the hospitals with CY 2023 claims data that we used to model the impact of the proposed CY 2025 APC relative payment weights (3,448 hospitals) because it is appropriate to use the same set of hospitals that are being used to calibrate the modeled CY 2025 OPPS. The cost report data for the hospitals in this dataset were from cost report periods with fiscal year ends ranging from 2019 to 2023; however, the cost reporting periods were predominantly from fiscal years ending in 2022 and 2023. We then removed the cost report data of the 49 hospitals located in Puerto Rico from our dataset because we did not believe their cost structure reflected the costs of most hospitals paid under the OPPS, and, therefore, their inclusion may bias the calculation of hospital-weighted statistics. We also removed the cost report data of 16 hospitals because these hospitals had cost report data that were not complete (missing aggregate OPPS payments, missing aggregate cost data, or missing both), so that all cost reports in the study would have both the payment and cost data necessary to calculate a PCR for each hospital, leading to a proposed analytic file of 3,421 hospitals with cost report data.

Using this smaller dataset of cost report data, we estimated that, on average, the OPPS payments to other hospitals furnishing services under the OPPS were approximately 87 percent of reasonable cost (weighted average PCR of 0.87). Therefore, after applying the 1.0 percentage point reduction, as required by section 16002(b) of the 21st Century Cures Act, using our standard process the payment amount associated with the cancer hospital payment adjustment to be determined at cost report settlement would be the additional payment needed to result in a target PCR equal to 0.86 for each cancer hospital.

In the CY 2024 OPPS/ASC final rule with comment period (88 FR 81586 through 81589), we explained that we believe we should begin to take into consideration the PCR of non-cancer hospitals based on the most recently available data for calculating the target PCR. We noted that we do not know if the changes in the data that have yielded lower PCRs for non-cancer hospitals are likely to continue in future years or if, when data from after the PHE is available, we will see the target PCR increase toward its historical norm. Therefore, in the CY 2024 OPPS/ASC final rule with comment period, we finalized our proposal to transition from the target PCR of 0.89 we finalized for CYs 2020 through 2024 (which included the 1.0 percentage point reduction as required by section 16002(b) of the 21st Century Cures Act) and incrementally reduce the target PCR by an additional 1.0 percentage point for each calendar year, beginning with CY 2024, until the target PCR equals the PCR of non-cancer hospitals calculated using the most recent data minus 1.0 percentage point as required by section 16002(b) of the 21st Century Cures Act. Therefore, utilizing this methodology for the CY 2025 OPPS/ASC proposed rule, since the target PCR that would otherwise apply under our standard process would be a target PCR of 0.86, we proposed to reduce the CY 2024 target PCR of 0.88 by 1 percentage point and proposed a cancer hospital target PCR of 0.87 for CY 2025.

Comment: Commenters supported the proposed target PCR of 0.87 for CY 2025. One commenter requested that CMS ensure that repayments to 340B hospitals are appropriately reflected in the final 2025 PCR calculation.

Response: We thank the commenters for their support. With respect to the commenter's request that the final 2025 PCR calculation include repayments to 340B hospitals, we refer to our response to that same comment in the CY 2024 OPPS/ASC final rule with comment period (88 FR 81588).

After consideration of the public comments we received, we are finalizing without modification our proposal to reduce the CY 2024 target PCR by 1 percentage point and apply a target PCR of 0.87 to the 11 specified cancer hospitals for CY 2025.

Table 12 shows the estimated percentage increase in OPPS payments to each cancer hospital for CY 2025, due to the cancer hospital payment adjustment policy. The actual, final amount of the CY 2025 cancer hospital payment adjustment for each cancer hospital will be determined at cost report settlement and will depend on each hospital's CY 2025 payments and costs from the settled CY 2025 cost report. We note that the requirements contained in section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs will be assessed, as usual, after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period.

TABLE 12: ESTIMATED CY 2025 HOSPITAL-SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS TO BE PROVIDED AT COST REPORT SETTLEMENT

Provider Number	Hospital Name	Estimated Percentage Increase in OPPS Payments for CY 2025 due to Payment Adjustment
050146	City of Hope Comprehensive Cancer Center	51.5%
050660	USC Norris Cancer Hospital	44.3%
100079	Sylvester Comprehensive Cancer Center	32.4%
100271	H. Lee Moffitt Cancer Center & Research Institute	23.9%
220162	Dana-Farber Cancer Institute	46.6%
330154	Memorial Sloan-Kettering Cancer Center	51.6%
330354	Roswell Park Cancer Institute	21.3%
360242	James Cancer Hospital & Solove Research Institute	16.0%
390196	Fox Chase Cancer Center	30.0%
450076	M.D. Anderson Cancer Center	45.1%
500138	Seattle Cancer Care Alliance	47.7%

G. Hospital Outpatient Outlier Payments

1. Background

The OPPS provides outlier payments to hospitals to help mitigate the financial risk associated with high-cost and complex procedures, where a very costly service could present a hospital with significant financial loss. As explained in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66832 through 66834), we set our projected target for aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS for the prospective year. Outlier payments are provided on a service-by-service basis when the cost of a service exceeds the APC payment amount multiplier threshold (the APC payment amount multiplied by a certain amount) as well as the APC payment amount plus a fixed-dollar amount threshold (the APC payment plus a certain dollar amount). In CY 2024, the outlier threshold was met when the hospital's cost of furnishing a service exceeded 1.75 times the APC payment amount (the multiplier threshold) and exceeded the APC payment amount plus $7,750 (the fixed-dollar amount threshold) (88 FR 81589 through 81591). If the hospital's cost of furnishing a service exceeds both the multiplier threshold and the fixed-dollar threshold, the outlier payment is calculated as 50 percent of the amount by which the hospital's cost of furnishing the service exceeds 1.75 times the APC payment amount. Beginning with CY 2009 payments, outlier payments are subject to a reconciliation process similar to the IPPS outlier reconciliation process for cost reports, as discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599).

It has been our policy to report the actual amount of outlier payments as a percent of total spending in the claims being used to model the OPPS. Our estimate of total outlier payments as a percent of total CY 2023 OPPS payments, using CY 2023 claims available for this CY 2025 OPPS/ASC final rule with comment period, is approximately 0.65 percent. Therefore, for CY 2023, we estimate that we did not meet the outlier target by 0.35 percent of total aggregated OPPS payments.

For this CY 2025 OPPS/ASC final rule with comment period, using CY 2023 claims data and CY 2024 payment rates, we estimate that the aggregate outlier payments for CY 2024 would be approximately 0.83 percent of the total CY 2024 OPPS payments. We provide estimated CY 2025 outlier payments for hospitals and CMHCs with claims included in the claims data that we used to model impacts in the Hospital–Specific Impacts—Provider-Specific Data file on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient*.

2. Outlier Calculation for CY 2025

For CY 2025, we proposed to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS. We proposed that a portion of that 1.0 percent, an amount equal to less than 0.01 percent of outlier payments (or 0.0001 percent of total OPPS payments), would be allocated to CMHCs for partial hospitalization program (PHP) and intensive outpatient program (IOP) outlier payments. This is the amount of estimated outlier payments that would result from the proposed CMHC outlier threshold as a proportion of total estimated OPPS

outlier payments. We proposed to continue our outlier policy that if a CMHC's cost for PHP and IOP services exceeds 3.40 times the APC payment rate, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the proposed APC payment rate.

For further discussion of CMHC outlier payments, we refer readers to section VIII.C of this final rule with comment period.

To ensure that the estimated CY 2025 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPPS, we proposed that the hospital outlier threshold be set so that outlier payments would be triggered when a hospital's cost of furnishing a service exceeds 1.75 times the APC payment amount and exceeds the APC payment amount plus the fixed-dollar threshold.

We calculated the proposed fixed-dollar threshold using the standard methodology most recently used for CY 2024 (88 FR 81589 through 81591). For purposes of estimating outlier payments for CY 2025, we use the hospital-specific overall ancillary CCRs available in the April 2024 update to the Outpatient Provider-Specific File (OPSF). The OPSF contains provider-specific data, such as the most current CCRs, which are maintained by the MACs and used by the OPPS Pricer to pay claims. The claims that we generally use to model each OPPS update lag by 2 years.

In order to estimate the CY 2025 hospital outlier payments, we inflated the charges on the CY 2023 claims using the same proposed charge inflation factor of 1.084555 that we used to estimate the IPPS fixed-loss cost threshold for the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 36572). We used an inflation factor of 1.04142 to estimate CY 2024 charges from the CY 2023 charges reported on CY 2023 claims before applying CY 2024 CCRs to estimate the percent of outliers paid in CY 2024. The proposed methodology for determining these charge inflation factors is discussed in the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 36572). As we stated in the CY 2005 OPPS final rule with comment period (69 FR 65844 through 65846), we believe that the use of the same charge inflation factors is appropriate for the OPPS because, with the exception of the inpatient routine service cost centers, hospitals use the same ancillary and cost centers to capture costs and charges for inpatient and outpatient services.

As noted in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68011), we are concerned that we could systematically overestimate the OPPS hospital outlier threshold if we did not apply a CCR inflation adjustment factor. Therefore, we proposed to apply the same CCR adjustment factor that we proposed to apply for the FY 2025 IPPS outlier calculation to the CCRs used to simulate the proposed CY 2025 OPPS outlier payments to determine the fixed-dollar threshold. Specifically, for CY 2025, we proposed to apply an adjustment factor of 1.03331 to the CCRs that were in the April 2024 OPSF to trend them forward from CY 2024 to CY 2025. The methodology for calculating the proposed CCR adjustment factor is discussed in the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 36572 through 36573).

To model hospital outlier payments for the CY 2025 proposed rule, we applied the overall CCRs from the April 2024 OPSF after adjustment (using the proposed CCR inflation adjustment factor of 1.03331 to approximate CY 2025 CCRs) to charges on CY 2023 claims that were adjusted (using the proposed charge inflation factor of 1.084555 to approximate CY 2025 charges). We simulated aggregated CY 2023 hospital outlier payments using these costs for several different fixed-dollar thresholds, holding the 1.75 multiplier threshold constant and assuming that outlier payments would continue to be made at 50 percent of the amount by which the cost of furnishing the service would exceed 1.75 times the APC payment amount, until the total outlier payments equaled 1.0 percent of aggregated estimated total CY 2025 OPPS payments. We estimated that a proposed fixed-dollar threshold of $8,000, combined with the proposed multiplier threshold of 1.75 times the APC payment rate, would allocate 1.0 percent of aggregated total OPPS payments to outlier payments. For CMHCs, we proposed that, if a CMHC's cost for partial hospitalization or intensive outpatient services exceeds 3.40 times the APC payment rate, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC payment rate.

Section 1833(t)(17)(A) of the Act, which applies to hospitals, as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to report data required for the quality measures selected by the Secretary, in the form and manner required by the Secretary under section 1833(t)(17)(B) of the Act, incur a 2.0 percentage point reduction to their OPD fee schedule increase factor; that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that would apply to certain outpatient items and services furnished by hospitals that are required to report outpatient quality data and that fail to meet the Hospital Outpatient Quality Reporting (OQR) Program requirements. For hospitals that fail to meet the Hospital OQR Program requirements, we proposed to continue the policy that we implemented in CY 2010 that the hospitals' costs would be compared to the reduced payments for purposes of outlier eligibility and payment calculation. For more information on the Hospital OQR Program, we refer readers to section XV of this final rule with comment period.

Comment: One commenter noted that they believe the CCR adjustment factors used for the IPPS and OPPS proposed rules overstate the effect of cost increases that took place from 2022 to 2023. The commenter argues that the CCR adjustment factor used in each final rule has been below 1.0; however, we proposed a CCR adjustment factor of 1.03331. The commenter recommended that we substitute a different CCR adjustment factor or cap the CCR adjustment factor at 1.0.

Response: As discussed in greater detail in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69955 through 69962), consistent with our usual practice, we are using more recent CCR data for this final rule with comment period which yields a CCR adjustment factor of 1.015123. We do not believe it is necessary to deviate from our usual practice of using the CCR adjustment factor for our calculation, which was finalized under the IPPS for FY 2025. Therefore, we are also not accepting this recommendation under the OPPS.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS and to use our established methodology to set the OPPS outlier fixed-dollar loss threshold for CY 2025.

3. Final Outlier Calculation

Consistent with historical practice, we used updated data for this final rule with comment period for outlier calculations. For CY 2025, we are applying the overall ancillary CCRs from the July 2024 OPSF file after adjustment (using the CCR adjustment factor of 1.015123 to approximate CY 2025 CCRs) to charges on CY 2023 claims that were adjusted using a charge inflation factor of 1.08406 to

approximate CY 2025 charges. These are the same CCR adjustment and charge inflation factors that were used to set the IPPS fixed-dollar thresholds for the FY 2025 IPPS/LTCH PPS final rule (89 FR 69955 through 69962). We simulated aggregated CY 2025 hospital outlier payments using these costs for several different fixed-dollar thresholds, holding the 1.75 multiple-threshold constant and assuming that outlier payments will continue to be made at 50 percent of the amount by which the cost of furnishing the service would exceed 1.75 times the APC payment amount, until the total outlier payment equaled 1.0 percent of aggregated estimated total CY 2025 OPPS payments. We estimate that a fixed-dollar threshold of $7,175 combined with the multiple threshold of 1.75 times the APC payment rate, will allocate the 1.0 percent of aggregated total OPPS payments to outlier payments.

For CMHCs, if a CMHC's cost for partial hospitalization or intensive outpatient services exceeds 3.40 times the APC payment rate, the outlier payment will be calculated as 50 percent of the amount by which the cost exceeds the 3.40 times the ACP payment rate.

H. Calculation of an Adjusted Medicare Payment From the National Unadjusted Medicare Payment

The national unadjusted payment rate is the payment rate for most APCs before accounting for the wage index adjustment or any applicable adjustments. The basic methodology for determining prospective payment rates for HOPD services under the OPPS is set forth in existing regulations at 42 CFR part 419, subparts C and D. For this CY 2025 OPPS/ASC final rule with comment period, the payment rate for most services and procedures for which payment is made under the OPPS is the product of the conversion factor calculated in accordance with section II.B of this final rule with comment period and the relative payment weight described in section II.A of this final rule with comment period. The national unadjusted payment rate for most APCs contained in Addendum A to this final rule with comment period (which is available via the CMS website *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/addendum-a-b-updates*) and for most HCPCS codes to which separate payment under the OPPS has been assigned in Addendum B to this final rule with comment period (which is available on the CMS website link above) is calculated by multiplying the final CY 2025 scaled weight for the APC by the CY 2025 conversion factor.

We note that section 1833(t)(17) of the Act, which applies to hospitals, as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to submit data required to be submitted on quality measures selected by the Secretary, in the form and manner and at a time specified by the Secretary, incur a reduction of 2.0 percentage points to their OPD fee schedule increase factor, that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data and that fail to meet the Hospital OQR Program requirements. For further discussion of the payment reduction for hospitals that fail to meet the requirements of the Hospital OQR Program, we refer readers to section XIV of this final rule with comment period.

Below we demonstrate the steps used to determine the APC payments that will be made in a CY under the OPPS to a hospital that fulfills the Hospital OQR Program requirements and to a hospital that fails to meet the Hospital OQR Program requirements for a service that has any of the following status indicator assignments: ''J1,'' ''J2,'' ''P,'' ''Q1,'' ''Q2,'' ''Q3,'' ''Q4,'' ''R,'' ''S,'' ''T,'' ''U,'' or ''V'' (as defined in Addendum D1 to this final rule with comment period, which is available via the internet on the CMS website), in a circumstance in which the multiple procedure discount does not apply, the procedure is not bilateral, and conditionally packaged services (status indicator of ''Q1'' and ''Q2'') qualify for separate payment. We note that, although blood and blood products with status indicator ''R'' and brachytherapy sources with status indicator ''U'' are not subject to wage adjustment, they are subject to reduced payments when a hospital fails to meet the Hospital OQR Program requirements.

Individual providers interested in calculating the payment amount that they would receive for a specific service from the national unadjusted payment rates presented in Addenda A and B to this final rule with comment period (which are available via the internet on the CMS website) should follow the formulas presented in the following steps. For purposes of the payment calculations below, we refer to the national unadjusted payment rate for hospitals that meet the requirements of the Hospital OQR Program as the ''full'' national unadjusted payment rate. We refer to the national unadjusted payment rate for hospitals that fail to meet the requirements of the Hospital OQR Program as the ''reduced'' national unadjusted payment rate. The reduced national unadjusted payment rate is calculated by multiplying the reporting ratio of 0.9806 times the ''full'' national unadjusted payment rate. The national unadjusted payment rate used in the calculations below is either the full national unadjusted payment rate or the reduced national unadjusted payment rate, depending on whether the hospital met its Hospital OQR Program requirements to receive the full CY 2025 OPPS fee schedule increase factor.

Step 1. Calculate 60 percent (the labor-related portion) of the national unadjusted payment rate. Since the initial implementation of the OPPS, we have used 60 percent to represent our estimate of that portion of costs attributable, on average, to labor. We refer readers to the April 7, 2000 OPPS/ASC final rule with comment period (65 FR 18496 through 18497) for a detailed discussion of how we derived this percentage. During our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553), we confirmed that this labor-related share for hospital outpatient services is appropriate.

The formula below is a mathematical representation of Step 1 and identifies the labor-related portion of a specific payment rate for a specific service.

X is the labor-related portion of the national unadjusted payment rate.

$X = .60 *$ (national unadjusted payment rate).

Step 2. Determine the wage index area in which the hospital is located and identify the wage index level that applies to the specific hospital. The wage index values assigned to each area would reflect the geographic statistical areas (which are based upon OMB standards) to which hospitals are assigned for FY 2025 in the FY 2025 IPPS, as corrected in the FY 2025 IPPS final rule correction (89 FR 80098), reclassifications through the Medicare Geographic Classification Review Board (MGCRB), section 1886(d)(8)(B) ''Lugar'' hospitals, and reclassifications under section 1886(d)(8)(E) of the Act, as implemented in § 412.103 of the regulations. We are continuing to apply for the CY 2025 OPPS wage index any adjustments for the FY 2025 IPPS final rule post-reclassified wage index, including, but not limited to, the rural floor adjustment and a wage index floor of 1.00 in frontier states, in accordance with section 10324 of the Affordable

Care Act of 2010. We are also including the low wage index hospital policy as part of the CY 2025 OPPS wage index. The adoption of this policy for CY 2025 for the OPPS wage index will create different effective wage index values for hospitals that benefit from the policy under the OPPS than the wage index value for those hospitals under the IPPS for FY 2025 as modified by the interim final action with comment period ''Changes to the Fiscal Year 2025 Hospital Inpatient Prospective Payment System (IPPS) Rates Due to Court Decision'' (89 FR 80405). For further discussion of the wage index we are applying for the CY 2025 OPPS, including the low wage index hospital policy, we refer readers to section II.C of this final rule with comment period.

Step 3. Adjust the wage index of hospitals located in certain qualifying counties that have a relatively high percentage of hospital employees who reside in the county, but who work in a different county with a higher wage index, in accordance with section 505 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173). Addendum L to this final rule with comment period (which is available via the internet on the CMS website) contains the qualifying counties and the associated wage index increase developed for the final FY 2025 IPPS wage index, which are listed in Table 3 associated with the FY 2025 IPPS final rule and available via the internet on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps.* (Click on the link on the left side of the screen titled ''FY 2025 IPPS Final Rule Home Page'' and select ''FY 2025 Final Rule Tables.'') This step is to be followed only if the hospital is not reclassified or redesignated under section 1886(d)(8) or section 1886(d)(10) of the Act.

Step 4. Multiply the applicable wage index determined under Steps 2 and 3 by the amount determined under Step 1 that represents the labor-related portion of the national unadjusted payment rate.

The formula below is a mathematical representation of Step 4 and adjusts the labor-related portion of the national unadjusted payment rate for the specific service by the wage index.

X_a is the labor-related portion of the national unadjusted payment rate (wage adjusted).

X_a = labor-portion of the national unadjusted payment rate * applicable wage index.

Step 5. Calculate 40 percent (the nonlabor-related portion) of the national unadjusted payment rate and add that amount to the resulting product of Step 4. The result is the wage index adjusted payment rate for the relevant wage index area.

The formula below is a mathematical representation of Step 5 and calculates the remaining portion of the national payment rate, the amount not attributable to labor, and the adjusted payment for the specific service.

Y is the nonlabor-related portion of the national unadjusted payment rate.

Y = 0.40 * (national unadjusted payment rate).

Step 6. If a provider is an SCH, as set forth in the regulations at § 412.92, or an EACH, which is considered to be an SCH under section 1886(d)(5)(D)(iii)(III) of the Act, and located in a rural area, as defined in § 412.64(b), or is treated as being located in a rural area under § 412.103, multiply the wage index adjusted payment rate by 1.071 to calculate the total payment.

The formula below is a mathematical representation of Step 6 and applies the rural adjustment for rural SCHs.

Adjusted Medicare Payment (SCH or EACH) = Adjusted Medicare Payment * 1.071.

Step 7. The adjusted payment rate is the sum of the wage adjusted labor-related portion of the national unadjusted payment rate and the nonlabor-related portion of the national unadjusted payment rate.

$X_a$is the labor-related portion of the national unadjusted payment rate (wage adjusted).

Y is the nonlabor-related portion of the national unadjusted payment rate.

Adjusted Medicare Payment = $X_a + Y$

We are providing examples below of the calculation of both the full and reduced national unadjusted payment rates that would apply to certain outpatient items and services performed by hospitals that meet and that fail to meet the Hospital OQR Program requirements, using the steps outlined previously. For purposes of this example, we are using a provider that is located in Brooklyn, New York that is assigned to CBSA 35614. This provider bills one service that is assigned to APC 5071 (Level 1 Excision/Biopsy/Incision and Drainage). The final CY 2025 full national unadjusted payment rate for APC 5071 is $703.59. The final reduced national adjusted payment rate for APC 5071 for a hospital that fails to meet the Hospital OQR Program requirements is $689.94. This reduced rate is calculated by multiplying the reporting ratio of 0.9806 by the full unadjusted payment rate for APC 5071.

Step 1. The labor-related portion of the final full national unadjusted payment is approximately $422.15 (0.60 * $703.59). The labor-related portion of the final reduced national adjusted payment is approximately $413.96 (0.60 * $689.94).

Step 2 & 3. The FY 2025 wage index for a provider located in CBSA 35614 in New York, which includes the adoption of the final IPPS 2025 wage index policies, is 1.3056.

Step 4. The wage adjusted labor-related portion of the final full national unadjusted payment is approximately $551.16 ($422.15 * 1.3056). The wage adjusted labor-related portion of the final reduced national adjusted payment is approximately $540.47 ($413.96 * 1.3056).

Step 5. The nonlabor-related portion of the final full national unadjusted payment is approximately $281.44 (0.40 * $703.59). The nonlabor-related portion of the final reduced national adjusted payment is approximately $275.98 (0.40 * $689.94).

Step 6. For this example of a provider located in Brooklyn, New York, the rural adjustment for rural SCHs does not apply.

Step 7. The sum of the labor-related and nonlabor-related portions of the final full national unadjusted payment is approximately $832.60 ($551.16 + $281.44). The sum of the portions of the final reduced national adjusted payment is approximately $816.45 ($540.47 + $275.98) as shown in Table 13.

TABLE 13: FINAL FULL NATIONAL UNADJUSTED PAYMENT RATE AND PROPOSED REDUCED NATIONAL ADJUSTED PAYMENT RATE

Final Full national unadjusted payment rate	Final Reduced national adjusted payment rate
$832.60	$816.45

We did not receive any public comments on these steps under the methodology that we included in the proposed rule to determine the APC payments for CY 2025. Therefore, we are using the steps in the methodology specified above to demonstrate the calculation of the final CY 2025 OPPS payments using the same parameters.

I. Beneficiary Copayments

1. Background

Section 1833(t)(3)(B) of the Act requires the Secretary to set rules for determining the unadjusted copayment amounts to be paid by beneficiaries for covered OPD services. Section 1833(t)(8)(C)(ii) of the Act specifies that the Secretary must reduce the national unadjusted copayment amount for a covered OPD service (or group of such services) furnished in a year in a manner so that the effective copayment rate (determined on a national unadjusted basis) for that service in the year does not exceed a specified percentage. As specified in section 1833(t)(8)(C)(ii)(V) of the Act, the effective copayment rate for a covered OPD service paid under the OPPS in CY 2006, and in CYs thereafter, shall not exceed 40 percent of the APC payment rate.

Section 1833(t)(3)(B)(ii) of the Act provides that, for a covered OPD service (or group of such services) furnished in a year, the national unadjusted copayment amount cannot be less than 20 percent of the OPD fee schedule amount. However, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure (including items such as drugs and biologicals) performed in a year to the amount of the inpatient hospital deductible for that year.

Section 4104 of the Affordable Care Act eliminated the Medicare Part B coinsurance for preventive services furnished on and after January 1, 2011, that meet certain requirements, including flexible sigmoidoscopies and screening colonoscopies, and waived the Part B deductible for screening colonoscopies that become diagnostic during the procedure. For a discussion of the changes made by the Affordable Care Act with regard to copayments for preventive services furnished on and after January 1, 2011, we refer readers to section XII.B of the CY 2011 OPPS/ASC final rule with comment period (75 FR 72013).

Section 122 of the Consolidated Appropriations Act (CAA) of 2021 (Pub. L. 116–260), Waiving Medicare Coinsurance for Certain Colorectal Cancer Screening Tests, amended section 1833(a) of the Act to offer a special coinsurance rule for screening flexible sigmoidoscopies and screening colonoscopies, regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure, that is furnished in connection with, as a result of, and in the same clinical encounter as the colorectal cancer screening test. We refer readers to section X.B, ''Changes to Beneficiary Coinsurance for Certain Colorectal Cancer Screening Tests,'' of the CY 2022 OPPS/ASC final rule with comment period for the full discussion of this policy (86 FR 63740 through 63743). Under the regulation at 42 CFR 410.152(l)(5)(i)(B), the Medicare Part B payment percentage for colorectal cancer screening tests described in the regulation at § 410.37(j) that are furnished in CY 2023 through CY 2026 is 85 percent, with beneficiary coinsurance equal to 15 percent.

On August 16, 2022, the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169) was signed into law. Section 11101(a) of the IRA amended section 1847A of the Act by adding a new subsection (i), which requires the payment of rebates into the Supplementary Medical Insurance Trust Fund for Part B rebatable drugs if the payment limit amount exceeds the inflation-adjusted payment amount, which is calculated as set forth in section 1847A(i)(3)(C) of the Act. The provisions of section 11101 of the IRA thus far have primarily been implemented through program instruction, as permitted under section 1847A(c)(5)(C) of the Act. As such, we issued guidance for the computation of inflation-adjusted beneficiary coinsurance under section 1847A(i)(5) of the Act and amounts paid under section 1833(a)(1)(EE) of the Act on February 9, 2023.[12] [13] For additional information regarding implementation of section 11101 of the IRA, please see the inflation rebates resources page at *https://www.cms.gov/inflation-reduction-act-and-medicare/inflation-rebates-medicare*.

Section 11101(b) of the IRA amended sections 1833(i) and 1833(t)(8) of the Act by adding a new paragraph (9) and subparagraph (F), respectively. Section 1833(i)(9) requires under the ASC payment system that, in the case of a Part B rebatable drug, in lieu of calculation of coinsurance that would otherwise apply under the ASC payment system, the provisions of section 1847A(i)(5) of the Act shall, as determined appropriate by the Secretary, apply for calculation of beneficiary coinsurance in the same manner as the provisions of section 1847A(i)(5) of the Act apply under that section. Similarly, section 1833(t)(8)(F) of the Act requires under the OPPS that in the case of a Part B rebatable drug (except for a drug that has no copayment applied under subparagraph (E) of such section or for which payment is packaged into the payment for a covered OPD service or group of services), in lieu of the calculation of the copayment amount that would otherwise apply under the OPPS, the provisions of section 1847A(i)(5) of the Act shall, as determined appropriate by the Secretary, apply in the same manner as the provisions of section 1847A(i)(5) of the Act apply under that section. Section 1847A(i)(5) of the Act requires that for Part B rebatable drugs, as defined in section 1847A(i)(2)(A) of the Act, furnished on or after April 1, 2023, in quarters in which the payment

[12] *https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-initial-guidance.pdf*.

[13] In addition, beginning with the April 2023 ASP Drug Pricing file, the file includes the coinsurance percentage for each drug and specifies ''inflation-adjusted coinsurance'' in the ''Notes'' column if the coinsurance for a drug is less than 20 percent of the Medicare Part B payment amount. Drug pricing files are available at *https://www.cms.gov/medicare/medicare-fee-for-service-part-b-drugs/mcrpartbdrugavgsalesprice*.

amount described in section 1847A(i)(3)(A)(ii)(I) of the Act (or, in the case of selected drugs described under section 1192(c) of the Act, the payment amount described in section 1847A(b)(1)(B) of the Act), exceeds the inflation-adjusted payment amount determined in accordance with section 1847A(i)(3)(C) of the Act, the coinsurance will be 20 percent of the inflation-adjusted payment amount for such quarter (hereafter, the inflation-adjusted coinsurance amount). This inflation-adjusted coinsurance amount is applied as a percent, as determined by the Secretary, to the payment amount that would otherwise apply for such calendar quarter in accordance with section 1847A(b)(1)(B) or (C) of the Act, as applicable, including in the case of a selected drug.

Paragraph (9) of section 1833(i) of the Act and subparagraph (F) of section 1833(t)(8) of the Act, as added by section 11101(b) of the IRA, also provide that in lieu of the amounts of payment otherwise applicable under the ASC payment system and the OPPS, the provisions of paragraph (1)(EE) of subsection (a) of section 1833 of the Act shall apply, as determined appropriate by the Secretary. Section 11101(b) of the IRA amended section 1833(a)(1) of the Act by adding a new subparagraph (EE), which requires that if the payment amount under section 1847A(i)(3)(A)(ii)(I) of the Act or, in the case of a selected drug, the payment amount described in section 1847A(b)(1)(B) of the Act, for that drug exceeds the inflation-adjusted payment amount for a Part B rebatable drug, the Part B payment amount would, subject to the Part B deductible and sequestration, equal the difference between such payment amount and the inflation-adjusted coinsurance amount. Consistent with the policy adopted in section 40 of the revised Medicare Part B Drug Inflation Rebate Guidance, the calculation to determine the applicable beneficiary coinsurance amount would not be adjusted for sequestration. CMS codified the Medicare payment for Part B rebatable drugs in the CY 2024 PFS final rule by adding new paragraph (m) to § 410.152.

In the CY 2024 OPPS/ASC final rule with comment period (88 FR 81594), we codified the OPPS program payment and cost sharing amounts for Part B rebatable drugs as required by section 1833(t)(8)(F) by adding a new paragraph (e) to § 419.41, which cross-references the regulations adopted in the CY 2024 PFS final rule (§§ 410.152(m) and 489.30(b)(6)). We also amended the regulation text to reflect our longstanding policies for calculating the Medicare program payment and cost sharing amounts for separately payable drugs and biologicals by adding a new paragraph (d) to § 419.41. Similarly, we codified the ASC cost sharing amounts for Part B rebatable drugs as required by section 1833(i)(9) of the Act by revising § 416.172(d) to include a cross-reference to 42 CFR 489.30(b)(6), which codified the cost sharing amounts for Part B rebatable drugs with prices increasing at a rate faster than inflation.

In the CY 2025 PFS proposed rule (89 FR 61956), CMS proposed to adopt new provisions at §§ 427.200 and 427.201 to codify the policies regarding the computation of the inflation-adjusted beneficiary coinsurance, defined in § 427.200, for Part B rebatable drugs as required by section 1847A(i)(5) of the Act. The proposed new provision at § 427.201 includes references to the existing provisions at §§ 410.152(m), 419.41(e), and 489.30(b)(6). CMS further proposed at § 427.201(c) that any category of products that is excluded from the identification of Part B rebatable drugs at § 427.101(b) is not subject to the inflation-adjusted beneficiary coinsurance. Examples of these excluded products include separately payable radiopharmaceuticals, skin substitute products, and qualifying biosimilar biological products.

Additionally, CMS proposed at § 427.201(b) that CMS would use the published payment amount in quarterly pricing files [14] [15] [16] to determine if a Part B rebatable drug should have an adjusted beneficiary coinsurance equal to 20 percent of the inflation-adjusted payment amount as described in section 1847A(i)(3)(C) for a calendar quarter. The proposed approach deviates from the rebate calculation approach proposed in § 427.302, which relies on the specified amount defined at § 427.20 even when the specified amount and the published payment amount in quarterly pricing files differ. The approach proposed at § 427.201(b) will be used only to determine whether there should be a coinsurance adjustment and will not impact the applicability or calculation of inflation rebates. CMS believes this approach is consistent with the statutory language and appropriately reflects the differences in the statutory text of section 1847A(i)(5) of the Act, which sets forth the payment amount that is used to determine whether coinsurance should be adjusted, and section 1847A(i)(3)(A) of the Act, which sets forth the ''specified amount'' used to determine rebate amounts.

We did not receive any public comments related to inflation-adjusted beneficiary coinsurance or program payment amounts.

2. OPPS Copayment Policy

For CY 2025, we proposed to determine copayment amounts for new and revised APCs using the same methodology that we implemented beginning in CY 2004. We refer readers to the November 7, 2003 OPPS final rule with comment period for a discussion of that methodology (68 FR 63458). In addition, we proposed to use the same standard rounding principles that we have historically used in instances where the application of our standard copayment methodology would result in a copayment amount that is less than 20 percent and cannot be rounded, under standard rounding principles, to 20 percent. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66687) in which we discuss our rationale for applying these rounding principles. The final national unadjusted copayment amounts for services payable under the OPPS that will be effective January 1, 2025, are included in Addenda A and B to this final rule with comment period (which are available via the internet on the CMS website).

As discussed in section XIV.E of this final rule with comment period, for CY 2025, the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies will equal the product of the reporting ratio and the national unadjusted copayment, or the product of the reporting ratio and the minimum unadjusted copayment, respectively, for the service.

We note that OPPS copayments may increase or decrease each year based on changes in the calculated APC payment rates, due to updated cost report and claims data, and any changes to the OPPS cost modeling process. However, as described in the CY 2004 OPPS final rule with comment period, the development of the copayment methodology generally moves beneficiary copayments closer to 20 percent of OPPS APC payments (68 FR 63458 through 63459).

In the CY 2004 OPPS final rule with comment period (68 FR 63459), we adopted a new methodology to calculate unadjusted copayment amounts in situations including reorganizing APCs,

[14] See: *https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files.*

[15] See: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/addendum-a-b-updates.*

[16] See: *https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-payment-rates-addenda.*

and we finalized the following rules to determine copayment amounts in CY 2004 and subsequent years.

- When an APC group consists solely of HCPCS codes that were not paid under the OPPS the prior year because they were packaged or excluded or are new codes, the unadjusted copayment amount would be 20 percent of the APC payment rate.
- If a new APC that did not exist during the prior year is created and consists of HCPCS codes previously assigned to other APCs, the copayment amount is calculated as the product of the APC payment rate and the lowest coinsurance percentage of the codes comprising the new APC.
- If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is equal to or *greater than* the prior year's rate, the copayment amount remains constant (unless the resulting coinsurance percentage is less than 20 percent).
- If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is *less than* the prior year's rate, the copayment amount is calculated as the product of the new payment rate and the prior year's coinsurance percentage.
- If HCPCS codes are added to or deleted from an APC and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in a decrease in the coinsurance percentage for the reconfigured APC, the copayment amount would not change (unless retaining the copayment amount would result in a coinsurance rate less than 20 percent).
- If HCPCS codes are added to an APC and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in an increase in the coinsurance percentage for the reconfigured APC, the copayment amount would be calculated as the product of the payment rate of the reconfigured APC and the lowest coinsurance percentage of the codes being added to the reconfigured APC.

We noted in the CY 2004 OPPS final rule with comment period that we would seek to lower the copayment percentage for a service in an APC from the prior year if the copayment percentage was greater than 20 percent. We noted that this principle was consistent with section 1833(t)(8)(C)(ii) of the Act, which accelerates the reduction in the national unadjusted coinsurance rate so that beneficiary liability will eventually equal 20 percent of the OPPS payment rate for all OPPS services to which a copayment applies, and with section 1833(t)(3)(B) of the Act, which achieves a 20-percent copayment percentage when fully phased in and gives the Secretary the authority to set rules for determining copayment amounts for new services. We further noted that the use of this methodology would, in general, reduce the beneficiary coinsurance rate and copayment amount for APCs for which the payment rate changes as the result of the reconfiguration of APCs and/or recalibration of relative payment weights (68 FR 63459).

We did not receive any public comments on our proposal and we are finalizing our proposal to determine copayment amounts for new and revised APCs using the same methodology that we implemented beginning in CY 2004. The finalized national unadjusted copayment amounts for services payable under the OPPS that will be effective January 1, 2025, are included in Addenda A and B to the CY 2025 OPPS/ASC final rule (which are available on the CMS website).

3. Calculation of an Adjusted Copayment Amount for an APC Group

Individuals interested in calculating the national copayment liability for a Medicare beneficiary for a given service provided by a hospital that met or failed to meet its Hospital OQR Program requirements should follow the formulas presented in the following steps.

Step 1. Calculate the beneficiary payment percentage for the APC by dividing the APC's national unadjusted copayment by its proposed payment rate. For example, using APC 5071, $140.72 is approximately 20 percent of the full national unadjusted payment rate of $703.59. For APCs with only a minimum unadjusted copayment in Addenda A and B to this final rule with comment period (which are available via the internet on the CMS website), the beneficiary payment percentage is 20 percent.

The formula below is a mathematical representation of Step 1 and calculates the national copayment as a percentage of national payment for a given service.

B is the beneficiary payment percentage.

B = National unadjusted copayment for APC/national unadjusted payment rate for APC.

Step 2. Calculate the appropriate wage-adjusted payment rate for the APC for the provider in question, as indicated in Steps 2 through 4 under section II.H of this final rule with comment period. Calculate the rural adjustment for eligible providers, as indicated in Step 6 under section II.H of this final rule with comment period.

Step 3. Multiply the percentage calculated in Step 1 by the payment rate calculated in Step 2. The result is the wage-adjusted copayment amount for the APC.

The formula below is a mathematical representation of Step 3 and applies the beneficiary payment percentage to the adjusted payment rate for a service calculated under section II.H of this final rule with comment period, with and without the rural adjustment, to calculate the adjusted beneficiary copayment for a given service.

Wage-adjusted copayment amount for the APC = Adjusted Medicare Payment * *B.*

Wage-adjusted copayment amount for the APC (SCH or EACH) = (Adjusted Medicare Payment * 1.071) * *B.*

Step 4. For a hospital that failed to meet its Hospital OQR Program requirements, multiply the copayment calculated in Step 3 by the reporting ratio of 0.9806.

The unadjusted copayments for services payable under the OPPS that will be effective January 1, 2025, are shown in Addenda A and B to this final rule with comment period (which are available via the CMS website). We note that the final national unadjusted payment rates and copayment rates shown in Addenda A and B to this final rule with comment period reflect the CY 2025 OPD fee schedule increase factor discussed in section II.B of this final rule with comment period.

In addition, as noted earlier, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure performed in a year to the amount of the inpatient hospital deductible for that year.

Comment: One commenter suggested beneficiaries should not be responsible for drug pricing increases and that CMS should limit or eliminate cost-sharing for beneficiaries. The commenter also stated that cost-sharing has unintended consequences and negative effects on access to health care and health outcomes, including increased use of emergency rooms. The commenter also acknowledged that CMS is limited by statute and that our copayment methodologies ensure that copayments are minimal.

Response: We thank the commenter for the input. We note that the beneficiary copayment is established by section 1833(t)(3)(B) of the Act and § 419.41(d). Section 1847A(i)(5) of the Act provides for an adjustment to the

beneficiary coinsurance for Part B rebatable drugs with prices that have increased faster than the rate of inflation beginning April 1, 2023. In the CY 2024 OPPS/ASC OPPS final rule and the CY 2024 Physician Fee Schedule final rule, CMS codified this inflation-adjusted coinsurance amount at §§ 419.41(e), 410.152(m), and 489.30(b)(6), respectively. For these drugs and biologicals, the beneficiary coinsurance is 20 percent of the inflation-adjusted payment amount, which is less than what the beneficiary would pay in coinsurance otherwise. Therefore, beneficiaries are insulated from coinsurance amounts calculated based on drug prices that outpace inflation. More information about the beneficiary coinsurance adjustment and the Medicare Part B Inflation Rebate Program is available at *https://www.cms.gov/inflation-reduction-act-and-medicare/inflation-rebates-medicare*.

III. OPPS Ambulatory Payment Classification (APC) Group Policies

A. OPPS Treatment of New and Revised HCPCS Codes

Payments for OPPS procedures, services, and items are generally based on medical billing codes, specifically, Healthcare Common Procedure Coding System (HCPCS) codes, that are reported on hospital outpatient department (HOPD) claims. HCPCS codes are used to report surgical procedures, medical services, items, and supplies under the hospital OPPS. The HCPCS is divided into two principal subsystems, referred to as Level I and Level II of the HCPCS. Level I is comprised of CPT (Current Procedural Terminology) codes, a numeric and alphanumeric coding system that is established and maintained by the American Medical Association (AMA), and consists of Category I, II, III, MAAA, and PLA CPT codes. Level II, which is established and maintained by CMS, is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes. Together, Level I and II HCPCS codes are used to report procedures, services, items, and supplies under the OPPS payment system. Specifically, we recognize the following codes on OPPS claims:

- Category I CPT codes, which describe surgical procedures, diagnostic and therapeutic services, and vaccine codes;
- Category III CPT codes, which describe new and emerging technologies, services, and procedures;
- MAAA CPT codes, which describe laboratory multianalyte assays with algorithmic analyses (MAA);
- PLA CPT codes, which describe proprietary laboratory analyses (PLA) services; and
- Level II HCPCS codes (also known as alpha-numeric codes), which are used primarily to identify drugs, devices, supplies, temporary procedures, and services not described by CPT codes.

The codes are updated and changed throughout the year. CPT and Level II HCPCS code changes that affect the OPPS are published through the annual rulemaking cycle and through the OPPS quarterly update Change Requests (CRs). Generally, these code changes are effective January 1, April 1, July 1, or October 1. CPT code changes are released by the AMA (via their website) while Level II HCPCS code changes are released to the public via the CMS HCPCS website. CMS recognizes the release of new CPT and Level II HCPCS codes outside of the formal rulemaking process via OPPS quarterly update CRs. Based on our review, we assign the new codes to interim status indicators (SIs) and APCs. These interim assignments are finalized in the OPPS/ASC final rules. This quarterly process offers hospitals access to codes that more accurately describe the items or services furnished and provides payment for these items or services in a timelier manner than if we waited for the annual rulemaking process. We solicit public comments on the new CPT and Level II HCPCS codes, status indicators, and APC assignments through our annual rulemaking process.

We note that, under the OPPS, the APC assignment determines the payment rate for an item, procedure, or service. The items, procedures, or services not exclusively paid separately under the hospital OPPS are assigned to appropriate status indicators. Certain payment status indicators provide separate payment while other payment status indicators do not. In section XI (CY 2025 Payment Status and Comment Indicators) of this final rule with comment period, we discuss the various status indicators and comment indicators used under the OPPS. We also provide a complete list of the status indicators and their definitions in Addendum D1 to this final rule with comment period.

1. April 2024 HCPCS Codes Proposed Rule Comment Solicitation

For the April 2024 update, 73 new HCPCS codes were established and made effective on April 1, 2024. Through the April 2024 OPPS quarterly update CR (Transmittal 12552, Change Request 13568, dated March 21, 2024), we recognized several new HCPCS codes for payment under the OPPS. We solicited public comments on the proposed APC and status indicator assignments for the codes listed in Table 10 (New HCPCS Codes Effective April 1, 2024) of the CY 2025 OPPS/ASC proposed rule (89 FR 59239 through 59241, which are also displayed in Table 14.

We received some public comments on the proposed OPPS APC and SI assignments for the new Level II HCPCS codes that were effective on April 1, 2024. The comments and our responses are addressed in the applicable sections of this final rule with comment period, which include, but are not limited to: sections III.C. (New Technology APCs); III.E. (OPPS APC-Specific Policies); and IV. (OPPS Payment for Devices). For those April 2024 codes for which we received no comments, we are finalizing the proposed APC and status indicator assignments as proposed. We note that several of the HCPCS C-codes have been replaced with HCPCS J-codes, effective January 1, 2025. Their replacement codes are listed in Table 14. In addition, in prior years we included the final OPPS status indicators and APC assignments in the coding preamble tables, however, because the same information can be found in Addendum B, we are no longer including them in Table 14. Therefore, readers are advised to refer to the OPPS Addendum B for the final OPPS status indicators, APC assignments, and payment rates for all codes reportable under the hospital OPPS. These new codes that were effective April 1, 2024, were assigned to comment indicator ''NP'' in Addendum B to the CY 2025 OPPS/APC proposed rule to indicate that the codes are assigned to an interim APC assignment and comments would be accepted on their interim APC assignments. The complete list of status indicators and definitions used under the OPPS can be found in Addendum D1 to this final rule with comment period, while the complete list comment indicators and definitions can be found in Addendum D2 to this final rule with comment period. We note that OPPS Addendum B (OPPS payment file by HCPCS code), Addendum D1 (OPPS Status Indicators), and Addendum D2 (OPPS Comment Indicators) are available via the internet on the CMS website.

BILLING CODE 4120–01–P

TABLE 14: NEW HCPCS CODES EFFECTIVE APRIL 1, 2024

April 2024 HCPCS Code	CY 2025 HCPCS Code	CY 2025 Long Descriptor
A2026	A2026	Restrata minimatrix, 5 mg
A4271	A4271	Integrated lancing and blood sample testing cartridges for home blood glucose monitor, per month
A4438	A4438	Adhesive clip applied to the skin to secure external electrical nerve stimulator controller, each
A4564	A4564	Pessary, disposable, any type
A4593	A4593	Neuromodulation stimulator system, adjunct to rehabilitation therapy regime, controller
A4594	A4594	Neuromodulation stimulator system, adjunct to rehabilitation therapy regime, mouthpiece each
A9293	A9293	Fertility cycle (contraception & conception) tracking software application, FDA cleared, per month, includes accessories (e.g., thermometer)
C9166	C9166	Injection, secukinumab, intravenous, 1 mg
C9167	C9167	Injection, adamts13, recombinant-krhn, 10 iu
C9168	C9168	Injection, mirikizumab-mrkz, 1 mg
C9796	C9796	Repair of enterocutaneous fistula small intestine or colon (excluding anorectal fistula) with plug (e.g., porcine small intestine submucosa [SIS])
C9797	C9797	Vascular embolization or occlusion procedure with use of a pressure-generating catheter (e.g., one-way valve, intermittently occluding), inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction
E0152	E0152	Walker, battery powered, wheeled, folding, adjustable or fixed height
E0468	E0468	Home ventilator, dual-function respiratory device, also performs additional function of cough stimulation, includes all accessories, components and supplies for all functions
E0736	E0736	Transcutaneous tibial nerve stimulator
E0738	E0738	Upper extremity rehabilitation system providing active assistance to facilitate muscle re-education, include microprocessor, all components and accessories
E0739	E0739	Rehab system with interactive interface providing active assistance in rehabilitation therapy, includes all components and accessories, motors, microprocessors, sensors
E2104	E2104	Home blood glucose monitor for use with integrated lancing/blood sample testing cartridge
E2298	E2298	Complex rehabilitative power wheelchair accessory, power seat elevation system, any type
G0138	G0138	Intravenous infusion of cipaglucosidase alfa-atga, including provider/supplier acquisition and clinical supervision of oral administration of miglustat in preparation of receipt of cipaglucosidase alfa-atga
H0051	H0051	Traditional healing service
C9161	J0177	Injection, aflibercept hd, 1 mg
J0209	J0209	Injection, sodium thiosulfate (hope), 100 mg
J0577	J0577	Injection, buprenorphine extended-release (brixadi), less than or equal to 7 days of therapy
J0578	J0578	Injection, buprenorphine extended-release (brixadi), greater than 7 days of therapy and up to 28 days of therapy

April 2024 HCPCS Code	CY 2025 HCPCS Code	CY 2025 Long Descriptor
C9160	J0589	Injection, daxibotulinumtoxina-lanm, 1 unit
J0650	J0650	Injection, levothyroxine sodium, not otherwise specified, 10 mcg
J0651	J0651	Injection, levothyroxine sodium (fresenius kabi), not therapeutically equivalent to J0650, 10 mcg
J0652	J0652	Injection, levothyroxine sodium (hikma), not therapeutically equivalent to J0650, 10mcg
J1010	J1010	Injection, methylprednisolone acetate, 1 mg
J1202	J1202	Miglustat, oral, 65 mg
J1203	J1203	Injection, cipaglucosidase alfa-atga, 5 mg
C9165	J1323	Injection, elranatamab-bcmm, 1 mg
J1434	J1434	Injection, fosaprepitant (focinvez), 1 mg
J2277	J2277	Injection, motixafortide, 0.25 mg
C9162	J2782	Injection, avacincaptad pegol, 0.1 mg
J2801	J2801	Injection, risperidone (rykindo), 0.5 mg
J2919	J2919	Injection, methylprednisolone sodium succinate, 5 mg
C9163	J3055	Injection, talquetamab-tgvs, 0.25 mg
J3424	J3424	Injection, hydroxocobalamin, intravenous, 25 mg
C9159	J7165	Injection, prothrombin complex concentrate, human-lans, per i.u. of factor ix activity
C9164	J7354	Cantharidin for topical administration, 0.7%, single unit dose applicator (3.2 mg)
J9073	J9073	Injection, cyclophosphamide (ingenus), 5 mg
J9074	J9074	Injection, cyclophosphamide (sandoz), 5 mg
J9075	J9075	Injection, cyclophosphamide, not otherwise specified, 5 mg
J9248	J9248	Injection, melphalan (hepzato), 1 mg
J9249	J9249	Injection, melphalan (apotex), 1 mg
J9376	J9376	Injection, pozelimab-bbfg, 1 mg
K1037	K1037	Docking station for use with oral device/appliance used to reduce upper airway collapsibility
L1320	L1320	Thoracic, pectus carinatum orthosis, sternal compression, rigid circumferential frame with anterior and posterior rigid pads, custom fabricated
L5783	L5783	Addition to lower extremity, user adjustable, mechanical, residual limb volume management system
L5841	L5841	Addition, endoskeletal knee-shin system, polycentric, pneumatic swing, and stance phase control
Q4305	Q4305	American amnion ac tri-layer, per square centimeter
Q4306	Q4306	American amnion ac, per square centimeter
Q4307	Q4307	American amnion, per square centimeter
Q4308	Q4308	Sanopellis, per square centimeter
Q4309	Q4309	Via matrix, per square centimeter
Q4310	Q4310	Procenta, per 100 mg
Q5133	Q5133	Injection, tocilizumab-bavi (tofidence), biosimilar, 1 mg
Q5134	Q5134	Injection, natalizumab-sztn (tyruko), biosimilar, 1 mg
S4988	S4988	Penile contracture device, manual, greater than 3 lbs traction force
S9002	S9002	Intra-vaginal motion sensor system, provides biofeedback for pelvic floor muscle rehabilitation device
0439U	0439U	Cardiology (coronary heart disease [CHD]), DNA, analysis of 5 single-nucleotide polymorphisms (SNPs) (rs11716050 [LOC105376934], rs6560711 [WDR37], rs3735222 [SCIN/LOC107986769], rs6820447

April 2024 HCPCS Code	CY 2025 HCPCS Code	CY 2025 Long Descriptor
		[intergenic], and rs9638144 [ESYT2]) and 3 DNA methylation markers (cg00300879 [transcription start site {TSS200} of CNKSR1], cg09552548 [intergenic], and cg14789911 [body of SPATC1L]), qPCR and digital PCR, whole blood, algorithm reported as a 4-tiered risk score for a 3-year risk of symptomatic CHD
0440U	0440U	Cardiology (coronary heart disease [CHD]), DNA, analysis of 10 single-nucleotide polymorphisms (SNPs) (rs710987 [LINC010019], rs1333048 [CDKN2B-AS1], rs12129789 [KCND3], rs942317 [KTN1-AS1], rs1441433 [PPP3CA], rs2869675 [PREX1], rs4639796 [ZBTB41], rs4376434 [LINC00972], rs12714414 [TMEM18], and rs7585056 [TMEM18]) and 6 DNA methylation markers (cg03725309 [SARS1], cg12586707 [CXCL1, cg04988978 [MPO], cg17901584 [DHCR24-DT], cg21161138 [AHRR], and cg12655112 [EHD4]), qPCR and digital PCR, whole blood, algorithm reported as detected or not detected for CHD
0441U	0441U	Infectious disease (bacterial, fungal, or viral infection), semiquantitative biomechanical assessment (via deformability cytometry), whole blood, with algorithmic analysis and result reported as an index
0442U	0442U	Infectious disease (respiratory infection), Myxovirus resistance protein A (MxA) and C-reactive protein (CRP), fingerstick whole blood specimen, each biomarker reported as present or absent
0443U	0443U	Neurofilament light chain (NfL), ultra-sensitive immunoassay, serum or cerebrospinal fluid
0444U	0444U	Oncology (solid organ neoplasia), targeted genomic sequence analysis panel of 361 genes, interrogation for gene fusions, translocations, or other rearrangements, using DNA from formalin-fixed paraffin-embedded (FFPE) tumor tissue, report of clinically significant variant(s)
0445U	0445U	β-amyloid (Abeta42) and phospho tau (181P) (pTau181), electrochemiluminescent immunoassay (ECLIA), cerebral spinal fluid, ratio reported as positive or negative for amyloid pathology
0446U	0446U	Autoimmune diseases (systemic lupus erythematosus [SLE]), analysis of 10 cytokine soluble mediator biomarkers by immunoassay, plasma, individual components reported with an algorithmic risk score for current disease activity
0447U	0447U	Autoimmune diseases (systemic lupus erythematosus [SLE]), analysis of 11 cytokine soluble mediator biomarkers by immunoassay, plasma, individual components reported with an algorithmic prognostic risk score for developing a clinical flare
0448U	0448U	Oncology (lung and colon cancer), DNA, qualitative, nextgeneration sequencing detection of single-nucleotide variants and deletions in EGFR and KRAS genes, formalin-fixed paraffinembedded (FFPE) solid tumor samples, reported as presence or absence of targeted mutation(s), with recommended therapeutic options
0449U	0449U	Carrier screening for severe inherited conditions (e.g., cystic fibrosis, spinal muscular atrophy, beta hemoglobinopathies [including sickle cell disease], alpha thalassemia), regardless of race or self-identified ancestry, genomic sequence analysis panel, must include analysis of 5 genes (CFTR, SMN1, HBB, HBA1, HBA2)

BILLING CODE 4120–01–C

2. July 2024 HCPCS Codes Proposed Rule Comment Solicitation

For the July 2024 update, 130 new codes were established and made effective July 1, 2024. Through the July 2024 OPPS quarterly update CR (Transmittal 12665, Change Request 13632, dated May 31, 2024), we recognized several new codes for payment and assigned them to appropriate interim OPPS status indicators and APCs. We solicited public comments on the proposed APC and status indicator assignments for the codes listed in Table 11 (New HCPCS Codes Effective July 1, 2024) of the CY 2025 OPPS/ASC proposed rule (89 FR 59242 through 59249), which are also listed in Table 15.

We received some public comments on the proposed OPPS APC and SI assignments for the new Level II HCPCS codes implemented on July 1, 2024. The comments and our responses are addressed in pertinent sections of this final rule with comment period, which include, but are not limited to: sections III.C (New Technology APCs); III.E (OPPS APC-Specific Policies); and IV (OPPS Payment for Devices). For those July 1, 2024, codes for which we received no comments, we are finalizing the proposed APC and status indicator assignments. Additionally, we note that in prior years we included the final OPPS status indicators and APC assignments in the coding preamble tables, however, because the same information can be found in Addendum B, we are no longer including them in Table 15. Therefore, readers are advised to refer to the OPPS Addendum B for the final OPPS status indicators, APC assignments, and payment rates for all codes reportable under the hospital OPPS. These new codes that were effective July 1, 2024, were assigned to comment indicator ''NP'' in Addendum B to the CY 2025 OPPS/ASC proposed rule to indicate that the codes are assigned to an interim APC assignment and comments would be accepted on their interim APC assignments. The complete list of status indicators and definitions used under the OPPS can be found in Addendum D1 to this final rule with comment period, while the complete list of comment indicators and definitions can be found in Addendum D2 to this final rule with comment period. We note that OPPS Addendum B (OPPS payment file by HCPCS code), Addendum D1 (OPPS Status Indicators), and Addendum D2 (OPPS Comment Indicators) are available via the internet on the CMS website.

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TABLE 15: NEW HCPCS CODES EFFECTIVE JULY 1, 2024

July 2024 HCPCS Code	CY 2025 HCPCS Code	CY 2025 Long Descriptor
90637	90637	Influenza virus vaccine, quadrivalent (qIRV), mRNA; 30 mcg/0.5 mL dosage, for intramuscular use
90638	90638	Influenza virus vaccine, quadrivalent (qIRV), mRNA; 60 mcg/0.5 mL dosage, for intramuscular use
C9901	C9901	Endoscopic defect closure within the entire gastrointestinal tract, including upper endoscopy (including diagnostic, if performed) or colonoscopy (including diagnostic, if performed), with all system and tissue anchoring components
C1605	C1605	Pacemaker, leadless, dual chamber (right atrial and right ventricular implantable components), rate-responsive, including all necessary components for implantation
C1606	C1606	Adapter, single-use (i.e. disposable), for attaching ultrasound system to upper gastrointestinal endoscope
G0519	G0519	Management of new patient-caregiver dyad with dementia, low complexity, for use in CMMI Model
G0520	G0520	Management of new patient-caregiver dyad with dementia, moderate complexity, for use in CMMI Model
G0521	G0521	Management of new patient-caregiver dyad with dementia, high complexity, for use in CMMI Model
G0522	G0522	Management of a new patient with dementia, low complexity, for use in CMMI Model
G0523	G0523	Management of a new patient with dementia, moderate to high complexity, for use in CMMI Model
G0524	G0524	Management of established patient-caregiver dyad with dementia, low complexity, for use in CMMI Model
G0525	G0525	Management of established patient-caregiver dyad with dementia, moderate complexity, for use in CMMI Model
G0526	G0526	Management of established patient-caregiver dyad with dementia, high complexity, for use in CMMI Model
G0527	G0527	Management of established patient with dementia, low complexity, for use in CMMI Model
G0528	G0528	Management of established patient with dementia, moderate to high complexity, for use in CMMI Model
G0529	G0529	In-home respite care, 4-hour unit, for use in CMMI Model
G0530	G0530	Adult day center, 8-hour unit, for use in CMMI Model
G0531	G0531	Facility-based respite, 24-hour unit, for use in CMMI Model
G9037	G9037	Interprofessional telephone/Internet/electronic health record clinical question/request for specialty recommendations by a treating/requesting physician or other qualified health care

July 2024 HCPCS Code	CY 2025 HCPCS Code	CY 2025 Long Descriptor
		professional for the care of the patient (i.e. not for professional education or scheduling) and may include subsequent follow up on the specialist's recommendations; 30 minutes
G9038	G9038	Co-management services with the following elements: New diagnosis OR acute exacerbation and stabilization of existing condition; Condition which may benefit from joint care planning; Condition for which specialist is taking a co-management role; Condition expected to last at least 3 months; Comprehensive care plan established, implemented, revised or monitored in partnership with co-managing clinicians; Ongoing communication and care coordination between co-managing clinicians furnishing care
J0211	J0211	Injection, sodium nitrite 3 mg and sodium thiosulfate 125 mg (nithiodote)
J0687	J0687	Injection, cefazolin sodium (wg critical care), not therapeutically equivalent to j0690, 500 mg
J0872	J0872	Injection, daptomycin (xellia), unrefrigerated, not therapeutically equivalent to j0878 or j0873, 1 mg
J0911	J0911	Instillation, taurolidine 1.35 mg and heparin sodium 100 units (central venous catheter lock for adult patients receiving chronic hemodialysis)
J1597	J1597	Injection, glycopyrrolate (glyrx-pf), 0.1 mg
J1598	J1598	Injection, glycopyrrolate (fresenius kabi), not therapeutically equivalent to J1596, 0.1 mg
J2183	J2183	Injection, meropenem (wg critical care), not therapeutically equivalent to j2185, 100 mg
J2246	J2246	Injection, micafungin in sodium (baxter), not therapeutically equivalent to j2248, 1 mg
J2267	J2267	Injection, mirikizumab-mrkz, 1 mg
J2373	J2373	Injection, phenylephrine hydrochloride (immphentiv), 20 micrograms
J2468	J2468	Injection, palonosetron hydrochloride (avyxa), not therapeutically equivalent to J2469, 25 micrograms
J2470	J2470	Injection, pantoprazole sodium, 40 mg
J2471	J2471	Injection, pantoprazole (hikma), not therapeutically equivalent to J2470, 40 mg
J3247	J3247	Injection, secukinumab, intravenous, 1 mg
J3263	J3263	Injection, toripalimab-tpzi, 1 mg
J3393	J3393	Injection, betibeglogene autotemcel, per treatment

July 2024 HCPCS Code	CY 2025 HCPCS Code	CY 2025 Long Descriptor
J3394	J3394	Injection, lovotibeglogene autotemcel, per treatment
J7171	J7171	Injection, adamts13, recombinant-krhn, 10 iu
J7355	J7355	Injection, travoprost, intracameral implant, 1 microgram
J8611	J8611	Methotrexate (jylamvo), oral, 2.5 mg
J8612	J8612	Methotrexate (xatmep), oral, 2.5 mg
J9361	J9361	Injection, efbemalenograstim alfa-vuxw, 0.5 mg
Q4311	Q4311	Acesso, per square centimeter
Q4312	Q4312	Acesso ac, per square centimeter
Q4313	Q4313	Dermabind fm, per square centimeter
Q4314	Q4314	Reeva ft, per square centimeter
Q4315	Q4315	Regenelink amniotic membrane allograft, per square centimeter
Q4316	Q4316	Amchoplast, per square centimeter
Q4317	Q4317	Vitograft, per square centimeter
Q4318	Q4318	E-graft, per square centimeter
Q4319	Q4319	Sanograft, per square centimeter
Q4320	Q4320	Pellograft, per square centimeter
Q4321	Q4321	Renograft, per square centimeter
Q4322	Q4322	Caregraft, per square centimeter
Q4323	Q4323	Alloply, per square centimeter
Q4324	Q4324	Amniotx, per square centimeter
Q4325	Q4325	Acapatch, per square centimeter
Q4326	Q4326	Woundplus, per square centimeter
Q4327	Q4327	Duoamnion, per square centimeter
Q4328	Q4328	Most, per square centimeter
Q4329	Q4329	Singlay, per square centimeter
Q4330	Q4330	Total, per square centimeter
Q4331	Q4331	Axolotl graft, per square centimeter
Q4332	Q4332	Axolotl dualgraft, per square centimeter

July 2024 HCPCS Code	CY 2025 HCPCS Code	CY 2025 Long Descriptor
Q4333	Q4333	Ardeograft, per square centimeter
Q5136	Q5136	Injection, infliximab-dyyb (zymfentra), biosimilar, 10 mg
Q5137	Q5137	Injection, ustekinumab-auub (wezlana), biosimilar, subcutaneous, 1 mg
Q5138	Q5138	Injection, ustekinumab-auub (wezlana), biosimilar, intravenous, 1 mg
0867T	0867T	Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance; prostate volume greater than or equal to 50 mL
0868T	0868T	High-resolution gastric electrophysiology mapping with simultaneous patient symptom profiling, with interpretation and report
0869T	0869T	Injection(s), bone-substitute material for bone and/or soft tissue hardware fixation augmentation, including intraoperative imaging guidance, when performed
0870T	0870T	Implantation of subcutaneous peritoneal ascites pump system, percutaneous, including pump-pocket creation, insertion of tunneled indwelling bladder and peritoneal catheters with pump connections, including all imaging and initial programming, when performed
0871T	0871T	Replacement of a subcutaneous peritoneal ascites pump, including reconnection between pump and indwelling bladder and peritoneal catheters, including initial programming and imaging, when performed
0872T	0872T	Replacement of indwelling bladder and peritoneal catheters, including tunneling of catheter(s) and connection with previously implanted peritoneal ascites pump, including imaging and programming, when performed
0873T	0873T	Revision of a subcutaneously implanted peritoneal ascites pump system, any component (ascites pump, associated peritoneal catheter, associated bladder catheter), including imaging and programming, when performed
0874T	0874T	Removal of a peritoneal ascites pump system, including implanted peritoneal ascites pump and indwelling bladder and peritoneal catheters
0875T	0875T	Programming of subcutaneously implanted peritoneal ascites pump system by physician or other qualified health care professional
0876T	0876T	Duplex scan of hemodialysis fistula, computer-aided, limited (volume flow, diameter, and depth, including only body of fistula)

July 2024 HCPCS Code	CY 2025 HCPCS Code	CY 2025 Long Descriptor
0877T	0877T	Augmentative analysis of chest computed tomography (CT) imaging data to provide categorical diagnostic subtype classification of interstitial lung disease; obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging
0878T	0878T	Augmentative analysis of chest computed tomography (CT) imaging data to provide categorical diagnostic subtype classification of interstitial lung disease; obtained with concurrent CT examination of the same structure
0879T	0879T	Augmentative analysis of chest computed tomography (CT) imaging data to provide categorical diagnostic subtype classification of interstitial lung disease; radiological data preparation and transmission
0880T	0880T	Augmentative analysis of chest computed tomography (CT) imaging data to provide categorical diagnostic subtype classification of interstitial lung disease; physician or other qualified health care professional interpretation and report
0881T	0881T	Cryotherapy of the oral cavity using temperature regulated fluid cooling system, including placement of an oral device, monitoring of patient tolerance to treatment, and removal of the oral device
0882T	0882T	Intraoperative therapeutic electrical stimulation of peripheral nerve to promote nerve regeneration, including lead placement and removal, upper extremity, minimum of 10 minutes; initial nerve (List separately in addition to code for primary procedure)
0883T	0883T	Intraoperative therapeutic electrical stimulation of peripheral nerve to promote nerve regeneration, including lead placement and removal, upper extremity, minimum of 10 minutes; each additional nerve (List separately in addition to code for primary procedure)
0884T	0884T	Esophagoscopy, flexible, transoral, with initial transendoscopic mechanical dilation (e.g., nondrug-coated balloon) followed by therapeutic drug delivery by drug-coated balloon catheter for esophageal stricture, including fluoroscopic guidance, when performed
0885T	0885T	Colonoscopy, flexible, with initial transendoscopic mechanical dilation (e.g., nondrug-coated balloon) followed by therapeutic drug delivery by drug-coated balloon catheter for colonic stricture, including fluoroscopic guidance, when performed
0886T	0886T	Sigmoidoscopy, flexible, with initial transendoscopic mechanical dilation (e.g., nondrug-coated balloon) followed

July 2024 HCPCS Code	CY 2025 HCPCS Code	CY 2025 Long Descriptor
		by therapeutic drug delivery by drug-coated balloon catheter for colonic stricture, including fluoroscopic guidance, when performed
0887T	0887T	End-tidal control of inhaled anesthetic agents and oxygen to assist anesthesia care delivery (List separately in addition to code for primary procedure)
0888T	0888T	Histotripsy (i.e., non-thermal ablation via acoustic energy delivery) of malignant renal tissue, including imaging guidance
0889T	0889T	Personalized target development for accelerated, repetitive high-dose functional connectivity MRI–guided theta-burst stimulation derived from a structural and resting-state functional MRI, including data preparation and transmission, generation of the target, motor threshold–starting location, neuronavigation files and target report, review and interpretation
0890T	0890T	Accelerated, repetitive high-dose functional connectivity MRI–guided theta-burst stimulation, including target assessment, initial motor threshold determination, neuronavigation, delivery and management, initial treatment day
0891T	0891T	Accelerated, repetitive high-dose functional connectivity MRI–guided theta-burst stimulation, including neuronavigation, delivery and management, subsequent treatment day
0892T	0892T	Accelerated, repetitive high-dose functional connectivity MRI–guided theta-burst stimulation, including neuronavigation, delivery and management, subsequent motor threshold redetermination with delivery and management, per treatment day
0893T	0893T	Noninvasive assessment of blood oxygenation, gas exchange efficiency, and cardiorespiratory status, with physician or other qualified health care professional interpretation and report
0894T	0894T	Cannulation of the liver allograft in preparation for connection to the normothermic perfusion device and decannulation of the liver allograft following normothermic perfusion
0895T	0895T	Connection of liver allograft to normothermic machine perfusion device, hemostasis control; initial 4 hours of monitoring time, including hourly physiological and laboratory assessments (e.g., perfusate temperature, perfusate pH, hemodynamic parameters, bile production, bile pH, bile

July 2024 HCPCS Code	CY 2025 HCPCS Code	CY 2025 Long Descriptor
		glucose, biliary bicarbonate, lactate levels, macroscopic assessment)
0896T	0896T	Connection of liver allograft to normothermic machine perfusion device, hemostasis control; each additional hour, including physiological and laboratory assessments (e.g., perfusate temperature, perfusate pH, hemodynamic parameters, bile production, bile pH, bile glucose, biliary bicarbonate, lactate levels, macroscopic assessment) (List separately in addition to code for primary procedure)
0897T	0897T	Noninvasive augmentative arrhythmia analysis derived from quantitative computational cardiac arrhythmia simulations, based on selected intervals of interest from 12-lead electrocardiogram and uploaded clinical parameters, including uploading clinical parameters with interpretation and report
0898T	0898T	Noninvasive prostate cancer estimation map, derived from augmentative analysis of image-guided fusion biopsy and pathology, including visualization of margin volume and location, with margin determination and physician interpretation and report
0899T	0899T	Noninvasive determination of absolute quantitation of myocardial blood flow (AQMBF), derived from augmentative algorithmic analysis of the dataset acquired via contrast cardiac magnetic resonance (CMR), pharmacologic stress, with interpretation and report by a physician or other qualified health care professional (List separately in addition to code for primary procedure)
0900T	0900T	Noninvasive estimate of absolute quantitation of myocardial blood flow (AQMBF), derived from assistive algorithmic analysis of the dataset acquired via contrast cardiac magnetic resonance (CMR), pharmacologic stress, with interpretation and report by a physician or other qualified health care professional (List separately in addition to code for primary procedure)
0450U	0450U	Oncology (multiple myeloma), liquid chromatography with tandem mass spectrometry (LCMS/MS), monoclonal paraprotein sequencing analysis, serum, results reported as baseline presence or absence of detectable clonotypic peptides
0451U	0451U	Oncology (multiple myeloma), LCMS/MS, peptide ion quantification, serum, results compared with baseline to determine monoclonal paraprotein abundance
0452U	0452U	Oncology (bladder), methylated PENK DNA detection by linear target enrichment-quantitative methylation-specific real-

July 2024 HCPCS Code	CY 2025 HCPCS Code	CY 2025 Long Descriptor
		time PCR (LTE-qMSP), urine, reported as likelihood of bladder cancer
0453U	0453U	Oncology (colorectal cancer), cellfree DNA (cfDNA), methylationbased quantitative PCR assay (SEPTIN9, IKZF1, BCAT1, Septin9-2, VAV3, BCAN), plasma, reported as presence or absence of circulating tumor DNA (ctDNA)
0454U	0454U	Rare diseases (constitutional/heritable disorders), identification of copy number variations, inversions, insertions, translocations, and other structural variants by optical genome mapping
0455U	0455U	Infectious agents (sexually transmitted infection), Chlamydia trachomatis, Neisseria gonorrhoeae, and Trichomonas vaginalis, multiplex amplified probe technique, vaginal, endocervical, gynecological specimens, oropharyngeal swabs, rectal swabs, female or male urine, each pathogen reported as detected or not detected
0456U	0456U	Autoimmune (rheumatoid arthritis), next-generation sequencing (NGS), gene expression testing of 19 genes, whole blood, with analysis of anticyclic citrullinated peptides (CCP) levels, combined with sex, patient global assessment, and body mass index (BMI), algorithm reported as a score that predicts nonresponse to tumor necrosis factor inhibitor (TNFi) therapy
0457U	0457U	Perfluoroalkyl substances (PFAS) (e.g., perfluorooctanoic acid, perfluorooctane sulfonic acid), 9 PFAS compounds by LC-MS/MS, plasma or serum, quantitative
0458U	0458U	Oncology (breast cancer), S100A8 and S100A9, by enzymelinked immunosorbent assay (ELISA), tear fluid with age, algorithm reported as a risk score
0459U	0459U	β-amyloid (Abeta42) and total tau (tTau), electrochemiluminescent immunoassay (ECLIA), cerebral spinal fluid, ratio reported as positive or negative for amyloid pathology
0460U	0460U	Oncology, whole blood or buccal, DNA single-nucleotide polymorphism (SNP) genotyping by real-time PCR of 24 genes, with variant analysis and reported phenotypes
0461U	0461U	Oncology, pharmacogenomic analysis of single-nucleotide polymorphism (SNP) genotyping by real-time PCR of 24 genes, whole blood or buccal swab, with variant analysis, including impacted gene-drug interactions and reported phenotypes

July 2024 HCPCS Code	CY 2025 HCPCS Code	CY 2025 Long Descriptor
0462U	0462U	Melatonin levels test, sleep study, 7 or 9 sample melatonin profile (cortisol optional), enzyme-linked immunosorbent assay (ELISA), saliva, screening/preliminary
0463U	0463U	Oncology (cervix), mRNA gene expression profiling of 14 biomarkers (E6 and E7 of the highest-risk human papillomavirus [HPV] types 16, 18, 31, 33, 45, 52, 58), by real-time nucleic acid sequence-based amplification (NASBA), exo- or endocervical epithelial cells, algorithm reported as positive or negative for increased risk of cervical dysplasia or cancer for each biomarker
0464U	0464U	Oncology (colorectal) screening, quantitative real-time target and signal amplification, methylated DNA markers, including LASS4, LRRC4 and PPP2R5C, a reference marker ZDHHC1, and a protein marker (fecal hemoglobin), utilizing stool, algorithm reported as a positive or negative result
0465U	0465U	Oncology (urothelial carcinoma), DNA, quantitative methylationspecific PCR of 2 genes (ONECUT2, VIM), algorithmic analysis reported as positive or negative
0466U	0466U	Cardiology (coronary artery disease [CAD]), DNA, genomewide association studies (564856 single-nucleotide polymorphisms [SNPs], targeted variant genotyping), patient lifestyle and clinical data, buccal swab, algorithm reported as polygenic risk to acquired heart disease
0467U	0467U	Oncology (bladder), DNA, nextgeneration sequencing (NGS) of 60 genes and whole genome aneuploidy, urine, algorithms reported as minimal residual disease (MRD) status positive or negative and quantitative disease burden
0468U	0468U	Hepatology (nonalcoholic steatohepatitis [NASH]), miR-34a5p, alpha 2-macroglobulin, YKL40, HbA1c, serum and whole blood, algorithm reported as a single score for NASH activity and fibrosis
0469U	0469U	Rare diseases (constitutional/heritable disorders), whole genome sequence analysis for chromosomal abnormalities, copy number variants, duplications/deletions, inversions, unbalanced translocations, regions of homozygosity (ROH),inheritance pattern that indicate uniparental disomy (UPD), and aneuploidy, fetal sample (amniotic fluid, chorionic villus sample, or products of conception),identification and categorization of genetic variants, diagnostic report of fetal results based on phenotype with maternal sample and paternal sample, if performed, as comparators and/or maternal cell contamination

July 2024 HCPCS Code	CY 2025 HCPCS Code	CY 2025 Long Descriptor
0470U	0470U	Oncology (oropharyngeal), detection of minimal residual disease by next-generation sequencing (NGS) based quantitative evaluation of 8 DNA targets, cell-free HPV 16 and 18 DNA from plasma
0471U	0471U	Oncology (colorectal cancer), qualitative real-time PCR of 35 variants of KRAS and NRAS genes (exons 2, 3, 4), formalinfixed paraffin-embedded (FFPE), predictive, identification of detected mutations
0472U	0472U	Carbonic anhydrase VI (CA VI), parotid specific/secretory protein (PSP) and salivary protein (SP1) IgG, IgM, and IgA antibodies, enzyme-linked immunosorbent assay (ELISA), semiqualitative, blood, reported as predictive evidence of early Sjögren syndrome
0473U	0473U	Oncology (solid tumor), nextgeneration sequencing (NGS) of DNA from formalin-fixed paraffinembedded (FFPE) tissue with comparative sequence analysis from a matched normal specimen (blood or saliva), 648 genes, interrogation for sequence variants, insertion and deletion alterations, copy number variants, rearrangements, microsatellite instability, and tumor-mutation burden
0474U	0474U	Hereditary pan-cancer (e.g., hereditary sarcomas, hereditary endocrine tumors, hereditary neuroendocrine tumors, hereditary cutaneous melanoma), genomic sequence analysis panel of 88 genes with 20 duplications/deletions using nextgeneration sequencing (NGS), Sanger sequencing, blood or saliva, reported as positive or negative for germline variants, each gene
0475U	0475U	Hereditary prostate cancer-related disorders, genomic sequence analysis panel using next-generation sequencing (NGS), Sanger sequencing, multiplex ligation-dependent probe amplification (MLPA), and array comparative genomic hybridization (CGH), evaluation of 23 genes and duplications/deletions when indicated, pathologic mutations reported with a genetic risk score for prostate cancer

3. October 2024 HCPCS Codes Final Rule Comment Solicitation

For the October 2024 update, 107 codes were established and made effective October 1, 2024. Through the October 2024 OPPS quarterly update CR (Transmittal 12816, Change Request 13784, dated August 29, 2024), we recognized several new codes for separate payment and assigned them to appropriate interim OPPS status indicators and APCs. For CY 2025, consistent with our established policy, we proposed in the CY 2025 OPPS/ASC proposed rule (89 FR 59250) that the HCPCS codes that would be effective October 1, 2024, would be flagged with comment indicator ''NI'' in Addendum B to the CY 2025 OPPS/ASC final rule with comment period to indicate that we have assigned the codes to interim OPPS status indicators for CY 2025. Table 16 lists the codes that were effective October 1, 2024. We note that one of the temporary C-codes has been replaced with a permanent J-code effective January 1, 2025. We are inviting public comments in this final rule with comment period on the interim payment indicators, which will be finalized in the CY 2026 OPPS/ASC final rule with comment period. We note the proposed APC assignments and status indicators for these same codes will be subject to comment in the CY 2026 OPPS/ASC proposed rule with comment period, and will be finalized in the CY 2026 OPPS/ASC final rule with comment period.

TABLE 16: NEW HCPCS CODES EFFECTIVE OCTOBER 1, 2024

October 2024 HCPCS Code	CY 2025 HCPCS Code	CY 2025 Long Descriptor
90624	90624	Meningococcal pentavalent vaccine, Men B-4C recombinant proteins and outer membrane vesicle and conjugated Men A, C, W, Y-diphtheria toxoid carrier, for intramuscular use
90683	90683	Respiratory syncytial virus vaccine, mRNA lipid nanoparticles, for intramuscular use
90684	90684	Pneumococcal conjugate vaccine, 21 valent (PCV21), for intramuscular use
90695	90695	Influenza virus vaccine, H5N8, derived from cell cultures, adjuvanted, for intramuscular use
0020M	0020M	Oncology (central nervous system), analysis of 30000 DNA methylation loci by methylation array, utilizing DNA extracted from tumor tissue, diagnostic algorithm reported as probability of matching a reference tumor subclass
0476U	0476U	Drug metabolism, psychiatry (e.g., major depressive disorder, general anxiety disorder, attention deficit hyperactivity disorder [ADHD], schizophrenia), whole blood, buccal swab, pharmacogenomic genotyping of 14 genes and CYP2D6 copy number variant analysis, and reported phenotypes
0477U	0477U	Drug metabolism, psychiatry (e.g., major depressive disorder, general anxiety disorder, attention deficit hyperactivity disorder [ADHD], schizophrenia), whole blood, buccal swab, pharmacogenomic genotyping of 14 genes and CYP2D6 copy number variant analysis, including impacted gene-drug interactions and reported phenotypes
0478U	0478U	Oncology (non-small cell lung cancer), DNA and RNA, digital PCR analysis of 9 genes (EGFR, KRAS, BRAF, ALK, ROS1, RET,

October 2024 HCPCS Code	CY 2025 HCPCS Code	CY 2025 Long Descriptor
		NTRK 1/2/3, ERBB2, and MET) in formalin-fixed paraffin-embedded (FFPE) tissue, interrogation for single nucleotide variants, insertions/deletions, gene rearrangements, and reported as actionable detected variants for therapy selection
0479U	0479U	Tau, phosphorylated, pTau217
0480U	0480U	Infectious disease (bacteria, viruses, fungi, and parasites), cerebrospinal fluid (CSF), metagenomic next-generation sequencing (DNA and RNA), bioinformatic analysis, with positive pathogen identification
0481U	0481U	IDH1 (isocitrate dehydrogenase 1[NADP+]), IDH2 (isocitrate dehydrogenase 2 [NADP+]), and TERT (telomerase reverse transcriptase) promoter (e.g., central nervous system [CNS] tumors), next-generation sequencing (single-nucleotide variants [SNV], deletions, and insertions)
0482U	0482U	Obstetrics (preeclampsia), biochemical assay of soluble fms-like tyrosine kinase 1 (sFlT-1) and placental growth factor (PIGF), serum, ratio reported for sFlT-1/PIGF, with risk of progression for preeclampsia with severe features within 2 weeks
0483U	0483U	Infectious disease (Neisseria gonorrhoeae), sensitivity, ciprofloxacin resistance (gyrA S91F point mutation), oral, rectal, or vaginal swab, algorithm reported as probability of fluoroquinolone resistance
0484U	0484U	Infectious disease (Mycoplasma genitalium), macrolide sensitivity (23S rRNA point mutation), oral, rectal, or vaginal swab, algorithm reported as probability of macrolide resistance
0485U	0485U	Oncology (solid tumor), cell-free DNA and RNA by next-generation sequencing, interpretative report for germline mutations, clonal hematopoiesis of indeterminate potential, and tumor-derived single-nucleotide variants, small insertions/deletions, copy number alterations, fusions, microsatellite instability, and tumor mutational burden
0486U	0486U	Oncology (pan-solid tumor), next-generation sequencing analysis of tumor methylation markers present in cell-free circulating tumor DNA, algorithm reported as quantitative measurement of methylation as a correlate of tumor fraction
0487U	0487U	Oncology (solid tumor), cell-free circulating DNA, targeted genomic sequence analysis panel of 84 genes, interrogation for sequence variants, aneuploidy-corrected gene copy number amplifications and losses, gene rearrangements, and microsatellite instability
0488U	0488U	Obstetrics (fetal antigen noninvasive prenatal test), cell-free DNA sequence analysis for the detection of the fetal presence or absence of 1 or more of the Rh, C, c, D, E, Duffy (Fya), or Kell (K) antigen in alloimmunized pregnancies, reported as selected antigen(s) detected or not detected

October 2024 HCPCS Code	CY 2025 HCPCS Code	CY 2025 Long Descriptor
0489U	0489U	Obstetrics (single-gene noninvasive prenatal test), cell-free DNA sequence analysis of 1 or more targets (e.g., CFTR, SMN1, HBB, HBA1, HBA2) to identify paternally inherited pathogenic variants, and relative mutation-dosage analysis based on molecular counts to determine the fetal inheritance of the maternal mutation, algorithm reported as a fetal risk score for the condition (e.g., cystic fibrosis, spinal muscular atrophy, beta hemoglobinopathies [including sickle cell disease], alpha thalassemia)
0490U	0490U	Oncology (cutaneous or uveal melanoma), circulating tumor cell selection, morphological characterization and enumeration based on differential CD146, high molecular–weight melanoma-associated antigen, CD34 and CD45 protein biomarkers, peripheral blood
0491U	0491U	Oncology (solid tumor), circulating tumor cell selection, morphological characterization and enumeration based on differential epithelial cell adhesion molecule (EpCAM), cytokeratins 8, 18, and 19, CD45 protein biomarkers, and quantification of estrogen receptor (ER) protein biomarker–expressing cells, peripheral blood
0492U	0492U	Oncology (solid tumor), circulating tumor cell selection, morphological characterization and enumeration based on differential epithelial cell adhesion molecule (EpCAM), cytokeratins 8, 18, and 19, CD45 protein biomarkers, and quantification of PD-L1 protein biomarker–expressing cells, peripheral blood
0493U	0493U	Transplantation medicine, quantification of donor-derived cell-free DNA using next-generation sequencing, plasma, reported as percentage of donor-derived cell-free DNA (cfDNA)
0494U	0494U	Red blood cell antigen (fetal RhD gene analysis), next-generation sequencing of circulating cell-free DNA (cfDNA) of blood in pregnant individuals known to be RhD negative, reported as positive or negative
0495U	0495U	Oncology (prostate), analysis of circulating plasma proteins (tPSA, fPSA, KLK2, PSP94, and GDF15), germline polygenic risk score (60 variants), clinical information (age, family history of prostate cancer, prior negative prostate biopsy), algorithm reported as risk of likelihood of detecting clinically significant prostate cancer
0496U	0496U	Oncology (colorectal), cell-free DNA, 8 genes for mutations, 7 genes for methylation by real-time RT-PCR, and 4 proteins by enzyme-linked immunosorbent assay, blood, reported positive or negative for colorectal cancer or advanced adenoma risk
0497U	0497U	Oncology (prostate), mRNA gene-expression profiling by real-time RT-PCR of 6 genes (FOXM1, MCM3, MTUS1, TTC21B, ALAS1, and PPP2CA), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as a risk score for prostate cancer
0498U	0498U	Oncology (colorectal), next-generation sequencing for mutation detection in 43 genes and methylation pattern in 45 genes, blood,

October 2024 HCPCS Code	CY 2025 HCPCS Code	CY 2025 Long Descriptor
		and formalin-fixed paraffin-embedded (FFPE) tissue, report of variants and methylation pattern with interpretation
0499U	0499U	Oncology (colorectal and lung), DNA from formalin-fixed paraffin-embedded (FFPE) tissue, next-generation sequencing of 8 genes (NRAS, EGFR, CTNNB1, PIK3CA, APC, BRAF, KRAS, and TP53), mutation detection
0500U	0500U	Autoinflammatory disease (VEXAS syndrome), DNA, UBA1 gene mutations, targeted variant analysis (M41T, M41V, M41L, c.118-2A>C, c.118-1G>C, c.118-9_118-2del, S56F, S621C)
0501U	0501U	Oncology (colorectal), blood, quantitative measurement of cell-free DNA (cfDNA)
0502U	0502U	Human papillomavirus (HPV), E6/E7 markers for high-risk types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68), cervical cells, branched-chain capture hybridization, reported as negative or positive for high risk for HPV
0503U	0503U	Neurology (Alzheimer disease), beta amyloid (Aβ40, Aβ42, Aβ42/40 ratio) and tau-protein (p-tau217, np-tau217, p-tau217/np-tau217 ratio), blood, immunoprecipitation with quantitation by liquid chromatography with tandem mass spectrometry (LC-MS/MS), algorithm score reported as the likelihood of positive or negative for amyloid plaques
0504U	0504U	Infectious disease (urinary tract infection), identification of 17 pathologic organisms, urine, real-time PCR, reported as positive or negative for each organism
0505U	0505U	*Infectious disease* (vaginal infection), identification of 32 pathogenic organisms, swab, real-time PCR, reported as positive or negative for each organism
0506U	0506U	Gastroenterology (Barrett's esophagus), esophageal cells, DNA methylation analysis by next-generation sequencing of at least 89 differentially methylated genomic regions, algorithm reported as likelihood for Barrett's esophagus
0507U	0507U	Oncology (ovarian), DNA, whole-genome sequencing with 5-hydroxymethylcytosine (5hmC) enrichment, using whole blood or plasma, algorithm reported as cancer detected or not detected
0508U	0508U	Transplantation medicine, quantification of donor-derived cell-free DNA using 40 single-nucleotide polymorphism (SNPs), plasma, and urine, initial evaluation reported as percentage of donor-derived cell-free DNA with risk for active rejection
0509U	0509U	Transplantation medicine, quantification of donor-derived cell-free DNA using up to 12 single-nucleotide polymorphism (SNPs) previously identified, plasma, reported as percentage of donor-derived cell-free DNA with risk for active rejection
0510U	0510U	Oncology (pancreatic cancer), augmentative algorithmic analysis of 16 genes from previously sequenced RNA whole-transcriptome data, reported as probability of predicted molecular subtype

October 2024 HCPCS Code	CY 2025 HCPCS Code	CY 2025 Long Descriptor
0511U	0511U	Oncology (solid tumor), tumor cell culture in 3D microenvironment, 36 or more drug panel, reported as tumor-response prediction for each drug
0512U	0512U	Oncology (prostate), augmentative algorithmic analysis of digitized whole-slide imaging of histologic features for microsatellite instability (MSI) status, formalin-fixed paraffin-embedded (FFPE) tissue, reported as increased or decreased probability of MSI-High (MSI-H)
0513U	0513U	Oncology (prostate), augmentative algorithmic analysis of digitized whole-slide imaging of histologic features for microsatellite instability (MSI) and homologous recombination deficiency (HRD) status, formalin-fixed paraffin-embedded (FFPE) tissue, reported as increased or decreased probability of each biomarker
0514U	0514U	Gastroenterology (irritable bowel disease [IBD]), immunoassay for the quantitative determination of adalimumab (ADL) levels in venous serum in patients undergoing adalimumab therapy, results reported as a numerical value as micrograms per milliliter (µg/mL)
0515U	0515U	Gastroenterology (irritable bowel disease [IBD]), immunoassay for the quantitative determination of infliximab (IXL) levels in venous serum in patients undergoing infliximab therapy, results reported as a numerical value as micrograms per milliliter (µg/mL)
0516U	0516U	Drug metabolism, whole blood, pharmacogenomic genotyping of 40 genes and CYP2D6 copy number variant analysis, reported as metabolizer status
0517U	0517U	Therapeutic drug monitoring, 80 or more psychoactive drugs or substances, LC-MS/MS, plasma, qualitative and quantitative therapeutic minimally and maximally effective dose of prescribed and non-prescribed medications
0518U	0518U	Therapeutic drug monitoring, 90 or more pain and mental health drugs or substances, LC-MS/MS, plasma, qualitative and quantitative therapeutic minimally effective range of prescribed and non-prescribed medications
0519U	0519U	Therapeutic drug monitoring, medications specific to pain, depression, and anxiety, LC-MS/MS, plasma, 110 or more drugs or substances, qualitative and quantitative therapeutic minimally effective range of prescribed, non-prescribed, and illicit medications in circulation
0520U	0520U	Therapeutic drug monitoring, 200 or more drugs or substances, LC-MS/MS, plasma, qualitative and quantitative therapeutic minimally effective range of prescribed and non-prescribed medications
A2027	A2027	Matriderm, per square centimeter
A2028	A2028	Micromatrix flex, per mg
A2029	A2029	Mirotract wound matrix sheet, per cubic centimeter

October 2024 HCPCS Code	CY 2025 HCPCS Code	CY 2025 Long Descriptor
A4543	A4543	Supplies for transcutaneous electrical nerve stimulator, for nerves in the auricular region, per month
A4544	A4544	Electrode for external lower extremity nerve stimulator for restless legs syndrome
A4545	A4545	Supplies and accessories for external tibial nerve stimulator (e.g., socks, gel pads, electrodes, etc.), needed for one month
A7021	A7021	Supplies and accessories for lung expansion airway clearance, continuous high frequency oscillation, and nebulization device (e.g., handset, nebulizer kit, biofilter)
C9150	A9610	Xenon xe-129 hyperpolarized gas, diagnostic, per study dose
C8000	C8000	Support device, extravascular, for arteriovenous fistula (implantable)
C9169	C9169	Injection, nogapendekin alfa inbakicept-pmln, for intravesical use, 1 microgram
C9170	C9170	Injection, tarlatamab-dlle, 1 mg
C9171	C9171	Injection, pegulicianine, 1 mg
C9172	C9172	Injection, fidanacogene elaparvovec-dzkt, per therapeutic dose
E0469	E0469	Lung expansion airway clearance, continuous high frequency oscillation, and nebulization device
E0683	E0683	Non-pneumatic, non-sequential, peristaltic wave compression pump
E0715	E0715	Intravaginal device intended to strengthen pelvic floor muscles during kegel exercises
E0716	E0716	Supplies and accessories for intravaginal device intended to strengthen pelvic floor muscles during kegel exercises
E0721	E0721	Transcutaneous electrical nerve stimulatory, stimulates nerves in the auricular region
E0737	E0737	Transcutaneous tibial nerve stimulator, controlled by phone application
E0743	E0743	External lower extremity nerve stimulator for restless legs syndrome, each
E0767	E0767	Intrabuccal, systemic delivery of amplitude-modulated, radiofrequency electromagnetic field device, for cancer treatment, includes all accessories
E2513	E2513	Accessory for speech generating device, electromyographic sensor
E3200	E3200	Gait modulation system, rhythmic auditory stimulation, including restricted therapy software, all components and accessories, prescription only
J0138	J0138	Injection, acetaminophen 10 mg and ibuprofen 3 mg

October 2024 HCPCS Code	CY 2025 HCPCS Code	CY 2025 Long Descriptor
J0175	J0175	Injection, donanemab-azbt, 2 mg
J1171	J1171	Injection, hydromorphone, 0.1 mg
J1749	J1749	Injection, iloprost, 0.1 mcg
J2002	J2002	Injection, lidocaine hcl in 5% dextrose, 1 mg
J2003	J2003	Injection, lidocaine hydrochloride, 1 mg
J2004	J2004	Injection, lidocaine hcl with epinephrine, 1 mg
J2252	J2252	Injection, midazolam in 0.8% sodium chloride, intravenous, not therapeutically equivalent to J2250, 1 mg
J2253	J2253	Injection, midazolam (seizalam), 1 mg
J2601	J2601	Injection, vasopressin (baxter), 1 unit
J8522	J8522	Capecitabine, oral, 50 mg
J8541	J8541	Dexamethasone (hemady), oral, 0.25 mg
J9329	J9329	Injection, tislelizumab-jsgr, 1mg
L1006	L1006	Scoliosis orthosis, sagittal-coronal control provided by a rigid lateral frame, extends from axilla to trochanter, includes all accessory pads, straps and interface, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L1653	L1653	Hip orthosis, bilateral thigh cuffs with adjustable abductor spreader bar, adult size, prefabricated, off the shelf
L1821	L1821	Knee orthosis, elastic with condylar pads and joints, with or without patellar control, prefabricated, off the shelf
L8720	L8720	External lower extremity sensory prosthesis, cutaneous stimulation of mechanoreceptors proximal to the ankle, per leg
P9027	P9027	Red blood cells, leukocytes reduced, oxygen/ carbon dioxide reduced, each unit
Q0519	Q0519	Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription injectable drug, per 30-days
Q0520	Q0520	Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription injectable drug, per 60-days
Q4334	Q4334	Amnioplast 1, per square centimeter
Q4335	Q4335	Amnioplast 2, per square centimeter

October 2024 HCPCS Code	CY 2025 HCPCS Code	CY 2025 Long Descriptor
Q4336	Q4336	Artacent c, per square centimeter
Q4337	Q4337	Artacent trident, per square centimeter
Q4338	Q4338	Artacent velos, per square centimeter
Q4339	Q4339	Artacent vericlen, per square centimeter
Q4340	Q4340	Simpligraft, per square centimeter
Q4341	Q4341	Simplimax, per square centimeter
Q4342	Q4342	Theramend, per square centimeter
Q4343	Q4343	Dermacyte ac matrix amniotic membrane allograft, per square centimeter
Q4344	Q4344	Tri-membrane wrap, per square centimeter
Q4345	Q4345	Matrix hd allograft dermis, per square centimeter
Q5135	Q5135	Injection, tocilizumab-aazg (tyenne), biosimilar, 1 mg
Q5136	Q5136	Injection, denosumab-bbdz (jubbonti/wyost), biosimilar, 1 mg

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4. January 2025 HCPCS Codes

a. New Level II HCPCS Codes Final Rule Comment Solicitation

Consistent with past practice, we are soliciting comments on the new Level II HCPCS codes that will be effective January 1, 2025, in this CY 2025 OPPS/ASC final rule with comment period, thereby allowing us to finalize the status indicators and APC assignments for the codes in the CY 2026 OPPS/ASC final rule with comment period. Unlike the CPT codes that are effective January 1 and are included in the OPPS/ASC proposed rules, and except for the proposed new C-codes and G-codes listed in Addendum O of the CY 2025 OPPS/ASC proposed rule, most Level II HCPCS codes are not released until sometime around November to be effective January 1. Because these codes are not available until November, we are unable to include them in the OPPS/ASC proposed rules. Consequently, for CY 2025, we propose to include the new Level II HCPCS codes that will be effective January 1, 2025 (that would be incorporated in the January 2025 OPPS quarterly update CR), in Addendum B to the CY 2025 OPPS/ASC final rule with comment period. Specifically, for CY 2025, we propose to continue our established policy of assigning comment indicator ''NI'' in Addendum B to the OPPS/ASC final rule with comment period to the new HCPCS codes that will be effective January 1, 2025, to indicate that we are assigning them an interim status indicator, which is subject to public comment. We are inviting public comments in this final rule with comment period on the status indicators and APC assignments, which would then be finalized in the CY 2026 OPPS/ASC final rule with comment period. Similar to the codes effective October 1, 2024, the proposed APC assignments and status indicators for these new Level II HCPCS codes that will be effective January 1, 2025, will also be subject to comment in the CY 2026 OPPS/ASC proposed rule with comment period, and will be finalized in the CY 2026 OPPS/ASC final rule with comment period.

b. New CPT Codes Proposed Rule Comment Solicitation

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66841 through 66844), we finalized a revised process of assigning APCs and status indicators for new and revised Category I and III CPT codes that would be effective January 1. Specifically, for the new/revised CPT codes that we receive in a timely manner from the AMA's CPT Editorial Panel, we finalized our proposal to include the codes that would be effective January 1 in the OPPS/ASC proposed rules, along with proposed APC and status indicator assignments for them, and to finalize the APC and status indicator assignments in the OPPS/ASC final rules beginning with the CY 2016 OPPS update. For those new/revised CPT codes that were received too late for inclusion in the OPPS/ASC proposed rule, we finalized our proposal to establish and use

HCPCS G-codes that mirror the predecessor CPT codes and retain the current APC and status indicator assignments for a year until we can propose APC and status indicator assignments in the following year's rulemaking cycle. We note that even if we find that we need to create HCPCS G-codes in place of certain CPT codes for the PFS proposed rule, we do not anticipate that these HCPCS G-codes will always be necessary for OPPS purposes. We will make every effort to include proposed APC and status indicator assignments for all new and revised CPT codes that the AMA makes publicly available in time for us to include them in the proposed rule, and to avoid resorting to use of HCPCS G-codes and the resulting delay in utilization of the most current CPT codes. Also, we finalized our proposal to make interim APC and status indicator assignments for CPT codes that are not available in time for the proposed rule and that describe wholly new services (such as new technologies or new surgical procedures), to solicit public comments in the final rule, and to finalize the specific APC and status indicator assignments for those codes in the following year's final rule.

For the CY 2025 OPPS update, we received the CPT codes that will be effective January 1, 2025, from the AMA in time to be included in the CY 2025 OPPS/ASC proposed rule. The new, revised, and deleted CPT codes were included in Addendum B to the proposed rule (which is available via the internet on the CMS website). We note that the new and revised CPT codes were assigned to comment indicator ''NP'' in Addendum B of the proposed rule to indicate that the code is new for the next calendar year or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to the current calendar year with a proposed APC assignment, and that comments would be accepted on the proposed APC assignment and status indicator.

Further, we noted that the CPT code descriptors that appeared in Addendum B were short descriptors and did not accurately describe the complete procedure, service, or item described by the CPT code. Therefore, we included the 5-digit placeholder codes and the long descriptors for the new and revised CY 2025 CPT codes in Addendum O to the proposed rule (which is available via the internet on the CMS website) so that the public could adequately comment on the proposed APCs and SI assignments. The 5-digit placeholder codes were included in Addendum O to the proposed rule, specifically under the column labeled ''CY 2025 OPPS/ASC Proposed Rule 5- Digit AMA Placeholder Code''. We noted that the final CPT code numbers would be included in this CY 2025 OPPS/ASC final rule with comment period. We also noted that not every code listed in Addendum O is subject to public comment. For the new and revised Category I and III CPT codes, we requested public comments on only those codes that are assigned comment indicator ''NP.''

In summary, in the CY 2025 OPPS/ASC proposed rule, we solicited public comments on the proposed CY 2025 SI and APC assignments for the new and revised Category I and III CPT codes that would be effective January 1, 2025. The CPT codes were listed in Addendum B to the proposed rule with short descriptors only. We listed them again, with long descriptors, in Addendum O to the proposed rule. We also proposed to finalize the SI and APC assignments for these codes (with their final CPT code numbers) in the CY 2025 OPPS/ASC final rule with comment period. The proposed SI and APC assignments for these codes were included in Addendum B to the proposed rule (which is available via the internet on the CMS website). We received comments on several of the new CPT codes that were assigned to comment indicator ''NP'' in Addendum B to the CY 2025 OPPS/ASC proposed rule. We have responded to those public comments in sections III.C, III.E, and IV of this CY 2025 OPPS/ASC final rule with comment period.

The final SIs, APC assignments, and payment rates for the new CPT codes that are effective January 1, 2025, can be found in Addendum B to this final rule with comment period. In addition, the SI definitions can be found in Addendum D1 (OPPS Payment Status Indicators for CY 2024) to this final rule with comment period. Addenda B and D1 are available via the internet on the CMS website.

Finally, Table 17, which is a reprint of Table 12 from the CY 2025 OPPS/ASC proposed rule (89 FR 59251), shows the comment timeframe for new and revised HCPCS codes. The table provides information on our current process for updating codes through our OPPS quarterly update CRs, seeking public comments, and finalizing the treatment of these codes under the OPPS.

TABLE 17: COMMENT AND FINALIZATION TIMEFRAMES FOR NEW AND REVISED OPPS-RELATED HCPCS CODES

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 2024	HCPCS (CPT and Level II codes)	April 1, 2024	CY 2025 OPPS/ASC proposed rule	CY 2025 OPPS/ASC final rule with comment period
July 2024	HCPCS (CPT and Level II codes)	July 1, 2024	CY 2025 OPPS/ASC proposed rule	CY 2025 OPPS/ASC final rule with comment period
October 2024	HCPCS (CPT and Level II codes)	October 1, 2024	CY 2025 OPPS/ASC final rule with comment period	CY 2026 OPPS/ASC final rule with comment period
January 2025	CPT Codes	January 1, 2025	CY 2025 OPPS/ASC proposed rule	CY 2025 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2025	CY 2025 OPPS/ASC final rule with comment period	CY 2026 OPPS/ASC final rule with comment period

B. OPPS Changes—Variations Within APCs

1. Background

Section 1833(t)(2)(A) of the Act requires the Secretary to develop a classification system for covered hospital outpatient department services. In addition, section 1833(t)(2)(B) of the Act provides that the Secretary may establish groups of covered OPD services within this classification system, so that services classified within each group are comparable clinically and with respect to the use of resources. In accordance with these provisions, we developed a grouping classification system, referred to as Ambulatory Payment Classifications (APCs), as set forth in the regulation at 42 CFR 419.31. We use Level I (also known as CPT codes) and Level II HCPCS codes (also known as alphanumeric codes) to identify and group the services within each APC. The APCs are organized such that each group is homogeneous both clinically and in terms of resource use. Using this classification system, we have established distinct groups of similar services. We also have developed separate APC groups for certain medical devices, drugs, biologicals, therapeutic radiopharmaceuticals, and brachytherapy devices that are not packaged into the payment for the procedure.

We have packaged into the payment for each procedure or service within an APC group, the costs associated with those items and services that are typically ancillary and supportive to a primary diagnostic or therapeutic modality and, in those cases, are an integral part of the primary service they support. Therefore, we do not make separate payment for these packaged items or services. In general, packaged items and services include, but are not limited to, the items and services listed in the regulation at 42 CFR 419.2(b). A further discussion of packaged services is included in section II.A.3 of this final rule with comment period.

Under the OPPS, we generally pay for covered hospital outpatient services on a rate-per-service basis, where the service may be reported with one or more HCPCS codes. Payment varies according to the APC group to which the independent service or combination of services is assigned. For CY 2025, we proposed that each APC relative payment weight represents the hospital cost of the services included in that APC, relative to the hospital cost of the services included in APC 5012 (Clinic Visits and Related Services). The APC relative payment weights are scaled to APC 5012 because it is the hospital clinic visit APC and clinic visits are among the most frequently furnished services in the hospital outpatient setting.

2. Application of the 2 Times Rule

Section 1833(t)(9)(A) of the Act requires the Secretary to review, not less

often than annually, and revise the APC groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to consider changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. Section 1833(t)(9)(A) of the Act also requires the Secretary to consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the APC groups and the relative payment weights. We note that the Advisory Panel on Hospital Outpatient Payment (also known as the HOP Panel or the Panel) recommendations for specific services for the CY 2025 OPPS update will be discussed in the relevant specific sections throughout this CY 2025 OPPS/ASC final rule with comment period.

In addition, section 1833(t)(2) of the Act provides that, subject to certain exceptions, the items and services within an APC group cannot be considered comparable regarding the use of resources if the highest cost for an item or service in the group is more than 2 times greater than the lowest cost for an item or service within the same group (referred to as the ''2 times rule''). The statute authorizes the Secretary to make exceptions to the 2 times rule in unusual cases, such as for low-volume items and services (but the Secretary may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug, and Cosmetic Act). In determining the APCs with a 2 times rule violation, we consider only those HCPCS codes that are significant based on the number of claims. We note that, for purposes of identifying significant procedure codes for examination under the 2 times rule, we consider procedure codes that have more than 1,000 single major claims or procedure codes that both have more than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC cost to be significant (75 FR 71832). This longstanding definition of when a procedure code is significant for purposes of the 2 times rule was selected because we believe that a subset of 1,000 or fewer claims is negligible within the set of approximately 100 million single procedure or single session claims we use for establishing costs. Similarly, a procedure code for which there are fewer than 99 single claims and that comprises less than 2 percent of the single major claims within an APC will have a negligible impact on the APC cost (75 FR 71832). In the CY 2025 OPPS/ASC proposed rule, for CY 2025, we proposed to make exceptions to this limit on the variation of costs within each APC group in unusual cases, such as for certain low-volume items and services.

For the CY 2025 OPPS update, we identified the APCs with violations of the 2 times rule, and we proposed changes to the procedure codes assigned to these APCs (with the exception of those APCs for which we proposed a 2 times rule exception) in Addendum B to CY 2025 OPPS/ASC proposed rule. We note that Addendum B does not appear in the printed version of the **Federal Register** as part of this final rule with comment period. Rather, it is published and made available via the internet on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*.

To eliminate a violation of the 2 times rule and improve clinical and resource homogeneity in the APCs for which we did not propose a 2 times rule exception, we proposed to reassign these procedure codes to new APCs that contain services that are similar with regard to both their clinical and resource characteristics. In many cases, the proposed procedure code reassignments and associated APC reconfigurations for CY 2025 included in the CY 2025 OPPS/ASC proposed rule are related to changes in costs of services that were observed in the CY 2023 claims data available for CY 2025 ratesetting. Addendum B to the CY 2025 OPPS/ASC proposed rule identifies with a comment indicator ''CH'' those procedure codes for which we proposed a change to the APC assignment or status indicator, or both, that were initially assigned in the July 1, 2024, OPPS Addendum B Update, which is available via the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/addendum-a-b-updates*.

3. APC Exceptions to the 2 Times Rule

While considering the APC changes that we proposed for CY 2025, we reviewed all of the APCs for which we identified 2 times rule violations to determine whether any of the APCs would qualify for an exception. We used the following criteria to evaluate whether to propose exceptions to the 2 times rule for affected APCs:

- Resource homogeneity;
- Clinical homogeneity;
- Hospital outpatient setting utilization;
- Frequency of service (volume); and
- Opportunity for upcoding and code fragments.

For a detailed discussion of these criteria, we refer readers to the April 7, 2000 final rule (65 FR 18457 and 18458).

Based on the CY 2023 claims data available for the CY 2025 OPPS/ASC proposed rule, we found 23 APCs with violations of the 2 times rule. We applied the criteria as described above to identify the APCs for which we proposed to make exceptions under the 2 times rule for CY 2025 and found that all of the 23 APCs we identified met the criteria for an exception to the 2 times rule based on the CY 2023 claims data available for the CY 2025 OPPS/APC proposed rule. We note that, on an annual basis, based on our analysis of the latest claims data, we identify violations to the 2 times rule and propose changes when appropriate. Those APCs that violate the 2 times rule are identified and appear in Table 18. In addition, we did not include in that determination those APCs where a 2 times rule violation was not a relevant concept, such as APC 5401 (Dialysis), which only has two HCPCS codes assigned to it that have similar geometric mean costs and do not create a 2 times rule violation. Therefore, we have only identified those APCs, including those with criteria-based costs, such as device-dependent CPT/HCPCS codes, with violations of the 2 times rule, where a 2 times rule violation is a relevant concept.

Table 13 of the CY 2025 OPPS/ASC proposed rule (89 FR 59253) listed the 23 APCs for which we proposed to make an exception under the 2 times rule for CY 2025 based on the criteria cited above and claims data submitted between January 1, 2023, and December 31, 2023, and CCRs, if available. The proposed geometric mean costs for covered hospital outpatient services for these and all other APCs that were used in the development of the proposed rule can be found on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*.

Based on the updated final rule CY 2023 claims data used for this CY 2025 final rule with comment period, we found a total of 28 APCs with violations of the 2 times rule. Of these 28 total APCs, 23 were identified in the proposed rule and five are newly identified in this final rule with comment period. The following two APCs appeared in Table 13 of the CY 2025 OPPS/ASC proposed rule (89 FR

59253) as violating the 2 times rule, however, after conducting our data analysis for this final rule with comment period, we found that the APCs no longer violate the 2 times rule:

- APC 5303 (Level 3 Upper GI Procedures)
- APC 5822 (Health and Behavior Services)
- In addition, the following five APCs are newly identified with 2 times rule violations using updated data for this final rule with comment period: APC 5024 (Level 4 Type A ED Visits)
- APC 5501 (Level 1 Extraocular, Repair, and Plastic Eye Procedures)
- APC 5613 (Level 3 Therapeutic Radiation Treatment Preparation)
- APC 5674 (Level 4 Pathology)
- APC 5722 (Level 2 Diagnostic Tests and Related Services)

Although we did not receive any comments on Table 13 of the CY OPPS/ASC proposed rule, we did receive comments on APC assignments for specific HCPCS codes. The comments, and our responses, can be found in section III.E. of this final rule with comment period.

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TABLE 18: FINAL CY 2025 APC EXCEPTIONS TO THE 2 TIMES RULE

APC	APC Group Title
5012	Clinic Visits and Related Services
5024	Level 4 Type A ED Visits
5053	Level 3 Skin Procedures
5071	Level 1 Excision/Biopsy/Incision and Drainage
5501	Level 1 Extraocular, Repair, and Plastic Eye Procedures
5521	Level 1 Imaging without Contrast
5522	Level 2 Imaging without Contrast
5523	Level 3 Imaging without Contrast
5524	Level 4 Imaging without Contrast
5572	Level 2 Imaging with Contrast
5593	Level 3 Nuclear Medicine and Related Services
5611	Level 1 Therapeutic Radiation Treatment Preparation
5613	Level 3 Therapeutic Radiation Treatment Preparation
5627	Level 7 Radiation Therapy
5674	Level 4 Pathology
5691	Level 1 Drug Administration
5692	Level 2 Drug Administration
5721	Level 1 Diagnostic Tests and Related Services
5722	Level 2 Diagnostic Tests and Related Services
5731	Level 1 Minor Procedures
5733	Level 3 Minor Procedures
5734	Level 4 Minor Procedures
5741	Level 1 Electronic Analysis of Devices
5743	Level 3 Electronic Analysis of Devices
5791	Pulmonary Treatment
5811	Manipulation Therapy
5821	Level 1 Health and Behavior Services
5823	Level 3 Health and Behavior Services

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We did not receive any public comments on our proposal. Based on our analysis of the CY 2023 costs from hospital claims and cost report data available for this CY 2025 final rule with comment period, we are finalizing our proposals with some modifications. Specifically, we are finalizing our proposal to except the 23 proposed APCs that continue to have 2 times violations in the final rule data from the 2 times rule for CY 2023 claims data and also excepting five additional APCs (APCs 5024, 5501, 5613, 5674, 5722) that did not violate the 2 times rule in the proposed rule data, but do violate the 2 times rule in the final rule data, for a total of 28 APCs for which we identified 2 times rule violations but that qualify for exceptions.

In summary, Table 18 lists the 28 APCs that we are excepting from the 2 times rule for CY 2025 based on the criteria described earlier and a review of updated claims data for dates of service between January 1, 2023, and December 31, 2023, that were processed on or before June 30, 2024, and updated CCRs, if available. We note that, for cases in which a recommendation by the HOP Panel appears to result in or allow a violation of the 2 times rule, we generally accept the HOP Panel's recommendation because those recommendations are based on explicit consideration of resource use, clinical homogeneity, site of service, and the quality of the claims data used to determine the APC payment rates. The geometric mean costs for hospital outpatient services for these and all other APCs that were used in the development of this final rule with comment period can be found on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*.

C. New Technology APCs

1. Background

In the CY 2002 OPPS final rule (66 FR 59903), we finalized changes to the time period in which a service can be eligible for payment under a New Technology APC. Beginning in CY 2002, we retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to an appropriate clinical APC. This policy allows us to move a service from a New Technology APC in less than 2 years if sufficient data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient data upon which to base a decision for reassignment have not been collected.

We also adopted in the CY 2002 OPPS final rule the following criteria for assigning a complete or comprehensive service to a New Technology APC: (1) the service must be truly new, meaning it cannot be appropriately reported by an existing HCPCS code assigned to a clinical APC and does not appropriately fit within an existing clinical APC; (2) the service is not eligible for transitional pass-through payment (however, a truly new, comprehensive service could qualify for assignment to a new technology APC even if it involves a device or drug that could, on its own, qualify for pass-through payment); and (3) the service falls within the scope of Medicare benefits under section 1832(a) of the Act and is reasonable and necessary in accordance with section 1862(a)(1)(A) of the Act (66 FR 59898 through 59903). For additional information about our New Technology APC policy, we refer readers to *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/pass-through-payment-status-new-technology-ambulatory-payment-classification-apc* on the CMS website and then follow the instructions to access the MEARIS™ system for OPPS New Technology APC applications.[17]

In the CY 2004 OPPS final rule with comment period (68 FR 63416), we restructured the New Technology APCs to make the cost intervals more consistent across payment levels and refined the cost bands for these APCs to retain two parallel sets of New Technology APCs: one set with a status indicator of ''S'' (Significant Procedures, Not Discounted when Multiple. Paid under OPPS; separate APC payment) and the other set with a status indicator of ''T'' (Significant Procedure, Multiple Reduction Applies. Paid under OPPS; separate APC payment). These current New Technology APC configurations allow us to price new technology services more appropriately and consistently.

For CY 2024, there were 52 New Technology APC levels, ranging from the lowest cost band assigned to APC 1491 (New Technology—Level 1A ($0–$10)) to the highest cost band assigned to APC 1908 (New Technology—Level 52 ($145,001–$160,000)). We note that the cost bands for the New Technology APCs, specifically, APCs 1491 through 1599 and 1901 through 1908, vary with increments ranging from $10 to $14,999. These cost bands identify the APCs to which new technology procedures and services with estimated service costs that fall within those cost bands are assigned under the OPPS. Payment for each APC is made at the mid-point of the APC's assigned cost band. For example, payment for New Technology APC 1507 (New Technology—Level 7 ($501–$600)) is made at $550.50.

Under the OPPS, one of our goals is to make payments that are appropriate for the services that are necessary for the treatment of Medicare beneficiaries. The OPPS, like other Medicare payment systems, is budget neutral and increases are limited to the annual hospital market basket increase reduced by the productivity adjustment. We believe that our payment rates reflect the costs that are associated with providing care to Medicare beneficiaries and are adequate to ensure access to services (80 FR 70374). For many emerging technologies, there is a transitional period during which utilization may be low, often because providers are first learning about the technologies and their clinical utility. Quite often, parties request that Medicare make higher payments under the New Technology APCs for new procedures in that transitional phase. These requests, and their accompanying estimates for expected total patient utilization, often reflect very low rates of patient use of expensive equipment, resulting in high per-use costs for which requesters believe Medicare should make full payment. Medicare does not, and we believe should not, assume responsibility for more than its share of the costs of procedures based on projected utilization for Medicare beneficiaries and does not set its payment rates based on initial projections of low utilization for services that require expensive capital equipment. For the OPPS, we rely on hospitals to make informed business decisions regarding the acquisition of high-cost capital equipment, taking into consideration their knowledge about their entire patient base (Medicare beneficiaries included) and an understanding of Medicare's and other payers' payment policies. We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68314) for further discussion regarding this payment policy.

Some services assigned to New Technology APCs have low annual volume, which we consider to be fewer than 100 claims in the year of claims data used for ratesetting (86 FR 63528). Where utilization of services assigned to a New Technology APC is low, it can lead to wide variation in payment rates from year to year, resulting in even lower utilization and potential barriers to access to new technologies, which

[17] Currently approved under OMB control number 0938–0860; expires 07/31/2024.

ultimately limits our ability to assign the service to the appropriate clinical APC. To mitigate these issues, we finalized a policy in the CY 2019 OPPS/ASC final rule with comment period to utilize our equitable adjustment authority at section 1833(t)(2)(E) of the Act to adjust how we determine the costs for low-volume services assigned to New Technology APCs (83 FR 58892 through 58893). Specifically, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58893), we established that, in each of our annual rulemakings, we would calculate and present the result of each statistical methodology (arithmetic mean, geometric mean, and median) based on up to 4 years of claims data and solicit public comment on which methodology should be used to establish the payment rate for the low-volume new technology service. In the CY 2022 OPPS/ASC final rule (86 FR 63529), we replaced the New Technology APC low volume policy with the universal low volume APC policy. Unlike the New Technology APC low volume policy, the universal low volume APC policy applies to clinical APCs and brachytherapy APCs, in addition to procedures assigned to New Technology APCs, and uses the highest of the geometric mean, arithmetic mean, or median based on up to 4 years of claims data to set the payment rate for the APC. We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63529) for further discussion regarding this policy.

Finally, we note that, in a budget-neutral system, payments may not fully cover hospitals' costs in a particular circumstance, including those for the purchase and maintenance of capital equipment. We rely on hospitals to make their decisions regarding the acquisition of high-cost equipment with the understanding that the Medicare program must be careful to establish its initial payment rates, including those made through New Technology APCs, for new services that lack hospital claims data based on realistic utilization projections for all such services delivered in cost-efficient hospital outpatient settings. As the OPPS acquires claims data regarding hospital costs associated with new procedures, we regularly examine the claims data and any available new information regarding the clinical aspects of new procedures to confirm that our OPPS payments remain appropriate for procedures as they transition into mainstream medical practice (77 FR 68314). For CY 2025, we included the proposed payment rates for New Technology APCs 1491 to 1599 and 1901 through 1908 in Addendum A to the proposed rule (which is available on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*).

Comment: We received a comment requesting that CMS revise the New Technology APC criteria to accommodate for forms of algorithm-based healthcare services (ABHS). The commenter explained that certain ABHS, that provide new clinical outputs that can impact the diagnosis or treatment of a patient's disease, and represent additional costs to hospitals not currently accounted for in the provision of an underlying service, would most likely not meet the New Technology APC criteria because the service provided by the technology is occurring at the same time as the performance of an underlying service. The commenter also requested that the New Technology APC process allow for the creation of new procedural C-codes when needed.

Response: We thank the commenter for their comment. As part of the existing New Technology APC process, CMS creates C-codes when we find that there is no existing code that can appropriately describe a service. CMS will assign a service to a New Technology APC when certain criteria are met, including the criterion that the service is truly new, meaning that it cannot be appropriately reported by an existing HCPCS code assigned to a clinical APC and does not appropriately fit within an existing clinical APC. In the past, we have found that several SaaS procedures, including those that are algorithm-based, meet the existing New Technology APC criteria. For CY 2025, we proposed to assign several SaaS procedures that meet our criteria to New Technology APCs, many of which have been assigned to New Technology APCs for several years. However, we recognize that software-based technologies are rapidly evolving and, therefore, we are considering for future rulemaking whether specific adjustments to payment policies, including our New Technology APC policies, are needed to more accurately and appropriately pay for these products and services across settings of care.

For CY 2025, we did not propose to make any changes to the existing New Technology APC criteria. After consideration of the public comments we received, we are not finalizing any changes to the New Technology APC criterion at this time.

2. Policy To Exempt Services With Very Low Claims Volume From APC Reassignment Based on the Universal Low Volume Policy

We continue to be concerned about payment stability for services assigned to New Technology APCs, specifically services with very low claims volume of fewer than 10 claims in the 4-year lookback period used under the universal low volume APC policy. Historically, we have used our equitable adjustment authority at section 1833(t)(2)(E) of the Act to exempt a number of services with very low claims volume from the universal low volume APC policy in instances where application of the universal low volume policy would lead to significant fluctuations in payment. Given the frequency with which we have needed to utilize our equitable adjustment authority to address significant fluctuations in payment for very low volume services, we noted in the proposed rule that we believed that refinements to our universal low volume policy for services assigned to New Technology APCs may be necessary. We also recognized that determining initial cost estimates for these services may be particularly challenging, given the lack of cost information for new and innovative technologies.

To allow time for us to consider these issues, we proposed for CY 2025 to exempt services assigned to New Technology APCs with fewer than 10 claims over the 4-year lookback period used for the universal low volume policy. Instead of assigning these services to a different New Technology APC based on the very few claims available, we proposed that we would maintain the New Technology APC assignment for each service from the prior year, which in this case would be the New Technology APC assignment for CY 2024. We explained that we believed it was appropriate to apply this policy to New Technology APCs because services assigned to New Technology APCs represent new technologies for which it may be more challenging to determine an appropriate cost than for other, more established services. We believed 10 claims was an appropriate ceiling for exempting services from reassignment based on the universal low volume policy because we believed that at 10 claims a rough standard distribution begins to appear. We also believed that services with so few claims over the 4-year lookback period would be especially vulnerable to large changes in payment rates year-to-year as a result of one or two new

claims being available or one or two claims from what was previously the fourth year of the lookback period no longer being included in that period.

Consistent with our overall policy regarding use of updated claims data in the final rule, we proposed to perform a similar analysis for the final rule using updated claims data, including determining whether specific HCPCS codes continue to meet the criteria for our universal low volume APC policy or our proposal to exempt services with fewer than 10 claims in the 4-year lookback period from the universal low volume APC policy and maintain their CY 2024 New Technology APC assignment. We noted we would update the APC placement as needed in the final rule.

Comment: Commenters agreed with our concerns that the application of the universal low volume APC policy may result in payment instability for certain services assigned to New Technology APCs, but offered different perspectives on how to address the issue. One commenter, representing artificial intelligence companies, supported our proposal to exempt certain services from the universal low volume APC policy and recommended that we utilize 25 claims, rather than 10 claims when determining whether to maintain a service's New Technology APC assignment from the previous year. Another commenter, representing manufacturers of medical imaging equipment, did not believe that the proposal sufficiently addressed the policy concern of payment stability for services assigned to New Technology APCs. This commenter also believed that the proposal would create a disincentive for hospitals to furnish the service and, therefore, discourage claims utilization where it would be more prudent to have no claims than to risk being assigned to a lower paying New Technology APC in future years by exceeding the 10-claim threshold.

Response: We agree with the commenters' concerns that applying the universal low volume APC policy can result in payment fluctuations from year-to-year. We also recognize that major payment fluctuations that do not reflect the actual cost of the service can have the effect of discouraging usage and keeping claims volume low, which prevents CMS from gathering sufficient claims data upon which to transition the service from a New Technology APC to an appropriate clinical APC. We disagree with one commenter's assertion that our proposal to maintain the New Technology APC placement of a service with extremely low claims volume would disincentivize usage of the service. By maintaining the APC placement for services with fewer than 10 claims in the four-year lookback period, we are removing the potential for a major payment change based on a handful of claims over multiple years, that may not reflect the actual cost of the service. We believe that this policy is an incremental step towards more stable and predictable payments while providers learn about these new technology services, which should have the effect of encouraging utilization in the long-term. We also disagree with the commenter's suggestion to increase the claims threshold from 10 to 25 claims. We proposed to exempt less than 10 claims from the universal low volume APC policy because at 10 claims a rough standard distribution begins to appear, and services with an extremely low number of claims are most vulnerable to significant payment fluctuations.

Our proposal is meant to serve as a first step to addressing the issue of payment stability for services assigned to New Technology APCs. As we stated in the proposed rule, we continue to believe that refinements to the universal low volume APC policy with respect to its application to services in New Technology APCs may be necessary. We are finalizing our policy as proposed for CY 2025 and will consider additional changes in future years.

Comment: One commenter expressed support for the universal low volume APC policy.

Response: We thank the commenter for their input.

After consideration of the public comments we received, we are finalizing our proposal to exempt services assigned to New Technology APCs with fewer than 10 claims in the four-year lookback period from the universal low volume APC policy and maintain their CY 2024 New Technology APC assignment as proposed.

3. Procedures Assigned to New Technology APCs for CY 2025

As we described in the CY 2002 OPPS final rule (66 FR 59902), we generally retain a procedure in the New Technology APC to which it is initially assigned until we have obtained sufficient claims data to justify reassignment of the procedure to a clinically appropriate APC. In addition, in cases where we find that our initial New Technology APC assignment was based on inaccurate or inadequate information (although it was the best information available at the time), where we obtain new information that was not available at the time of our initial New Technology APC assignment, or where the New Technology APCs are restructured, we may, based on more recent resource utilization information (including claims data) or the availability of refined New Technology APC cost bands, reassign the procedure or service to a different New Technology APC that more appropriately reflects its cost (66 FR 59903).

Consistent with our current policy, for CY 2025, we proposed to retain services within New Technology APC groups until we obtain sufficient claims data to justify reassignment of the service to an appropriate clinical APC. The flexibility associated with this policy allows us to reassign a service from a New Technology APC in less than 2 years if we have obtained sufficient claims data. It also allows us to retain a service in a New Technology APC for more than 2 years if we have not obtained sufficient claims data upon which to base a reassignment decision (66 FR 59902).

a. Administration of Subretinal Therapies Requiring Vitrectomy (APC 1563)

Effective January 1, 2021, CMS established HCPCS code C9770 (Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent) and assigned it to a New Technology APC based on the geometric mean cost of CPT code 67036 (Vitrectomy, mechanical, pars plana approach) due to similar resource utilization. For CY 2021, HCPCS code C9770 was assigned to APC 1561 (New Technology—Level 24 ($3001–$3500)). This code may be used to describe the administration of HCPCS code J3398 (Injection, voretigene neparvovec-rzyl, 1 billion vector genomes). This procedure was previously discussed in depth in the CY 2021 OPPS/ASC final rule with comment period (85 FR 85939 through 85940). For CY 2022, we maintained the APC assignment of APC 1561 (New Technology—Level 24 ($3001–$3500)) for HCPCS code C9770 (86 FR 63531 through 63532).

HCPCS code J3398 (Injection, voretigene neparvovec-rzyl, 1 billion vector genomes) is for a gene therapy product indicated for a rare mutation-associated retinal dystrophy. Voretigene neparvovec-rzyl (Luxturna®) was approved by FDA in December of 2017 and is an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy.[18] This therapy is administered through a subretinal injection, which interested parties describe as an extremely delicate and sensitive surgical procedure. The FDA-approved package insert describes one of the steps for administering Luxturna as, ''after completing a vitrectomy, identify the intended site of administration. The subretinal injection can be introduced via pars plana.''

Interested parties, including the manufacturer of Luxturna®, recommended CPT code 67036 (Vitrectomy, mechanical, pars plana approach) for the administration of the gene therapy.[19] However, the manufacturer previously contended the administration was not accurately described by any existing codes as CPT code 67036 (Vitrectomy, mechanical, pars plana approach) does not account for the administration itself.

CMS recognized the need to accurately describe the unique procedure that is required to administer the therapy described by HCPCS code J3398. Therefore, in the CY 2021 OPPS/ASC proposed rule (85 FR 48832), we proposed to establish a new HCPCS code, C97X1 (Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent) to describe this process. We stated that we believed this new HCPCS code accurately described the unique service associated with intraocular administration of HCPCS code J3398. We recognized that CPT code 67036 represents a clinically similar procedure and process that approximates similar resource utilization to C97X1. However, we also recognized that it is not prudent for the code that describes the administration of this unique gene therapy, C97X1, to be assigned to the same C–APC to which CPT code 67036 is assigned, as this would package the primary therapy, HCPCS code J3398, into the code that represents the process to administer the gene therapy.

Therefore, for CY 2021, we proposed to assign the services described by C97X1 to a New Technology APC with a cost band that contains the geometric mean cost for CPT code 67036. The placeholder code C97X1 was replaced by HCPCS code C9770. For CY 2021, we finalized our proposal to create HCPCS code C9770 (Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent), and we assigned this code to APC 1561 (New Technology—Level 24 ($3001–$3500)) using the geometric mean cost of CPT code 67036. For CY 2022, we continued to assign HCPCS code C9770 to APC 1561 (New Technology—Level 24 ($3001–$3500)) using the geometric mean cost of CPT code 67036.

CY 2023 was the first year that claims data were available for HCPCS code C9770; therefore, we proposed and finalized a policy to base the payment rate of HCPCS code C9770 on claims data for that code rather than on the geometric mean cost of CPT code 67036. Given the low number of claims for this procedure, we designated HCPCS code C9770 as a low volume procedure under our universal low volume APC policy and used the greater of the geometric mean, arithmetic mean, or median cost calculated based on the available claims data to calculate an appropriate payment rate for purposes of assigning HCPCS code C9770 to a New Technology APC.

Based on the claims data available for the CY 2023 OPPS/ASC final rule with comment period, we found the median was the statistical methodology that estimated the highest cost for the service. The payment rate calculated using this methodology fell within the cost band for New Technology APC 1562 (New Technology—Level 25 ($3501–$4000)). Therefore, we finalized our proposal to assign HCPCS code C9770 to APC 1562 for CY 2023.

For CY 2024, we proposed and finalized that we would delete HCPCS code C9770 effective December 31, 2023, and recognize CPT code 0810T (Subretinal injection of a pharmacologic agent, including vitrectomy and 1 or more retinotomies) starting January 1, 2024 (88 FR 81617 through 81619). We determined the payment rate for CPT code 0810T using the claims data for HCPCS code C9770 and designated CPT code 0810T as a low volume procedure under our universal low volume APC policy and used the greater of the geometric mean, arithmetic mean, or median cost calculated based on the available claims data for HCPCS code C9770 to calculate an appropriate payment rate for purposes of assigning CPT code 0810T to a New Technology APC. For CY 2024, we finalized assignment of CPT code 0810T to APC 1563 (New Technology—Level 26 ($4001–$4500)) (88 FR 81617 through 81619).

Since CMS recognized CPT code 0810T starting January 1, 2024, we do not have claims data for CPT code 0810T available for CY 2025 rulemaking. However, as HCPCS code C9770 was still in use until December 31, 2023, we proposed to determine the payment rate for CPT code 0810T using the claims data for HCPCS code C9770. This is similar to the policy we finalized for CY 2024. For CY 2025, we proposed to designate CPT code 0810T as a low volume procedure under our universal low volume APC policy, given that there were only 34 claims available for HCPCS code C9770 and none for CPT code 0810T. This is below the threshold of 100 claims for a service within a year required to designate a service as a low volume service and apply our universal low volume APC policy. Therefore, we proposed to use the greater of the geometric mean, arithmetic mean, or median cost calculated based on the available claims data for HCPCS code C9770 to calculate an appropriate payment rate for purposes of assigning CPT code 0810T to a New Technology APC.

Using all available claims from the 4-year lookback period, which was 34 claims, we determined the geometric mean cost to be $3,934, the arithmetic mean cost to be $4,173, and the median cost to be $4,103. Because the arithmetic mean is the statistical methodology that estimated the highest cost for the service, we proposed to use this cost to determine the New Technology APC placement. The arithmetic mean of $4,173 falls within the cost band for New Technology APC 1563 (New Technology—Level 26 ($4001–$4500)). Therefore, we proposed to assign CPT code 0810T to APC 1563 for CY 2025. Additionally, we proposed to perform a similar analysis using updated claims data in this final rule with comment period, including determining if CPT code 0810T continues to meet the criteria for our universal low volume APC policy, and update the APC assignment as needed.

Please refer to Table 19 below for the final CY 2024 and proposed CY 2025 OPPS New Technology APC and status indicator assignments for CPT code 0810T. The proposed CY 2025 payment rates can be found in Addendum B to the CY 2025 OPPS/ASC proposed rule via the internet on the CMS website.

[18] Luxturna. FDA Package Insert. Available: *https://www.fda.gov/media/109906/download.*

[19] LUXTURNA REIMBURSEMENT GUIDE FOR TREATMENT CENTERS. *https://mysparkgeneration.com/uploads/2022/09/LUXTURNA-Reimbursement-Guide-for-Treatment-Centers-ISI-Update-April-2022-P-RPE65-US-320025.pdf.*

TABLE 19: FINAL CY 2024 AND PROPOSED CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODE 0810T

HCPCS Code	Long Descriptor	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
0810T	Subretinal injection of a pharmacologic agent, including vitrectomy and 1 or more retinotomies	T	1563	T	1563

We did not receive any public comments on our proposal to continue to assign HCPCS code 0810T to APC 1563 for CY 2025.

Additional claims for CY 2023 have been processed since the proposed rule. Our analysis of the updated claims data found that the greater of the geometric mean, arithmetic mean, or median cost calculated for HCPCS code C9770 is approximately $4,240. This continues to fall into the cost band of New Technology APC 1563. Therefore, we are finalizing our proposal without modification to continue to assign HCPCS code 0810T to APC 1563. Please refer to Table 20 for the final OPPS New Technology APC and status indicator assignment for HCPCS codes 0810T for CY 2025. The final CY 2025 payment rates can be found in Addendum B to this final rule with comment period via the internet on the CMS website. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

TABLE 20: FINAL CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODE 0810T

HCPCS Code	Long Descriptor	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
0810T	Subretinal injection of a pharmacologic agent, including vitrectomy and 1 or more retinotomies	T	1563

b. BgRT (APCs 1521 and 1525)

Biology Guided Radiation Therapy (BgRT) uses positron-emitting radiopharmaceuticals to control delivery of radiation therapy to treat primary and metastatic lung or bone tumors. During radiation treatment delivery, the same system applies these firing filters to the real-time positron emission tomography (PET) data collected by the radiation treatment delivery machine. Effective January 1, 2024, CMS created HCPCS codes C9794 (Therapeutic radiology simulation-aided field setting; complex, including acquisition of PET and CT imaging data required for radiopharmaceutical-directed radiation therapy treatment planning (*i.e.,* modeling) and C9795 (Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance and real-time positron emissions-based delivery adjustments to 1 or more lesions, entire course not to exceed 5 fractions) to describe the modeling and treatment delivery portions of the BgRT service. We assigned HCPCS code C9794 to APC 1521 (New Technology—Level 21 ($1901–$2000)) and HCPCS code C9795 to APC 1525 (New Technology—Level 25 ($3501–$4000)) for CY 2024.

For CY 2025, the OPPS payment rates were proposed based on available CY 2023 claims data. As HCPCS codes C9794 and C9795 were effective January 1, 2024, we do not have any claims data for the service. Therefore, for CY 2025, we proposed to continue to assign HCPCS code C9794 to APC 1521 (New Technology—Level 21 ($1901–$2000)) with a payment rate of $1,950.50 and HCPCS code C9795 to APC 1525 (New Technology—Level 25 ($3501–$4000)) with a payment rate of $3,750.50. Please refer to Table 21 below for the proposed

OPPS New Technology APC and status indicator assignment for HCPCS codes C9794 and C9795 for CY 2025. The proposed CY 2025 payment rates can be found in Addendum B to the CY 2025 OPPS/ASC proposed rule via the internet on the CMS website. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

TABLE 21: PROPOSED CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR BIOLOGY GUIDED RADIATION THERAPY

HCPCS	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
C9794	Therapeutic radiology simulation-aided field setting; complex, including acquisition of PET and CT imaging data required for radiopharmaceutical-directed radiation therapy treatment planning (i.e., modeling)	S	1521
C9795	Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance and real-time positron emissions-based delivery adjustments to 1 or more lesions, entire course not to exceed 5 fractions	S	1525

Comment: We received several comments supporting our proposal to maintain the APC assignments for HCPCS code C9794 and C9795 until claims data are received.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing our proposal without modification. Specifically, for CY 2025 we are finalizing our proposal to assign C9794 and C9795 to APCs 1521 (New Technology—Level 21 ($1901–$2000)) and 1525 (New Technology—Level 25 ($3501–$4000)), respectively.

We note that, effective January 1, 2025, two new G-codes are replacing HCPCS codes C9794 and C9795. Specifically, effective January 1, 2025, HCPCS codes C9794 and C9795 are being deleted and replaced by G0562 and G0563, respectively, to allow for payment in settings other than hospital outpatient departments for CY 2025. The descriptors for the new G-codes are the same as existing HCPCS codes C9794 and C9795.

Please refer to Table 22 for the final OPPS New Technology APC and status indicator assignments for HCPCS codes G0562 and G0563 for CY 2025. The CY 2025 payment rates can be found in Addendum B to this final rule with comment period via the internet on the CMS website. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

TABLE 22: FINAL CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR BIOLOGY GUIDED RADIATION THERAPY

HCPCS	Long Descriptor	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
G0562	Therapeutic radiology simulation-aided field setting; complex, including acquisition of PET and CT imaging data required for radiopharmaceutical-directed radiation therapy treatment planning (i.e., modeling)	S	1521
G0563	Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance and real-time positron emissions-based delivery adjustments to 1 or more lesions, entire course not to exceed 5 fractions	S	1525

c. Blinded Procedure for NYHA Class III/IV Heart Failure (APC 1590)

A randomized, double-blinded, controlled IDE study is currently in progress for the V-Wave interatrial shunt. The V-Wave interatrial shunt is for patients with severe symptomatic heart failure and is designed to regulate left atrial pressure in the heart. All participants who passed initial screening for the study receive a right heart catheterization procedure described by CPT code 93451 (Right heart catheterization including measurement(s) of oxygen saturation and cardiac output, when performed). Participants assigned to the experimental group also receive the V-Wave interatrial shunt procedure while participants assigned to the control group only receive right heart catheterization. The developer of V-Wave was concerned that the current coding of these services by Medicare would reveal to the study participants whether they had received the interatrial shunt because an additional procedure code, CPT code 93799 (Unlisted cardiovascular service or procedure), would be included on the claims for participants receiving the interatrial shunt. Therefore, for CY 2020, we created a temporary HCPCS code to describe the V-Wave interatrial shunt procedure for both the experimental group and the control group in the study. Specifically, we established HCPCS code C9758 (Blinded procedure for NYHA class III/IV heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, trans-esophageal echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved investigational device exemption (IDE) study) to describe the service, and we assigned the service to New Technology APC 1589 (New Technology—Level 38 ($10,001–$15,000)) with a payment rate of $12,500.50.

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 85946), we stated that we believe similar resources and device costs are involved with the V-Wave interatrial shunt procedure and the Corvia Medical interatrial shunt procedure (HCPCS code C9760), except that payment for HCPCS codes C9758 and C9760 differs based on how often the interatrial shunt is implanted when each code is billed. An interatrial shunt is implanted one-half of the time HCPCS code C9758 is billed, whereas an interatrial shunt is implanted every time HCPCS code C9760 is billed. Accordingly, for CY 2021, we reassigned HCPCS code C9758 to New Technology APC 1590 (New Technology—Level 39 ($15,001–$20,000)), which reflects the cost of furnishing the interatrial shunt one-half of the time the procedure is performed.

For CY 2022, we used the same claims data from CY 2019 that we did for the CY 2021 OPPS/ASC final rule with comment period. Because there were no claims reporting HCPCS code C9758, we continued to assign HCPCS code C9758 to New Technology APC 1590 with a payment rate of $17,500.50 for CY 2022. For CY 2023 we used claims data from CY 2019 through CY 2022. Because there were no claims reporting HCPCS code C9758 in CY 2023 or CY 2024, we continued to assign HCPCS code C9758 to New Technology APC 1590 with a payment rate of $17,500.50 for CY 2023 and 2024.

For CY 2025, the OPPS payment rates were proposed based on available CY 2023 claims data. There were only three claims for HCPCS code C9758 within this time period. As this is below the threshold of 100 claims for a service within a year, we would designate C9758 as a low volume service and apply our universal low volume APC policy. Under this policy, we would use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign HCPCS code C9758 to the appropriate New Technology APC. Given our proposal, which we are finalizing, to maintain current New Technology APC assignments for CY 2025 for New Technology APC services with fewer than 10 claims in the 4-year lookback period applicable for the universal low volume APC policy, we proposed to continue assigning HCPCS code C9758 to New Technology APC 1590 with a proposed payment rate of $17,500.50.

Please refer to Table 23 for the proposed OPPS New Technology APC and status indicator assignments for HCPCS code C9758 for CY 2025.

TABLE 23: PROPOSED CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR BLINDED INTRATRIAL SHUNT PROCEDURE

HCPCS	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
C9758	Blinded procedure for NYHA class III/IV heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, trans-esophageal echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved investigational device exemption (IDE) study	T	1590

Comment: We received one comment supporting our proposal to continue to assign HCPCS code C9758 to New Technology APC 1590.

Response: We thank the commenter for their support. Our updated claims data for the 4-year lookback period for the universal low volume APC policy continues to show only 3 claims for HCPCS code C9758. Therefore, we are finalizing our proposal without modification to continue assigning HCPCS code C9758 to New Technology APC 1590. Please refer to Table 24 for the final OPPS New Technology APC and status indicator assignment for HCPCS code C9758 for CY 2025. The final CY 2025 payment rates can be found in Addendum B to this final rule with comment period via the internet on the CMS website. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

TABLE 24: FINAL CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR BLINDED INTRATRIAL SHUNT PROCEDURE

HCPCS	Long Descriptor	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
C9758	Blinded procedure for NYHA class III/IV heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, trans-esophageal echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved investigational device exemption (IDE) study	T	1590

d. Bronchoscopy With Transbronchial Ablation of Lesion(s) by Microwave Energy (APC 1562)

Effective January 1, 2019, CMS established HCPCS code C9751 (Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3-D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (*e.g.,* aspiration[s]/biopsy[ies]) and all mediastinal and/or hilar lymph node stations or structures and therapeutic intervention(s)). This microwave ablation procedure utilizes a flexible catheter to access the lung tumor via a working channel and may be used as an alternative procedure to a percutaneous microwave approach. Based on our review of the New Technology APC application for this service and the service's clinical similarity to existing services paid under the OPPS, we estimated the likely cost of the procedure would be between $8,001 and $8,500. We assigned the procedure to New Technology APC 1571 (New Technology—Level 34 ($8001–$8500)) for CY 2019.

In claims data available from CY 2019 for the CY 2021 OPPS/ASC final rule with comment period, there were four claims reported for bronchoscopy with transbronchial ablation of lesions by microwave energy. Given the low volume of claims for the service, we proposed for CY 2021 to apply the universal low volume APC policy we adopted in CY 2019, under which we utilize our equitable adjustment

authority under section 1833(t)(2)(E) of the Act to calculate the geometric mean, arithmetic mean, and median costs to determine an appropriate payment rate for purposes of assigning bronchoscopy with transbronchial ablation of lesions by microwave energy to a New Technology APC. We found the geometric mean cost for the service to be approximately $2,693, the arithmetic mean cost to be approximately $3,086, and the median cost to be approximately $3,708. The median was the statistical methodology that estimated the highest cost for the service. The payment rate calculated using this methodology fell within the cost band for New Technology APC 1562 (New Technology—Level 25 ($3501–$4000)). Therefore, we assigned HCPCS code C9751 to APC 1562 for CY 2021.

In CY 2022, we again used the claims data from CY 2019 for HCPCS code C9751. Because the claims data was unchanged from when it was used in CY 2021, the values for the geometric mean cost ($2,693), the arithmetic mean cost ($3,086), and the median cost ($3,708) for the service described by HCPCS code C9751 remained the same. The highest cost metric using these methodologies was again the median and within the cost band for New Technology APC 1562 (New Technology—Level 25 ($3,501–$4,000)). Therefore, we continued to assign HCPCS code C9751 to APC 1562 (New Technology—Level 25 ($3501–$4000)), with a payment rate of $3,750.50 for CY 2022.

There were no new claims for HCPCS code C9751 for the CY 2024 OPPS/ASC final rule with comment period. Therefore, we continued to use claims from CY 2019 to determine the payment rate for the service; and continued to assign HCPCS code C9751 to APC 1562 (New Technology—Level 25 ($3501–$4000)), with a payment rate of $3,750.50.

There continue to be no separately payable claims for HCPCS code C9751 since 2019. Consistent with our proposal to maintain current New Technology APC assignments for CY 2025 for New Technology APC services with fewer than 10 claims in the 4-year lookback period applicable for the universal low volume APC policy, we proposed, for CY 2025, to continue to assign HCPCS code C9751 to APC 1562 (New Technology—Level 25 ($3501–$4000)), with a payment rate of $3,750.50.

Please refer to Table 25 for the proposed OPPS New Technology APC and status indicator assignments for HCPCS code C9751 for CY 2025.

TABLE 25: PROPOSED CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR HCPCS CODE C9751

HCPCS Code	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
C9751	Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3-D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (e.g., aspiration[s]/biopsy[ies]	T	1562

We did not receive any public comments on our proposal to continue to assign HCPCS code C9751 to APC 1562 (New Technology—Level 25 ($3501–$4000)). Additionally, our updated claims data continues to show that there are no new claims for C9751 for CY 2025. Therefore, we are finalizing our proposal without modification to continue to assign HCPCS code C9751 to APC 1562. Please refer to Table 26 for the final OPPS New Technology APC and status indicator assignment for HCPCS codes C9751 for CY 2025. The final CY 2025 payment rates can be found in Addendum B to this final rule with comment period via the internet on the CMS website. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

TABLE 26: FINAL CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR HCPCS CODE C9751

HCPCS Code	Long Descriptor	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
C9751	Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3-D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (e.g., aspiration[s]/biopsy[ies]	T	1562

e. Cardiac Positron Emission Tomography (PET)/Computed Tomography (CT) Studies (APCs 1520 and 1522)

For CY 2025, the OPPS payment rates for the service described by CPT codes 78431, 78432, and 78433 were proposed to be based on available CY 2023 claims data. CPT code 78431 had over 26,000 single frequency claims in CY 2023. The geometric mean cost for CPT code 78431 was approximately $2,350. The geometric mean falls within APC 1522 (New Technology—Level 22 ($2001–$2500)) with a payment rate of $2,250.50, which is the current APC assignment for this service. Therefore, we proposed, for CY 2025, to continue to assign CPT code 78431 to APC 1522 (New Technology—Level 22 ($2001–$2500)) with a payment rate of $2,250.50.

There were only 19 single frequency claims in CY 2023 for CPT code 78432. As this is below the threshold of 100 claims for a service within a year, we proposed to apply our universal low volume New Technology APC policy and used the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign CPT code 78432 to the appropriate New Technology APC. Using available claims data from CY 2021, CY 2022, and CY 2023, our analysis found the geometric mean cost of the service was approximately $1,760, the arithmetic mean cost of the service was approximately $1,920, and the median cost of the service was approximately $1,540. The arithmetic mean was the statistical methodology that estimated the highest cost for the service. The arithmetic mean cost of $1,923, is an amount that is above the cost band for APC 1520 (New Technology—Level 20 ($1801–$1900)), where the procedure is currently assigned for CY 2024. Therefore, we proposed, for CY 2025, to assign CPT code 78432 to APC 1521 (New Technology—Level 21 ($1901–$2000)) with a payment rate of $1950.50.

There were over 1,400 single frequency claims for CPT code 78433 in CY 2023. The geometric mean cost for CPT code 78433 was approximately $2,010, which is an amount that is above the current New Technology APC cost band for APC 1521 (New Technology—Level 21 ($1901-$2000)) to which it is assigned for CY 2024. Therefore, for CY 2025, we proposed to reassign CPT code 78433 to APC 1522 (New Technology—Level 22 ($2001–$2500)) with a payment rate of $2,250.50.

Please refer to Table 27 below for the proposed OPPS New Technology APC and status indicator assignments for CPT codes 78431, 78432, and 78433 for CY 2025. The proposed CY 2025 payment rates can be found in Addendum B to the CY 2025 OPPS/ASC proposed rule via the internet on the CMS website.

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TABLE 27: FINAL CY 2024 AND PROPOSED CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODES 78431, 78432, AND 78433

CPT Code	Long Descriptor	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
78431	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan	S	1522	S	1522
78432	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (e.g., myocardial viability);	S	1520	S	1521
78433	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (e.g., myocardial viability); with concurrently acquired computed tomography transmission scan	S	1521	S	1522

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Comment: We received comments supporting our proposals to assign CPT codes 78431 and 78433 to APC 1522 (New Technology—Level 22 ($2001–$2500)) and to assign CPT code 78432 to APC 1521 (New Technology—Level 21 ($1901–$2000)). One commenter noted that the geometric mean costs and hospital reporting for PET/CT services is stabilizing and that the claims data will support stable payment rates in future years.

Response: We thank the commenters for their support. We agree that the claims data for these services have been stabilizing in recent years, and any payment adjustments have been, generally, minor. As we have begun to gather adequate claims data, we will consider whether to assign CPT codes 78431 and 78433 to clinical APCs in future rulemaking.

Comment: One commenter supported our proposals to assign CPT codes 78431 and 78433 to APC 1522 but did not support our proposal to assign CPT code 78432 to APC 1521. The commenter explained that CPT code 78431 should be assigned to APC 1522 or higher because, from a clinical workflow perspective, CPT code 78432 requires more resources than CPT code 78431. The commenter explained that they believe the low claims volume is responsible for the lower payment rate for CPT codes 78432.

Response: We thank the commenter for their input. We note that New Technology APCs are cost bands rather than clinical groupings. Unlike when we assign a service to a clinical APC and consider resource and clinical similarities to other services in a clinical APC, we assign services to New Technology APCs based on cost. While we appreciate the commenter's information regarding the clinical differences between CPT codes 78431 and 78432, we adjust New Technology APC assignments based on the claims

data available rather than clinical characteristics of a service.

We note that additional claims for CPT codes 78431 through 78433 have been processed since the proposed rule. Based on updated claims data, CPT code 78431 has an updated geometric mean cost of approximately $2,300. Because the geometric mean cost of CPT code 78431 is still within the range for APC 1522, the proposed APC assignment for CPT code 78431 for CY 2025, we are finalizing the proposed APC assignment of CPT code 78431 without modification.

There were close to 15 additional single frequency claims for CY 2023 processed for CPT code 78432 since the proposed rule, bringing the total number of single frequency claims to approximately 33 for CPT code 78432 for CY 2023. Based on the updated claims data for CPT code 78432, the geometric mean cost is approximately $1,750; the arithmetic mean cost is approximately $1,890; and the median cost is approximately $1,590. Of these, the highest statistical methodology is the arithmetic mean cost of $1,890. Since the updated arithmetic mean cost for CPT code 78432 is outside of the cost band for APC 1521 (New Technology—Level 21 ($1901–$2000), we are not finalizing our proposal to assign CPT code 78432 to APC 1521 for CY 2025. Based on the updated statistical methodologies, we are assigning CPT code 78432 to APC 1520 for CY 2025 (New Technology—Level 20 ($1801–$1900)) with a payment rate of $1,850.50.

For CPT code 78433, the geometric mean cost based on the updated claims data has changed to approximately $1964, down from approximately $2010 at the time of the proposed rule. Therefore, we are not finalizing the assignment of CPT code 78433 to APC 1522 as proposed because the geometric mean cost falls outside of the cost band for proposed APC 1522 (New Technology—Level 22 ($2001–$2500)). We are assigning CPT code 78433 to APC 1521 (New Technology—Level 21 ($1901–$2000)) for CY 2025, which is the same New Technology APC to which it is currently assigned for CY 2024.

Please refer to Table 28 for the final OPPS New Technology APC and status indicator assignments for CPT codes 7843, 78432, and 78433 for CY 2025. The final CY 2025 payment rates can be found in Addendum B to this final rule with comment via the internet on the CMS website. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

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TABLE 28: FINAL CY 2024 AND FINAL CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODES 78431, 78432, AND 78433

CPT Code	Long Descriptor	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
78431	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan	S	1522	S	1522
78432	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (e.g., myocardial viability);	S	1520	S	1520
78433	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (e.g., myocardial viability); with concurrently acquired computed tomography transmission scan	S	1521	S	1521

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f. CardiAMP (APC 1590)

The CardiAMP cell therapy IDE studies are two randomized, double-blinded, controlled IDE studies: the CardiAMP Cell Therapy Chronic Myocardial Ischemia Trial [20] and the CardiAMP Cell Therapy Heart Failure Trial.[21] The two trials are designed to investigate the safety and efficacy of autologous bone marrow mononuclear cell treatment for the following: (1) patients with medically refractory and symptomatic ischemic cardiomyopathy; and (2) patients with refractory angina pectoris and chronic myocardial ischemia. On April 1, 2022, we established HCPCS code C9782 to describe the CardiAMP cell therapy IDE studies and assigned HCPCS code C9782 to APC 1574 (New Technology—Level 37 ($9,501–$10,000)) with the status indicator ''T.'' We subsequently revised the descriptor for HCPCS code C9782 to: (Blinded procedure for New York Heart Association (NYHA) Class II or III heart failure, or Canadian Cardiovascular Society (CCS) Class III or IV chronic refractory angina; transcatheter intramyocardial transplantation of autologous bone marrow cells (*e.g.,* mononuclear) or placebo control, autologous bone marrow harvesting and preparation for transplantation, left heart catheterization including ventriculography, all laboratory services, and all imaging with or without guidance (*e.g.,* transthoracic

[20] *ClinicalTrials.gov.* ''Randomized Controlled Pivotal Trial of Autologous Bone Marrow Cells Using the CardiAMP Cell Therapy System in Patients With Refractory Angina Pectoris and Chronic Myocardial Ischemia.'' Accessed May 10, 2022. *https://clinicaltrials.gov/ct2/show/NCT03455725?term=NCT03455725&rank=1.*

[21] *ClinicalTrials.gov.* ''Randomized Controlled Pivotal Trial of Autologous Bone Marrow Mononuclear Cells Using the CardiAMP Cell Therapy System in Patients With Post Myocardial Infarction Heart Failure.'' Accessed May 10, 2022. *https://clinicaltrials.gov/ct2/show/NCT02438306.*

echocardiography, ultrasound, fluoroscopy), all device(s), performed in an approved Investigational Device Exemption (IDE) study) to clarify the inclusion of the Helix trans endocardial injection catheter device in the descriptor. Additionally, we determined that APC 1590 (New Technology—Level 39 ($15,001–$20,000)) most accurately accounted for the resources associated with furnishing the procedure described by HCPCS code C9782.

For CY 2025, the proposed OPPS payment rates were based on available CY 2023 claims data. We identified three single frequency paid claims for C9782 for ratesetting for CY 2025. As this is below the threshold of 100 claims for a service within a year, we would designate C9782 as a low volume service and apply our universal low volume APC policy. Under this policy, we would use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign CPT codes C9782 to the appropriate New Technology APC. Our analysis of the data found the geometric mean cost of the service is approximately $18,045, the arithmetic mean cost of the service is approximately $18,332, and the median cost of the service is approximately $20,394. The median was the statistical methodology that estimated the highest cost for the service. However, because there are only three claims for HCPCS code C9782 from the CY 2023 claims data, we had concerns that the universal low volume APC policy calculations would not accurately capture the cost of the service. Given our proposal to maintain current New Technology APC assignments for CY 2025 for New Technology APC services with fewer than 10 claims in the 4-year lookback period applicable for the universal low-volume APC policy, we proposed to continue to assign HCPCS code C9782 to New Technology APC 1590 with a payment rate of $17,050.50.

Please refer to Table 29 below for the proposed OPPS New Technology APC and status indicator assignments for HCPCS code C9782 for CY 2025. The proposed CY 2025 payment rates can be found in Addendum B to the CY 2025 OPPS/ASC proposed rule via the internet on the CMS website.

TABLE 29: PROPOSED CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE CARDIAMP CELL THERAPY IDE STUDIES

HCPCS Code	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
C9782	Blinded procedure for New York Heart Association (NYHA) Class II or III heart failure, or Canadian Cardiovascular Society (CCS) Class III or IV chronic refractory angina; transcatheter intramyocardial transplantation of autologous bone marrow cells (e.g., mononuclear) or placebo control, autologous bone marrow harvesting and preparation for transplantation, left heart catheterization including ventriculography, all laboratory services, and all imaging with or without guidance (e.g., transthoracic echocardiography, ultrasound, fluoroscopy), all device(s), performed in an approved Investigational Device Exemption (IDE) study	T	1590

We did not receive any public comments on our proposal and are finalizing it without modification. HCPCS code C9782 will be assigned to New Technology APC 1590 with a status indication of ''T'' for CY 2025. Please refer to Table 30 for the final OPPS New Technology APC and status indicator assignment for CPT code C9782. The final CY 2025 payment rates can be found in Addendum B to this final rule with comment via the internet on the CMS website.

TABLE 30: FINAL CY 2025 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE CARDIAMP CELL THERAPY IDE STUDIES

HCPCS Code	Long Descriptor	Final CY 2025 OPPS SI	Final CY 202 OPPS APC
C9782	Blinded procedure for New York Heart Association (NYHA) Class II or III heart failure, or Canadian Cardiovascular Society (CCS) Class III or IV chronic refractory angina; transcatheter intramyocardial transplantation of autologous bone marrow cells (e.g., mononuclear) or placebo control, autologous bone marrow harvesting and preparation for transplantation, left heart catheterization including ventriculography, all laboratory services, and all imaging with or without guidance (e.g., transthoracic echocardiography, ultrasound, fluoroscopy), all device(s), performed in an approved Investigational Device Exemption (IDE) study	T	1590

g. Atherosclerosis Imaging-Quantitative Computer Tomography (AI–QCT) (APC 1511)

Atherosclerosis Imaging-Quantitative Computer Tomography (AI–QCT) is a Software as a Service (SaaS) that assesses the extent of coronary artery disease severity. This procedure is performed to quantify the extent of coronary plaque and stenosis in patients who have undergone coronary computed tomography analysis (CCTA). The AMA CPT Editorial Panel established the following four codes associated with this service, effective January 1, 2021:

0623T: Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; data preparation and transmission, computerized analysis of data, with review of computerized analysis output to reconcile discordant data, interpretation, and report.

0624T: Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; data preparation and transmission.

0625T: Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; computerized analysis of data from coronary computed tomographic angiography.

0626T: Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; review of computerized analysis output to reconcile discordant data, interpretation and report.

Of these four CPT codes, only CPT code 0625T was determined to be separately payable in the OPPS and was assigned to status indicator = ''S'' (Procedure or Service, Not Discounted When Multiple) starting October 1, 2022. We assigned CPT code 0625T to a separately payable status indicator based on the technology and its potential utilization in the HOPD setting, our evaluation of the service, as well as input from our medical advisors. The procedure was assigned to APC 1511 (New Technology—Level 11 ($900–$1000)) with a payment rate of $950.50.

For CY 2024, the OPPS payment rates were proposed to be based on available CY 2022 claims data. There were 37 claims for CPT code 0625T during this time period. As this was below the threshold of 100 claims for a service within a year, we explained that we could propose to designate CPT code 0625T as a low volume service under our universal low volume New Technology APC policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign code 0625T to the appropriate New Technology APC. We found the geometric mean cost for the service to be approximately $3.70, the arithmetic mean cost to be approximately $4.10, and the median cost to be approximately $3.50. Under our universal low volume New Technology APC policy, we would use the greatest of the statistical methodologies, the arithmetic mean, to assign CPT code 0625T to New Technology 1491 (New Technology Level 1A—(0–$10)) with a payment rate of $5.00. However, we acknowledged that, because CPT code 0625T was only made separately payable as part of the OPPS in October 2022, and, therefore, the claims available only reflect two months of data, we were concerned that we did not have sufficient claims data to justify reassignment to another New Technology APC (66 FR 69902). Therefore, consistent with our current policy to retain services within New Technology APC groups until we obtain sufficient claims data to justify reassignment (66 FR 59902), for CY 2024 we adopted as final our proposal

to maintain CPT code 0625T's current assignment to APC 1511 (New Technology—Level 11 ($901–$1000) with a payment rate of $950.50.

For setting CY 2025 payment rates, there were only three separately payable claims in the CY 2023 data reported for CPT code 0625T indicating a geometric mean cost of approximately $180, which is substantially lower than the code's current payment rate of $950.50. Additionally, in CY 2022 and CY 2023, there were a total of 40 separately payable claims reported for CPT code 0625T, but it is unlikely that a service with a current payment rate of $950.50 would have a geometric mean of $4.20, an arithmetic mean of $6.60, and a median of $3.52. These findings lead to uncertainty about the appropriate payment rate for the service described by CPT code 0625T. A review of the evidence submitted by the developer of the procedure when this procedure was originally assigned to a New Technology APC, and before any claims data were available, indicated the procedure had a cost between $901 and $1,000. Claims for CPT code 0625T from CY 2021 and CY 2022 indicate that the cost of the procedure is less than $10, which would not appear to cover the basic cost of this procedure, including computing time, generating a report, and having medical personnel interpret the report. For CY 2023, the geometric mean cost of approximately $180 based on three claims may better reflect the cost of the procedure described by CPT code 0625T, but there were not enough claims to be confident about the result. Therefore, we proposed to use our authority under section 1833(t)(2)(E) for CY 2025 to continue to assign CPT code 0625T to APC 1511 (New Technology—Level 11 ($901–$1000) with a payment rate of $950.50 based on the data currently available to us, which we believe best reflects the cost of the service as described by the New Technology APC application.

Refer to Table 31 for the proposed OPPS New Technology APC and status indicator assignments for CPT code 0625T for CY 2025.

TABLE 31: PROPOSED CY 2025 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR ATHEROSCLEROSIS IMAGING-QUANTITATIVE COMPUTER TOMOGRAPHY (AI-QCT) CPT CODE 0625T

CPT Code	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
0625T	Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; computerized analysis of data from coronary computed tomographic angiography	S	1511

Comment: We received several comments supporting the assignment of CPT code 0625T to APC 1511 (New Technology—Level 11 ($901–$1000) for CY 2025.

Response: We thank the commenters for their support. We note that since the CY 2025 OPPS/ASC proposed rule was issued, two additional claims for CPT code 0625T have been processed, with the updated geometric mean cost increasing to approximately $498. Although we have two additional claims, we are not certain that we have enough claims data to be confident in the calculated geometric mean cost for CPT code 0625T. Therefore, we are finalizing our proposal, without modification, to continue to assign CPT code 0625T to APC 1511 (New Technology—Level 11 ($901–$1000). Please refer to Table 32 for the final OPPS New Technology APC and status indicator assignment for CPT code 0625T. The final CY 2025 payment rates can be found in Addendum B to this final rule with comment period via the internet on the CMS website.

TABLE 32: PROPOSED CY 2025 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR ATHEROSCLEROSIS IMAGING-QUANTITATIVE COMPUTER TOMOGRAPHY (AI-QCT) CPT CODE 0625T

CPT Code	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
0625T	Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; computerized analysis of data from coronary computed tomographic angiography	S	1511

h. Corvia Medical Interatrial Shunt Procedure (APC 1592)

On July 1, 2020, we established HCPCS code C9760 (Non-randomized, non-blinded procedure for nyha class ii, iii, iv heart failure; transcatheter implantation of interatrial shunt, including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography (tee)/intracardiac echocardiography (ice), and all imaging with or without guidance (for example, ultrasound, fluoroscopy) performed in an approved investigational device exemption (ide) study, performed in an approved investigational device exemption (ide) study) to facilitate payment for the implantation of the Corvia Medical interatrial shunt.

As we stated in the CY 2021 OPPS final rule with comment period (85 FR 85947), we believe that similar resources and device costs are involved with the Corvia Medical interatrial shunt procedure and the V-Wave interatrial shunt procedure. Unlike the V-Wave interatrial shunt, which is implanted half the time the associated interatrial shunt procedure described by HCPCS code C9758 is billed, the Corvia Medical interatrial shunt is implanted every time the associated interatrial shunt procedure (HCPCS code C9760) is billed. Therefore, for CY 2021, we assigned HCPCS code C9760 to New Technology APC 1592 (New Technology—Level 41 ($25,001–$30,000)) with a payment rate of $27,500.50. We also modified the code descriptor for HCPCS code C9760 to remove the phrase ''or placebo control,'' from the descriptor. In CY 2022, we generally used the same claims data as was used in the CY 2021 OPPS final rule to set the payment rates for that year. Accordingly, because there were no claims for this service in CY 2019, we continued to assign HCPCS code C9760 to New Technology APC 1592 in CY 2022. There continued to be no claims data for this service in CY 2021, so we continued to assign HCPCS code C9760 to New Technology APC 1592 in CY 2023, the year for which we used CY 2021 data for ratesetting. While there was one claim in CY 2022, we continued to assign HCPCS code C9760 to New Technology APC 1592 for CY 2024 due to the extremely limited claims data available.

For CY 2025, the OPPS payment rates were proposed to be based on available CY 2023 claims data. There were no claims for HCPCS code C9760 in CY 2023. Therefore, we proposed to continue assigning HCPCS code C9760 to New Technology APC 1592.

Please refer to Table 33 for the proposed OPPS New Technology APC and status indicator assignments for HCPCS code C9760. The proposed CY 2025 payment rates can be found in Addendum B to the CY 2025 OPPS/ASC proposed rule via the internet on the CMS website.

TABLE 33: PROPOSED CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR NON-BLINDED INTRATRIAL SHUNT PROCEDURE

HCPCS	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
C9760	(Non-randomized, non-blinded procedure for nyha class ii, iii, iv heart failure; transcatheter implantation of interatrial shunt, including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography (tee)/intracardiac echocardiography (ice), and all imaging with or without guidance (for example, ultrasound, fluoroscopy) performed in an approved investigational device exemption (ide) study	T	1592

We did not receive any public comments on our proposal, and we still do not have any claims for the service. Therefore, for CY 2025, we are finalizing our proposal without modification. Specifically for CY 2025, we are assigning HCPCS code C9760 to APC 1592 (New Technology—Level 41 ($25,001–$30,000)) with a payment rate of $27,500.50.

Please refer to Table 34 below for the final OPPS New Technology APC and status indicator assignments for HCPCS code C9760 for CY 2025. The CY 2025 payment rates can be found in Addendum B to this final rule with comment period via the internet on the CMS website. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

TABLE 34: FINAL CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR NON-BLINDED INTRATRIAL SHUNT PROCEDURE

HCPCS	Long Descriptor	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
C9760	(Non-randomized, non-blinded procedure for nyha class ii, iii, iv heart failure; transcatheter implantation of interatrial shunt, including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography (tee)/intracardiac echocardiography (ice), and all imaging with or without guidance (for example, ultrasound, fluoroscopy) performed in an approved investigational device exemption (ide) study	T	1592

i. DARI Motion Procedure (APC 1505)

Effective January 1, 2022, CPT code 0693T (Comprehensive full body computer-based markerless 3D kinematic and kinetic motion analysis and report) is associated with the DARI Motion Procedure, a service that provides human motion analysis to aid clinicians in pre- and post-operative surgical intervention and in making other treatment decisions, including selecting the best course of physical therapy and rehabilitation. The technology consists of eight cameras that surround a patient, which send live video to a computer workstation that analyzes the video to create a 3D reconstruction of the patient without the need for special clothing, markers, or devices attached to the patient's clothing or skin. For CY 2022, we assigned CPT code 0693T to New Technology APC 1505 (New Technology—Level 5 ($301–$400)). For CY 2023, the OPPS payment rates were based on claims submitted between January 1, 2021, and December 31, 2021, processed through June 30, 2022. Due to its effective date of January 1, 2022, there were no claims available for CPT

code 0693T for rate setting in CY 2023. Therefore, in CY 2023, we continued to assign CPT code 0693T to New Technology APC 1505. For CY 2024, there were no claims available, so we again continued to assign CPT code 0693T to New Technology APC 1505.

For CY 2025, the OPPS payment rates were proposed based on available CY 2023 claims data. Although CPT code 0693T was effective January 1, 2022, we have no claims data at this time. Because we have no claims data, for CY 2025, we proposed to continue to assign CPT code 0693T to APC 1505 with a proposed payment rate of $350.50.

Refer to Table 35 for the proposed OPPS New Technology APC and status indicator assignments for CPT code 0693T for CY 2025. The proposed CY 2025 payment rates can be found in Addendum B to the CY 2025 OPPS/ASC proposed rule via the internet on the CMS website.

TABLE 35: PROPOSED CY 2024 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE DARI MOTION PROCEDURE

CPT Code	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
0693T	Comprehensive full body computer-based markerless 3D kinematic and kinetic motion analysis and report	S	1505

We did not receive any public comments on our proposal, and we still do not have any claims for the service. Therefore, for CY 2025, we are finalizing our proposal without modification. Specifically, for CY 2025, we are assigning CPT code 0693T to APC 1505 with a status indicator of ''S''. The final New Technology APC and status indicator assignments for CPT code 0693T for CY 2025 are found in Table 36. The CY 2025 payment rates can be found in Addendum B to this final rule with comment period via the internet on the CMS website. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

TABLE 36: FINAL CY 2024 AND CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE DARI MOTION PROCEDURE

CPT Code	Long Descriptor	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
0693T	Comprehensive full body computer-based markerless 3D kinematic and kinetic motion analysis and report	S	1505	S	1505

j. Instillation of Anti-Neoplastic Pharmacologic/Biologic Agent Into Renal Pelvis (APC 1558)

Effective October 1, 2023, CMS established HCPCS code C9789 (Instillation of anti-neoplastic pharmacologic/biologic agent into renal pelvis, any method, including all imaging guidance, including volumetric measurement if performed) and assigned it to New Technology APC 1559 (New Technology—Level 22 ($2001–$2500)), with a payment rate of $2,250.50 based on our review of the clinical and resource characteristics of this service.

This code may be used to describe the unique procedure associated with the administration of the drug described by HCPCS code J9281 (Mitomycin pyelocalyceal instillation, 1 mg) or similar products. HCPCS code J9281 may be used to describe the product, Jelmyto (mitomycin for pyelocalyceal solution). The FDA approved Jelmyto in 2020, and the FDA approved indication and usage for Jelmyto is as an alkylating drug indicated for the treatment of adult patients with low-grade Upper Tract Urothelial Cancer (LG–UTUS).[22]

Because we created HCPCS code C9789 effective October 1, 2023, we have limited claims data from CY 2023 available for CY 2025 rulemaking. Specifically, we only had 6 claims available. Given our proposal to

[22] Jelmyto Package Insert. 01/14/2021. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/211728s002lbl.pdf.*

maintain current New Technology APC assignments for CY 2025 for New Technology APC services with fewer than 10 claims in the 4-year lookback period applicable for the universal low-volume APC policy, we proposed to continue to assign HCPCS code C9789 to New Technology APC 1559 (New Technology—Level 22 ($2001–$2500)).

Please refer to Table 37 for the proposed OPPS New Technology APC and status indicator assignments for CPT code C9789 for CY 2025.

TABLE 37: FINAL CY 2024 AND PROPOSED CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR HCPCS CODE C9789

HCPCS Code	Long Descriptor	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
C9789	Instillation of anti-neoplastic pharmacologic/biologic agent into renal pelvis, any method, including all imaging guidance, including volumetric measurement if performed	T	1559	T	1559

Comment: We received one comment in support of our proposal.

Response: We thank the commenter for their support.

Our updated claims data during the 4-year lookback period applicable for the universal low-volume APC policy continues to show only 6 claims for HCPCS code C9789. Therefore, we are finalizing our proposal without modification to continue assigning HCPCS code C9758 to New Technology APC 1559 (New Technology—Level 22 ($2001–$2500)). Please refer to Table 38 below for the final OPPS New Technology APC and status indicator assignment for HCPCS code C9789 for CY 2025. The final CY 2025 payment rates can be found in Addendum B to this final rule with comment period via the internet on the CMS website. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

TABLE 38: FINAL CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR HCPCS CODE C9789

HCPCS Code	Long Descriptor	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
C9789	Instillation of anti-neoplastic pharmacologic/biologic agent into renal pelvis, any method, including all imaging guidance, including volumetric measurement if performed	T	1559

k. LimFlow TADV Procedure CPT Code 0620T (APC 1579)

The LimFlow TADV procedure, which is described by CPT code 0620T (Endovascular venous arterialization, tibial or peroneal vein, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed), is an endovascular procedure that is used

to treat patients with chronic limb-threatening ischemia. According to the developer, these patients are no longer eligible for conventional endovascular or open bypass surgery to treat their artery blockage, and without this procedure, they are likely to face limb amputation.

CPT code 0620T was established in January 2021 and was assigned to APC 5194 (Level 4 Endovascular Procedures) with a payment rate of approximately $17,400, which is the highest-paying APC for endovascular procedures. While we proposed to continue to assign CPT code 0620T to APC 5194 for CY 2024, we finalized a reassignment from a clinical APC to a New Technology APC with a higher payment rate based on comments received expressing concern that the low payment rate of the procedure would discourage providers from performing the procedure and deny access to the procedure. To determine the appropriate New Technology APC assignment for CY 2024, we looked at the available cost information. There were only 15 claims for the procedure for CY 2021 and CY 2022, so the LimFlow TADV procedure was subject to our new technology procedure low volume APC policy. An analysis of the median, arithmetic mean, and geometric mean of CPT code 0620T for CY 2024 rulemaking found that the median was approximately $25,800, the arithmetic mean was approximately $28,600, and the geometric mean was approximately $26,700. Because the arithmetic mean had the highest value of the three cost statistics, for CY 2024, we assigned CPT code 0620T to New Technology APC 1578 (New Technology—Level 41 ($25,001–$30,000)) with a payment rate of $27,500.50.

For CY 2025, the OPPS payment rates were proposed to be based on available CY 2023 claims data. We identified only six single frequency claims for CPT code 0620T in the CY 2023 claims data. As this is below the threshold of 100 claims for a service within a year, we proposed to again apply our universal low volume APC policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign the service to the appropriate New Technology APC. Based on our review of the available claims, we determined that the arithmetic mean was approximately $35,000; the median was approximately $36,000; and the geometric mean cost was approximately $33,000. Of these, the median was the statistical methodology that estimated the highest cost for the service. The payment rate calculated using this methodology fell within the cost band for New Technology APC 1579 (New Technology—Level 42 ($30,001–$40,000)) with a payment rate of $35,000.50. Therefore, for CY 2025, we proposed to designate this service as a low volume service under our universal low volume APC policy and to assign HCPCS code 0620T to New Technology APC 1579.

TABLE 39: PROPOSED CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR LIMFLOW

CPT Code	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
0620T	Endovascular venous arterialization, tibial or peroneal vein, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed	S	1579

Comment: We received a comment from the manufacturer supporting our proposal to designate CPT code 0620T as a low volume service under the universal low volume APC policy and assign the service to New Technology APC 1579 for CY 2025, as they believe the proposed assignment more accurately reflects the resources used in the procedure.

Response: We thank the commenter for their support.

We note that there are an additional five claims for CPT code 0620T for CY 2023 that have been processed since the proposed rule. Based on the 11 single frequency claims available for CY 2023, in addition to the other 26 claims in the 4-year lookback period, we determined that the arithmetic mean is $35,700; the median is $36,400; and the geometric mean cost is $33,900. Since the total number of claims for CPT code 0620T for CY 2023 is still below the 100-claim threshold, we are finalizing our proposal to designate 0620T as a low volume service under the universal low volume APC policy. The payment rate calculated using the highest of these methodologies, the median, continues to fall within the cost band for New Technology APC 1579 (New Technology—Level 42 ($30,001–$40,000)) with a payment rate of $35,000.50. Therefore, we are also finalizing our proposal without modification to assign CPT code 0620T to New Technology APC 1579 for CY 2025.

Please refer to Table 40 for the final OPPS New Technology APC and status indicator assignments for CPT code

0662T for CY 2025. The final CY 2025 payment rates can be found in Addendum B to this final rule with comment period via the internet on the CMS website. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

TABLE 40: FINAL CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR LIMFLOW

CPT Code	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
0620T	Endovascular venous arterialization, tibial or peroneal vein, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed	S	1579

l. Liver Histotripsy Service (APC 1576)

CPT code 0686T (Histotripsy (*i.e.,* non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance) was first effective July 1, 2021, and describes the histotripsy service associated with the use of the HistoSonics system. Histotripsy is a non-invasive, non-thermal, mechanical process that uses a focused beam of sonic energy to destroy cancerous liver tumors and is currently in a non-randomized, prospective clinical trial to evaluate the efficacy and safety of the device for the treatment of primary or metastatic tumors located in the liver.[23] When HCPCS code 0686T was first effective, the histotripsy procedure was designated as a Category A IDE clinical study (NCT04573881). Since devices in Category A IDE studies are excluded from Medicare payment, payment for CPT code 0686T only reflected the cost of the service that is performed (absent the cost of the device) each time it is reported on a claim. On March 2, 2023, the histotripsy IDE clinical study was re-designated as a Category B (Non-experimental/Investigational) IDE study. Due to this new designation, payment for CPT code 0686T in CY 2024 reflects payment for both the service that is performed and the device used each time it is reported on a claim. For CY 2024, we assigned CPT code 0686T to New Technology APC 1576 (New Technology—Level 39 ($15,001–$20,000)) with a payment rate of $17,500.50.

For CY 2025, proposed OPPS payment rates were based on available CY 2023 claims data. We have identified one claim for CPT code 0686T within the CY 2023 claims data. As the available claims data is below the threshold of 100 claims for a service within a year, we would propose to designate CPT code 0686T as a low volume service under our universal low volume APC policy, and use the highest of the geometric mean cost, arithmetic mean cost, or median cost to assign CPT code 0686T to the appropriate New Technology APC. However, because there is only a single claim in the CY 2023 data, we have concerns that the universal low volume APC policy calculations do not accurately capture the cost of the service.

Given our proposal to maintain current New Technology APC assignments for CY 2025 for New Technology APC services with fewer than 10 claims in the 4-year lookback period applicable for the universal low volume APC policy, and based on the fact that there have only been 3 claims for CPT code 0686T in the prior 4-year period, we proposed to continue to assign CPT code 0686T to APC 1576 (New Technology—Level 39 ($15,001–$20,000)) with a payment rate of $17,500.50 as shown in Table 25.

Please refer to Table 41 for the proposed OPPS New Technology APC and status indicator assignments for CPT code 0686T for CY 2025. The proposed CY 2025 payment rates can be found in Addendum B to the CY 2025 OPPS/ASC proposed rule.

[23] *ClinicalTrials.gov.* ''The HistoSonics System for Treatment of Primary and Metastatic Liver Tumors Using Histotripsy (#HOPE4LIVER) (#HOPE4LIVER).'' Accessed May 10, 2022. *https://clinicaltrials.gov/ct2/show/study/NCT04573881.*

TABLE 41: PROPOSED CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE LIVER HISTOTRIPSY SERVICE

CPT Code	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
0686T	Histotripsy (i.e., non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance	S	1576

We did not receive any public comments on our proposal and are finalizing it without modification. HCPCS code 0686T will be assigned to New Technology APC 1576 with a status indication of ''S'' for CY 2025. Please refer to Table 42 below for the final OPPS New Technology APC and status indicator assignment for CPT code 0686T. The final CY 2025 payment rates can be found in Addendum B to this final rule with comment via the internet on the CMS website. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

TABLE 42: FINAL CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE LIVER HISTOTRIPSY SERVICE

CPT Code	Long Descriptor	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
0686T	Histotripsy (i.e., non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance	S	1576

m. LiverMultiScan Service (APC 1511)

Effective July 1, 2021, CPT codes 0648T (Quantitative magnetic resonance for analysis of tissue composition (*e.g.,* fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic mri examination of the same anatomy (*e.g.,* organ, gland, tissue, target structure) during the same session; single organ) and 0649T (Quantitative magnetic resonance for analysis of tissue composition (*e.g.,* fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic mri examination of the same anatomy (*e.g.,* organ, gland, tissue, target structure); single organ (list separately in addition to code for primary procedure)) are associated with the LiverMultiScan service. LiverMultiScan is a Software as a medical Service (SaaS) that is intended to aid the diagnosis and management of chronic liver disease, the most prevalent of which is Non-Alcoholic Fatty Liver Disease (NAFLD). It provides standardized, quantitative imaging biomarkers for the characterization and assessment of inflammation, hepatocyte ballooning, and fibrosis, as well as steatosis, and iron accumulation. LiverMultiScan receives MR images acquired from patients' providers and analyzes the images using their proprietary Artificial Intelligence (AI) algorithms. It then sends the providers a quantitative metric report of the patient's liver fibrosis and inflammation. In accordance with our SaaS add-on codes policy (87 FR 72032 to 72033), SaaS CPT add-on codes are assigned to the same APCs and status indicators as their standalone codes. Thus, CPT code 0649T, the add-on code for LiverMultiScan, is assigned to the identical APC and status indicator as CPT code 0648T, the standalone code for the same service. For CY 2024, we assigned CPT codes 0648T and 0649T to New Technology APC 1511 (New Technology—Level 11 ($901–$1,000) with a payment rate of $950.50.

For CY 2025, the OPPS payment rates were proposed to be based on available CY 2023 claims data. We identified 71 claims for CPT code 0648T and 72 claims for CPT code 0649T for CY 2023. As this is below the threshold of 100 claims for each code within a year, we

proposed to utilize our universal low volume APC policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign CPT codes 0648T and 0649T to the appropriate New Technology APC. There are available claims data from CY 2021 and CY 2022 for CPT codes 0648T and 0649T. Our analysis of the combined data, 114 claims for CPT code 0648T and 115 claims for CPT code 0649T, yielded a geometric mean cost of approximately $180, an arithmetic mean cost of approximately $234, and a median cost of approximately $197. We explained that we believed it was appropriate to utilize our universal low volume APC policy to assign the LiverMultiScan service to a New Technology APC because we stated that we believed that the combined claims data from CY 2021 to CY 2023 provided sufficient claims to capture the cost of the service. The arithmetic mean was the statistical methodology that estimated the highest cost for CPT codes 0648T and 0649T. Therefore, we proposed to reassign CPT codes 0648T and 0649T to New Technology APC 1504 (New Technology—Level 4 ($201–$300)) with a payment rate of $250.50 as shown in Table 43.

TABLE 43: PROPOSED CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE LIVER MULTISCAN SERVICE

CPT Code	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
0648T	Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic mri examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session; single organ	S	1504
0649T	Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (e.g., organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)	S	1504

Comment: We received several comments, including a comment from the manufacturer, requesting that we maintain the APC assignment for the CPT codes 0648T and 0649T at APC 1511. Many commenters stated that the cost of each of the services is at least $950, and that the proposed payment rate of $250 would be inadequate to ensure patient access. Commenters noted that the claims data used to determine the CY 2025 OPPS proposed APC assignment for this service represent an insufficient number of claims to estimate the cost for this service. One commenter expressed concern about the wide data variability present in the claims data for CPT codes 0648T and 0649T. One commenter requested that we develop a payment policy for SaaS like CPT codes 0648T and 0649T that results in appropriate and consistent payment for innovative new services. We also received one comment signed by ten radiologists stating that the current payment rate for the procedures was too high.

Response: We recognize that software-based technologies, like those described by CPT codes 0648T and 0649T, are rapidly evolving and, therefore, we are considering for future rulemaking whether specific adjustments to payment policies, including our New Technology APC policies, are needed to more accurately and appropriately pay for these products and services across settings of care. For CY 2025, we recognize that the few claims available for CPT codes 0648T and 0649T may not truly represent the cost of this service. While we received a comment expressing concern over the potential overpayment of the service, we do not believe we have sufficient claims to justify a reassignment at this time. Therefore, we agree with the commenters that, for both CPT codes 0648T and 0649T, we should maintain the payment rates for CY 2025 until we have additional claims data.

Comment: One commenter supported the proposed reassignment of CPT codes 0648T and 0649T to New Technology APC 1504. The commenter stated that the payment rate of $950 created a paradigm where the third-party automated quantitative analytic service was valued greater than the MRI procedure that included technologist staffing, professional interpretation and liability. The commenter believed that the payment of the service should be

based on the true cost of these automated digital quantitative services at New Technology APC 1504.

Response: We thank the commenter for its support of our proposal. We reiterate that the few claims for CPT codes 0648T and 0649T may not truly represent the cost of this service or justify a reassignment at this time.

After consideration of the public comments we received, we are finalizing our proposal with modifications. We are using our equitable adjustment authority under section 1833(t)(2)(E) to continue to assign CPT codes 0648T and 0649T to New Technology APC 1511 (New Technology—Level 11 ($901–$1,000) with a payment rate of $950.50 for CY 2025. Please refer to Table 44 below for the final OPPS New Technology APC and status indicator assignments for CPT codes 0648T and 0649T for CY 2025. The final CY 2025 payment rates can be found in Addendum B to this final rule via the internet on the CMS website. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

TABLE 44: FINAL CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE LIVER MULTISCAN SERVICE

CPT Code	Long Descriptor	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
0648T	Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic mri examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session; single organ	S	1511
0649T	Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (e.g., organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)	S	1511

n. Optellum Lung Cancer Prediction (LCP) (APC 1508)

CPT codes 0721T (Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging) and 0722T (Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained with concurrent CT examination of any structure contained in the concurrently acquired diagnostic imaging dataset (list separately in addition to code for primary procedure)) became effective July 1, 2022, and are associated with the Optellum LCP technology. The Optellum LCP applies an algorithm to a patient's CT scan to produce a raw risk score for a patient's pulmonary nodule. The physician uses the risk score to quantify the risk of lung cancer and to determine what the next management step should be for the patient (for example, CT surveillance versus invasive procedure). In accordance with our SaaS add-on codes policy (87 FR 72032 and 72033), SaaS CPT add-on codes are assigned to the same APCs and status indicators as their standalone codes. Thus, CPT code 0722T, the add-on code for the Optellum LCP service, is assigned to the identical APC and status indicator as CPT code 0721T, the standalone code for the same service. For CY 2024, we assigned CPT codes 0721T and 0722T to APC New Technology 1508 (New Technology—Level 8 ($601–$700)).

For CY 2025, the OPPS payment rates were proposed based on available CY 2023 claims data. We identified three claims for CPT codes 0721T and 0722T for ratesetting for CY 2025. As this is below the threshold of 100 claims for a service within a year, we would usually propose to apply our universal low volume APC policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign CPT codes 0721T and 0722T to the appropriate New Technology APC. There are available claims data only from CY 2023 for CPT codes 0721T and 0722T. Our analysis of the data for CPT code 0721T found the geometric mean cost of the service is approximately $84, the arithmetic mean cost of the service is approximately $98, and the median

cost of the service is approximately $130. We did not identify any reported claims for CPT code 0722T. However, because there were only three claims for the Optellum LCP service and these claims show a much lower cost than would be expected based on the current APC assignment of this service, we have concerns that the universal low volume APC policy calculations do not accurately capture the cost of the service. Given our proposal to maintain current New Technology APC assignments for CY 2025 for New Technology APC services with fewer than 10 claims in the 4-year lookback period applicable for the universal low-volume APC policy, we proposed to continue to assign CPT codes 0721T and 0722T to New Technology APC 1508 (New Technology—Level 8 ($601–$700)) with a proposed payment rate of $650.50.

Please refer to Table 45 below for the proposed OPPS New Technology APC and status indicator assignments for HCPCS codes 0721T and 0722T for CY 2025. The proposed CY 2025 payment rates can be found in Addendum B to the CY 2025 OPPS/ASC proposed rule via the internet on the CMS website.

TABLE 45: PROPOSED CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE OPTELLUM LCP PROCEDURE

CPT Code	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
0721T	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging	S	1508
0722T	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained with concurrent CT examination of any structure contained in the concurrently acquired diagnostic imaging dataset (list separately in addition to code for primary procedure)	S	1508

We did not receive any public comments on our proposal, and we are finalizing our proposal without modification. We are assigning HCPCS codes 0721T and 0722T to New Technology APC 1508 with a status indication of ''S'' for CY 2025. Please refer to Table 46 below for the final OPPS New Technology APC and status indicator assignment for CPT codes 0721T and 0722T. The final CY 2025 payment rates can be found in Addendum B to this final rule with comment via the internet on the CMS website. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

TABLE 46: FINAL CY 2025 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE OPTELLUM LCP PROCEDURE

CPT Code	Long Descriptor	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
0721T	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging	S	1508
0722T	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained with concurrent CT examination of any structure contained in the concurrently acquired diagnostic imaging dataset (list separately in addition to code for primary procedure)	S	1508

o. Quantitative Magnetic Resonance (QMR) for Analysis of Tissue Composition (APC 1511)

Effective January 1, 2022, CPT codes 0697T (Quantitative magnetic resonance for analysis of tissue composition (*e.g.,* fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic mri examination of the same anatomy (*e.g.,* organ, gland, tissue, target structure) during the same session; multiple organs) and 0698T (Quantitative magnetic resonance for analysis of tissue composition (*e.g.,* fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic mri examination of the same anatomy (*e.g.,* organ, gland, tissue, target structure); multiple organs (list separately in addition to code for primary procedure)) are associated with the CoverScan Software as a medical Service (SaaS). This service is a medical image management and processing software package that analyzes MR data and provides quantified metrics of multiple organs such as the heart, lungs, liver, spleen, pancreas, and kidney. In accordance with our SaaS add-on codes policy (87 FR 72032 to 72033), SaaS CPT add-on codes are assigned to the same APCs and status indicators as their standalone codes. Thus, CPT code 0698T, the add-on code for CoverScan is be assigned to the same APC and status indicator as CPT code 0697T, the standalone code for the same service. For CY 2024, we assigned CPT codes 0697T and 0698T to New Technology APC 1511 (New Technology—Level 11 ($900–$1,000)).

For CY 2025, the proposed OPPS payment rates were based on available CY 2023 claims data. We identified 48 claims for CPT code 0698T and no claims for CPT code 0697T in CY 2023. As this is below the threshold of 100 claims for a service within a year, we proposed to apply our universal low volume APC policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign CPT codes 0697T and 0698T to the appropriate New Technology APC. There are also available claims data from CY 2022 for CPT code 0698T. Our analysis of the combined data, approximately 80 claims, yielded a geometric mean cost of approximately $444, an arithmetic mean cost of approximately $622, and a median cost of approximately $786. The median cost is the statistical methodology that estimates the highest cost for CPT codes 0697T and 0698T. Therefore, we proposed, for CY 2025, to reassign CPT codes 0697T and 0698T to APC 1509 (New Technology—Level 9 ($701–$800)) with a payment rate of $750.50.

Refer to Table 47 below for the proposed OPPS New Technology APC and status indicator assignments for CPT codes 0697T and 0698T for CY 2025. The proposed CY 2025 payment rates can be found in Addendum B to the CY 2025 OPPS/ASC proposed rule via the internet on the CMS website.

TABLE 47: PROPOSED CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE QMRCP PROCEDURE

CPT Code	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
0697T	Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic mri examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session; multiple organs	S	1509
0698T	Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic mri examination of the same anatomy (e.g., organ, gland, tissue, target structure); multiple organs (list separately in addition to code for primary procedure)	S	1509

Comment: Commenters requested that we maintain the APC assignment for the CPT codes 0697T and 0698T at APC 1511 for CY 2025. Many commenters stated that the cost of each of the services is at least $950, and that the proposed payment rate of $750 does not cover the cost of this service. One commenter noted that the claims data used to determine the CY 2025 OPPS proposed rate for this service represent an insufficient number of claims to estimate the cost for this service. Additionally, the commenter stated that wide variability in claims data distorts the applicability of the universal low volume APC policy and skews the arithmetic mean value. Commenters were concerned that the proposed payment rate would hinder patient access to these services.

Response: We recognize that software-based technologies, like those described by CPT codes 0697T and 0698T, are rapidly evolving and, therefore, we are considering for future rulemaking whether specific adjustments to payment policies, including our New Technology APC policies, are needed to more accurately and appropriately pay for these products and services across settings of care. For CY 2025, we recognize that the few claims available for CPT codes 0697T and 0698T may not truly represent the cost of this service. We agree with the commenters that, for both CPT codes 0697T and 0698T, we should maintain the payment rates for CY 2025 until we have additional claims data.

After consideration of the public comments we received, we are finalizing our proposal with modifications. We will use our equitable adjustment authority under section 1833(t)(2)(E) to continue to assign CPT codes 0697T and 0698T to New Technology APC 1511 (New Technology—Level 11 ($901–$1,000) with a payment rate of $950.50 for CY 2025. Please refer to Table 48 below for the final OPPS New Technology APC and status indicator assignments for CPT codes 0697T and 0698T for CY 2025. The final CY 2025 payment rates can be found in Addendum B to this final rule via the internet on the CMS website. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

TABLE 47: PROPOSED CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE QMRCP PROCEDURE

CPT Code	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
0697T	Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic mri examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session; multiple organs	S	1509
0698T	Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic mri examination of the same anatomy (e.g., organ, gland, tissue, target structure); multiple organs (list separately in addition to code for primary procedure)	S	1509

p. Quantitative Magnetic Resonance Cholangiopancreatography (QMRCP) (APC 1511)

Effective July 1, 2022, CPT codes 0723T (Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained without diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (*e.g.,* organ, gland, tissue, target structure) during the same session) and 0724T (Quantitative magnetic resonance cholangiopancreatography (QMRCP), including data preparation and transmission, interpretation and report, obtained with diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (*e.g.,* organ, gland, tissue, target structure) (list separately in addition to code for primary procedure)) are associated with the QMRCP Software as a medical Service (SaaS). The service performs quantitative assessment of the biliary tree and gallbladder. It uses a proprietary algorithm that produces a three-dimensional reconstruction of the biliary tree and pancreatic duct and also provides precise quantitative information of biliary tree volume and duct metrics. In accordance with our SaaS add-on codes policy (87 FR 72032 and 72033), SaaS CPT add-on codes are assigned to the same APCs and status indicators as their standalone codes. Consistent with our SaaS add-on codes policy, CPT code 0724T, the add-on code for QMRCP is assigned to the identical APC and status indicator as CPT code 0723T, the standalone code for the same service. For CY 2024, we assigned CPT codes 0723T and 0724T to New Technology APC 1511 (New Technology—Level 11 ($900–$1,000)).

For CY 2025, the proposed OPPS payment rates were based on available CY 2023 claims data. We identified 3 claims for CPT code 0724T and no claims for CPT code 0723T in CY 2023. As this is below the threshold of 100 claims for a service within a year, we would usually propose to apply our universal low volume APC policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign CPT codes 0723T and 0724T to the appropriate New Technology APC. There is only one single claim from CY 2022 for CPT code 0724T and no claims for CPT code 0723T. For CY 2023, we received 3 claims for CPT code for CPT 0724T and no claims for CPT code 0723T. Our analysis of the combined CY 2022 and CY 2023 data for CPT code 0723T and 0724T found the geometric mean cost of the service is approximately $26, the arithmetic mean cost of the service is approximately $26, and the median cost of the service is approximately $27. Given our proposal to maintain current New Technology APC assignments for CY 2025 for New Technology APC services with fewer than 10 claims in the 4-year lookback period applicable for the universal low volume APC policy, we proposed to continue to assign the CPT codes 0723T and 0724T to New Technology APC 1511 (New Technology—Level 11 ($901–$1,000)) with a payment rate of $950.50.

Refer to Table 49 for the proposed OPPS New Technology APC and status indicator assignments for CPT codes 0723T and 0724T for CY 2025.

TABLE 49: PROPOSED CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE QMRCP PROCEDURE

CPT Code	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
0723T	Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained without diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session	S	1511
0724T	Quantitative magnetic resonance cholangiopancreatography (QMRCP), including data preparation and transmission, interpretation and report, obtained with diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (e.g., organ, gland, tissue, target structure) (list separately in addition to code for primary procedure)	S	1511

We did not receive any public comments on our proposal to continue to assign the CPT codes 0723T and 0724T to New Technology APC 1511 (New Technology—Level 11 ($901–$1,000)). Our updated claims data did not show any additional claims for CY 2023 for CPT codes 0723T and 0724T. Therefore, we are finalizing our proposal without modification to continue to assign CPT codes 0723T and 0724T to APC 1511. Please refer to Table 50 for the final OPPS New Technology APC and status indicator assignment for CPT codes 0723T and 0724T for CY 2025. The final CY 2025 payment rates can be found in Addendum B to this final rule with comment period via the internet on the CMS website. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

TABLE 50: FINAL CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE QMRCP PROCEDURE

CPT Code	Long Descriptor	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
0723T	Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained without diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session	S	1511
0724T	Quantitative magnetic resonance cholangiopancreatography (QMRCP), including data preparation and transmission, interpretation and report, obtained with diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (e.g., organ, gland, tissue, target structure) (list separately in addition to code for primary procedure)	S	1511

q. Scalp Cooling (APC 1519)

CPT code 0662T (Scalp cooling, mechanical; initial measurement and calibration of cap) became effective on July 1, 2021, to describe initial measurement and calibration of a scalp cooling device for use during chemotherapy administration to prevent hair loss. According to Medicare's National Coverage Determination (NCD) policy, specifically, NCD 110.6 (Scalp Hypothermia During Chemotherapy to Prevent Hair Loss), the scalp cooling cap itself is classified as an incident to supply to a physician service, and would not be paid under the OPPS; however, interested parties have indicated that there are substantial resource costs of around $1,900 to $2,400 associated with calibrating and fitting the cap. CPT guidance states that CPT code 0662T should be billed once per chemotherapy session, which we interpret to mean once per course of chemotherapy. Therefore, if a course of chemotherapy involves, for example, 6 or 18 sessions, HOPDs should report CPT 0662T only once for that 6 or 18 therapy sessions.

For CY 2022, we assigned CPT code 0662T to APC New Technology 1520 (New Technology—Level 20 ($1,801–$1,900)) with a payment rate of $1,850.50. For CY 2023, we did not have any claims data, so we continued to assign CPT code 0662T to APC 1520. For CY 2024 we finalized reassignment of CPT code 0662T to APC 1514 (New Technology—Level 14 ($1,201–$1,300)) with a payment rate of $1,250.50 based on 11 single frequency claims.

For CY 2025, the OPPS payment rates were proposed to be based on available CY 2023 claims data. The Scalp Cooling service became effective in the OPPS in CY 2022, and we identified 38 single frequency paid claims for CPT code 0662T for CY 2023. As this is below the threshold of 100 claims for a service within a year, we proposed to designate CPT code 0662T as a low volume service under our universal low volume APC policy and to use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign the service to the appropriate New Technology APC. Based on our review of the available claims, we determined that the geometric mean cost for CPT code 0662T was approximately $841; the median was approximately $1,351; and the arithmetic mean was approximately $1,361. Therefore, for CY 2025, we proposed to designate this service as a low volume service under our universal low volume APC policy and to reassign CPT code 0662T to APC 1515 (New Technology—Level 15 ($1301–$1400)) with a payment rate of $1,350.50 for CY 2025 based on the arithmetic mean of approximately $1,361.Please refer to Table 51 below for the proposed OPPS New Technology APC and status indicator assignment for CPT code 0662T. The proposed CY 2025 payment rates can be found in Addendum B CY 2025 OPPS/ASC proposed rule via the internet on the CMS website.

TABLE 51: PROPOSED CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR SCALP COOLING

HCPCS	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
0662T	Scalp cooling, mechanical; initial measurement and calibration of cap	S	1515

We did not receive any public comments on our proposal. We note that additional claims for CPT code 0662T have been processed since the proposed rule. Specifically, there are 50 single frequency claims for CPT code 0662T for CY 2023. Since this is below the threshold of 100 claims, we are finalizing our proposal to designate CPT code 0662T as a low volume service under our universal low volume APC policy and use the greater of the geometric mean, arithmetic mean, or median cost based on the available claims data for CPT code 0662T to calculate an appropriate payment rate for purposes of assigning CPT code 0662T to a New Technology APC. Based on the updated claims data available for this final rule, we found the geometric mean cost to be approximately $1,110, the median to be $1,750, and the arithmetic mean to be $1,420. The median was the statistical methodology that estimated the highest cost for the service. The payment rate calculated using this methodology falls within the cost band for New Technology APC 1519 (New Technology—Level 19 ($1701–$1800)). Therefore, we are assigning CPT code 0662T to APC 1519 for CY 2025.

Please refer to Table 52 for the final OPPS New Technology APC and status indicator assignments for CPT code 0662T for CY 2025. The final CY 2025 payment rates can be found in Addendum B to this final rule with comment period via the internet on the CMS website. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

TABLE 52: PROPOSED AND FINAL CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR SCALP COOLING

HCPCS	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
0662T	Scalp cooling, mechanical; initial measurement and calibration of cap	S	1515	S	1519

r. Supervised Visits for Esketamine Self-Administration (APCs 1513 and 1518)

On March 5, 2019, FDA approved Spravato™ (esketamine) nasal spray, used in conjunction with an oral antidepressant, for treatment of depression in adults who have tried other antidepressant medicines but have not benefited from them (treatment-resistant depression (TRD)). This is the first FDA approval of esketamine for any use.

Esketamine is a noncompetitive N-methyl D-aspartate (NMDA) receptor antagonist. It is a nasal spray supplied as an aqueous solution of esketamine hydrochloride in a vial with a nasal spray device. Each device delivers two sprays containing a total of 28 mg of esketamine. Patients would require either two (2) devices (for a 56 mg dose) or three (3) devices (for an 84 mg dose) per treatment.

Because of the risk of serious adverse outcomes resulting from sedation and dissociation caused by esketamine nasal spray administration, and the potential for misuse of the product, it is only available through a restricted distribution system under a Risk Evaluation and Mitigation Strategy (REMS). A REMS is a drug safety program that the FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. The Spravato™ REMS program requires the esketamine nasal spray to be dispensed and administered to enrolled patients in health care settings that are certified in the REMS. See *www.fda.gov* for more information regarding the Spravato™ REMS program compliance requirements.

A treatment session of esketamine consists of instructed nasal self-administration by the patient followed by a period of at least 2 hours post-administration observation of the patient under direct supervision of a health care professional in the certified health care setting. Refer to the CY 2020 PFS final rule and interim final rule for

more information about supervised visits for esketamine nasal spray self-administration (84 FR 63102 through 63105).

To facilitate prompt beneficiary access to the new, potentially life-saving treatment for TRD using esketamine, we created two new HCPCS G codes, G2082 and G2083, effective January 1, 2020. HCPCS code G2082 is for an outpatient visit for the evaluation and management of an established patient who requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine through nasal self-administration and includes 2 hours of post-administration observation. For CY 2020, HCPCS code G2082 was assigned to New Technology APC 1508 (New Technology—Level 8 ($601–$700)) with a payment rate of $650.50. HCPCS code G2083 describes a similar service to HCPCS code G2082 but involves the administration of more than 56 mg of esketamine. For CY 2020, HCPCS code G2083 was assigned to New Technology APC 1511 (New Technology—Level 11 ($901–$1000)) with a payment rate of $950.50. Updates to the APC assignments for G2082 and G2083 have been made in past rules. See the CY 2021 OPPS/ASC final rule with comment period (85 FR 85948), CY 2022 OPPS/ASC final rule with comment period (86 FR 63538), CY 2023 OPPS/ASC final rule with comment period (87 FR 71816–71817), and CY 2024 OPPS/ASC final rule with comment period (88 FR 81628—81630) for these updates.

For CY 2025, the OPPS payment rates were proposed based on available CY 2023 claims data as the available single frequency claims exceed the 100 claims threshold generally used for our universal low volume policy. Therefore, for CY 2025, we proposed to assign HCPCS codes G2082 and G2083 to New Technology APCs based on the codes' geometric mean costs. Specifically, we proposed to assign HCPCS code G2082 to New Technology APC 1512 (New Technology—Level 12 ($1001–$1100)) with a payment rate of $1,050.50 based on its geometric mean cost of $1,087, which was calculated using the available 424 single frequency claims from CY 2023 claims data. We also proposed to assign HCPCS code G2083 to New Technology APC 1518 (New Technology—Level 18 ($1601–$1700)) with a payment rate of $1,650.50 based on its geometric mean cost of $1,643, which was calculated using the available 2,482 single frequency claims from CY 2023 claims data.

Refer to Table 53 for the New Technology APC and status indicator assignments for HCPCS codes G2082 and G2083. The proposed CY 2025 payment rates for these HCPCS codes can be found in Addendum B to the CY 2025 OPPS/ASC proposed rule.

TABLE 53: FINAL CY 2024 AND PROPOSED CY 2025 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR HCPCS CODES G2082 AND G2083

HCPCS Code	Long Descriptor	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
G2082	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation	S	1513	S	1512
G2083	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of greater than 56 mg esketamine nasal self-administration, includes 2 hours post-administration observation	S	1520	S	1518

We did not receive any public comments on our proposal. We note however that the geometric mean costs for both HCPCS code G2082 and HCPCS code G2083 have changed since the proposed rule. Based on the updated claims data available for this final rule, the geometric mean cost for HCPCS code G2082 is $1,104.71 and the geometric mean cost for G2083 is $1,448.83. Based on updated claims data available for this final rule with comment period, we are finalizing a New Technology APC assignment for HCPCS code G2082 to APC 1513 (New Technology—Level 13 ($1101–$1200)) with a payment of $1150.50 and we are finalizing a New Technology APC assignment for HCPCS code G2083 to APC 1516 (New Technology—Level 16 ($1401–$1500)) with a payment of $1450.50.

Please refer to Table 54 for the CY 2025 proposed and final APC and SI assignments for HCPCS codes G2082 and G2083. The CY 2025 payment rates can be found in Addendum B to this final rule with comment period via the internet on the CMS website.

Finally, we note that because we have gathered additional claims data and seen increases in claims volume, we are considering placing HCPCS codes G2082 and G2083 into clinical APCs through future rulemaking.

TABLE 54: PROPOSED AND FINAL CY 2025 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR HCPCS CODES G2082 AND G2083

HCPCS Code	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
G2082	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of up to 56mg of esketamine nasal self-administration, includes 2 hours post-administration observation.	S	1512	S	1513
G2083	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of up to 56mg of esketamine nasal self-administration, includes 2 hours post-administration observation.	S	1518	S	1516

s. Surfacer® Inside-Out® Access Catheter System (APC 1534)

HCPCS code C9780 (Insertion of central venous catheter through central venous occlusion via inferior and superior approaches (*e.g.,* inside-out technique), including imaging guidance) describes the procedure associated with the use of the Surfacer® Inside-Out® Access Catheter System that is designed to address central venous occlusion. HCPCS code C9780 was established on October 1, 2021, and since its establishment the code has been assigned to New Technology APC 1534 (New Technology—Level 34 ($8001–$8500)).

For CY 2025, there were only 3 single frequency claims in CY 2023 for HCPCS code C9780. There were no available claims from CY 2021 or CY 2022. Given our proposal to maintain current New Technology APC assignments for CY 2025 for New Technology APC services with fewer than 10 claims in the 4-year lookback period applicable for the universal low volume APC policy, we proposed to continue to assign HCPCS code C9780 to APC 1534 (New Technology—Level 34 ($8001–$8500)) with a payment rate of $8,250.50. Refer to Table 55 for the proposed New Technology APC and status indicator assignments for HCPCS code C9780.

TABLE 55: PROPOSED CY 2025 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENT FOR SURFACER® INSIDE-OUT® ACCESS CATHETER SYSTEM PROCEDURE

HCPCS Code	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
C9780	Insertion of central venous catheter through central venous occlusion via inferior and superior approaches (e.g., inside-out technique), including imaging guidance	S	1534

We did not receive any public comments on our proposal to continue to assign CPT code C9870 to APC 1534 (New Technology—Level 34 ($8001–$8500)). We note that there was one additional claim in our updated claims data, however, the total number of claims for CY 2023 is still under 10. Therefore, given our new policy to maintain current New Technology APC assignments for CY 2025 for New Technology APC services with fewer than 10 claims in the 4-year lookback period applicable for the universal low volume APC policy, we are finalizing as proposed to continue to assign CPT code C9870 to APC 1534. Please refer to Table 56 below for the final OPPS New Technology APC and status indicator assignment for HCPCS code C9780. The final CY 2025 payment rates can be found in Addendum B to this final rule with comment period via the internet on the CMS website.

TABLE 56: FINAL CY 2025 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENT FOR SURFACER® INSIDE-OUT® ACCESS CATHETER SYSTEM PROCEDURE

HCPCS Code	Long Descriptor	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
C9780	Insertion of central venous catheter through central venous occlusion via inferior and superior approaches (e.g., inside-out technique), including imaging guidance	S	1534

t. TASS (APC 1537)

The Transcatheter Atrial Shunt System (TASS) is a nitinol self-expanding cardiovascular implant consisting of four arms including two left atrial (LA) arms and two coronary sinus (CS) arms placed between the left atrium and coronary sinus to create a 7mm flow diameter channel for blood to flow from the high pressure region of the left atrium to the lower pressure region of the right atrium via the coronary sinus. TASS is currently in a Category B IDE clinical trial. Effective October 1, 2023 CMS created HCPCS code C9792 (Blinded or nonblinded procedure for symptomatic New York Heart Association (NYHA) Class II, III, IV a heart failure; transcatheter implantation of left atrial to coronary sinus shunt using jugular vein access, including all imaging necessary to intra procedurally map the coronary sinus for optimal shunt placement (*e.g.,* TEE or ICE ultrasound, fluoroscopy), performed under general anesthesia in an approved investigational device exemption (IDE) study) to describe the TASS service and assigned it to APC 1537 (New Technology—Level 37 ($9501–$10000)) with a payment rate of $9,750.50.

For CY 2025, the proposed OPPS payment rates were based on available CY 2023 claims data. Due to the effective date of the code of October 1, 2023, there were no claims available for HCPCS code C9792 for rate setting in CY 2024. Therefore, in CY 2025, we proposed to continue to assign HCPCS code C9792 to APC 1537.

Please refer to Table 57 below for the current and proposed OPPS New Technology APC and status indicator assignments for HCPCS code C9792. The proposed CY 2025 payment rates can be found in Addendum B to the proposed rule via the internet on the CMS website.

TABLE 57: PROPOSED CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR TRANSCATHETER ATRIAL SHUNT SYSTEM

HCPCS	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
C9792	Blinded or nonblinded procedure for symptomatic New York Heart Association (NYHA) Class II, III, IVa heart failure; transcatheter implantation of left atrial to coronary sinus shunt using jugular vein access, including all imaging necessary to intra procedurally map the coronary sinus for optimal shunt placement (e.g., TEE or ICE ultrasound, fluoroscopy), performed under general anesthesia in an approved investigational device exemption (IDE) study	S	1537

Comment: We received a comment supporting our proposal to continue to assign HCPCS code C9792 to APC 1537.

Response: We appreciate the commenter's support for our proposal.

After consideration of the public comments we received, we are finalizing our proposal without modification to assign CPT code C9792 to APC 1537 (New Technology—Level 37 ($9501–$10000)) with a payment rate of $9,750.50 for CY 2025. Please refer to Table 58 for the final OPPS New Technology APC and status indicator assignment for HCPCS code C9792. The final CY 2024 payment rates can be found in Addendum B to this final rule with comment period via the internet on the CMS website.

TABLE 58: FINAL CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR TRANSCATHETER ATRIAL SHUNT SYSTEM

HCPCS	Long Descriptor	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
C9792	Blinded or nonblinded procedure for symptomatic New York Heart Association (NYHA) Class II, III, IVa heart failure; transcatheter implantation of left atrial to coronary sinus shunt using jugular vein access, including all imaging necessary to intra procedurally map the coronary sinus for optimal shunt placement (e.g., TEE or ICE ultrasound, fluoroscopy), performed under general anesthesia in an approved investigational device exemption (IDE) study	S	1537

u. Magnetic Resonance Imaging With Inhaled Hyperpolarized Xenon-129 Contrast Agent (APC 1551)

HCPCS code C9791 (Magnetic resonance imaging with inhaled hyperpolarized xenon-129 contrast agent, chest, including preparation and administration of agent) was established on October 1, 2023. For CY 2023, we assigned HCPCS code C9791 to New Technology APC 1551 (New Technology—Level 14 ($1201–$1300)). For CY 2024, the OPPS payment rates were based on claims submitted between January 1, 2022, and December 31, 2022, processed through June 30, 2023. Due to the effective date of the service of October 1, 2023, there were no claims available for HCPCS code C9791 for rate setting in CY 2024. Therefore, in CY 2024, we continued to assign HCPCS code C9791 to New Technology APC 1551.

For CY 2025, the proposed OPPS payment rates were based on available CY 2023 claims data. Although HCPCS code C9791 was effective October 1, 2023, we did not have any claims data for the service for the proposed rule. Therefore, for CY 2025, we proposed to continue to assign HCPCS code C9791 to New Technology APC 1551 (New Technology—Level 14) with a proposed payment rate of $1,250.50.

Please refer to Table 59 for the proposed OPPS New Technology APC and status indicator assignment for HCPCS code C9791 for CY 2025.

TABLE 59: PROPOSED CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR MAGNETIC RESONANCE IMAGING WITH INHALED HYPERPOLARIZED XENON-129 CONTRAST AGENT PROCEDURE

CPT Code	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
C9791	Magnetic resonance imaging with inhaled hyperpolarized xenon-129 contrast agent, chest, including preparation and administration of agent	T	1551

We did not receive any public comments on our proposal, and we still do not have any claims for the service. Therefore, for CY 2025, we are finalizing our proposal without modification to assign HCPCS code C9791 to New Technology APC 1551 (New Technology—Level 14 ($1201–$1300)) and SI ''T''. The final New Technology APC and status indicator assignments for HCPCS code C9791 for CY 2025 are found in Table 60. The CY 2025 payment rates can be found in Addendum B to this final rule with comment period via the internet on the CMS website. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

TABLE 60: FINAL CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR MAGNETIC RESONANCE IMAGING WITH INHALED HYPERPOLARIZED XENON-129 CONTRAST AGENT PROCEDURE

CPT Code	Long Descriptor	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
C9791	Magnetic resonance imaging with inhaled hyperpolarized xenon-129 contrast agent, chest, including preparation and administration of agent	T	1551

v. SAINT Neuromodulation System

The SAINT Neuromodulation System is a non-invasive repetitive transcranial magnetic stimulation (rTMS) system that identifies an individualized target and delivers navigationally directed repetitive magnetic pulses to that individualized target located within the left dorsolateral prefrontal cortex to treat major depressive disorder (MDD). The patient first receives structural MRI and functional MRI scans that are analyzed by the provider to identify and localize the personalized stimulation target in the patient's dorsolateral prefrontal cortex. Once the areas targeted for treatment are identified, the patient receives non-invasive magnetic stimulation in the targeted area. The patient has 10 treatment sessions per day with each treatment session lasting 10 minutes followed by 50 minutes of rest before another treatment session occurs. The treatment is administered over five days for a total of 50 sessions of non-invasive magnetic stimulation therapy. There are four CPT codes listed in Table 61 that describe the MRI scans that are used to target the treatment and describe the administration of the non-invasive magnetic stimulation therapy.

TABLE 61: SAINT NEUROMODULATION SYSTEM CPT CODES AND DESCRIPTORS

CPT Code	Long Descriptor
0889T	Personalized target development for accelerated, repetitive high-dose functional connectivity MRI–guided theta-burst stimulation derived from a structural and resting-state functional MRI, including data preparation and transmission, generation of the target, motor threshold–starting location, neuronavigation files and target report, review and interpretation
0890T	Accelerated, repetitive high-dose functional connectivity MRI–guided theta-burst stimulation, including target assessment, initial motor threshold determination, neuronavigation, delivery and management, initial treatment day
0891T	Accelerated, repetitive high-dose functional connectivity MRI–guided theta-burst stimulation, including neuronavigation, delivery and management, subsequent treatment day
0892T	Accelerated, repetitive high-dose functional connectivity MRI–guided theta-burst stimulation, including neuronavigation, delivery and management, subsequent motor threshold redetermination with delivery and management, per treatment day

For CY 2025, the OPPS payment rates were proposed based on available CY 2023 claims data. However, CPT codes 0889T, 0890T, 0891T, and 0892T did not become effective until July 1, 2024, which means there was no claims data for the procedures described these CPT codes. We assigned our proposed rates for these services based on our evaluation of the resources needed to perform these services. Table 62 lists CPT codes 0889T, 0890T, 0891T, and 0892T and our proposed status indicator and APC assignment for CY 2025.

TABLE 62: PROPOSED CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR SERVICES ASSOCIATED WITH THE SAINT NEUROMODULATION SYSTEM

CPT Code	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
0889T	Personalized target development for accelerated, repetitive high-dose functional connectivity MRI–guided theta-burst stimulation derived from a structural and resting-state functional MRI, including data preparation and transmission, generation of the target, motor threshold–starting location, neuronavigation files and target report, review and interpretation	S	1511
0890T	Accelerated, repetitive high-dose functional connectivity MRI–guided theta-burst stimulation, including target assessment, initial motor threshold determination, neuronavigation, delivery and management, initial treatment day	S	1522
0891T	Accelerated, repetitive high-dose functional connectivity MRI–guided theta-burst stimulation, including neuronavigation, delivery and management, subsequent treatment day	S	1522
0892T	Accelerated, repetitive high-dose functional connectivity MRI–guided theta-burst stimulation, including neuronavigation, delivery and management, subsequent motor threshold redetermination with delivery and management, per treatment day	S	1522

Comment: Several commenters, including clinicians and other interested parties, believe that the payment rate of $2,250.50 for the proposed APC assignment to New Technology APC 1522 (New Technology—Level 22 ($2001–$2500)) for CPT codes 0890T, 0891T, and 0892T that describes the administration of the non-invasive magnetic stimulation therapy is too low. The commenters are concerned that the proposed payment rate will discourage providers from using the SAINT neuromodulation system to treat MDD. The commenters supported assigning CPT codes 0890T, 0891T, and 0892T to New Technology APC 1528 (New Technology—Level 28 ($5001–$5500)) with a payment rate of $5,250.50 to better reflect the resource cost of each of these three services. Multiple commenters also felt that the IPPS new technology add-on payment amount for the SAINT neuromodulation system acknowledged the cost of the SAINT system.

Response: We do not have any claims data to directly determine the cost of the procedures described by CPT codes 0890T, 0891T, and 0892T. Therefore, we make our assessment of the resource costs to perform the procedure based on our judgment of the clinical and resource information presented to us about the SAINT neuromodulation system and the treatment approach in the manufacturer's OPPS New Technology APC application and through comments on the proposed rule. We agree with the commenters that the cost per case used for purposes of determining the IPPS maximum new technology add-on payment amount (88 FR 58938) was a more appropriate estimate of the cost of the SAINT neuromodulation system than our original cost estimate for the procedure in the CY 2025 OPPS proposed rule. For purposes of determining the new technology add-on payment amount, the cost estimate for the entire SAINT course of treatment, which included fifty sessions over five days of the non-invasive magnetic stimulation therapy and related operating costs, was $19,500.

Our review has determined that the cost estimate of the procedure described by CPT code 0899T should remain the same and CPT code 0899T should

continue to be assigned to New Technology APC 1511 (New Technology—Level 11 ($901–$1000)) with a payment rate of $950.50. However, we now have determined that the per day cost of the services described by CPT codes 0890T, 0891T, and 0892T is around $3,710 instead of our proposed estimate of around $2,250. We are changing the APC assignment for CPT codes 0890T, 0891T, and 0892T to New Technology APC 1525 (New Technology—Level 25 ($3501–$4000)) with a payment rate of $3,750.50.

Comment: Several commenters described their experiences with MDD and receiving treatment for their MDD using the SAINT neuromodulation system. All of these commenters claimed that the SAINT therapy was beneficial to them and helped to reduce the symptoms of MDD, which substantially improved their mental health. Many of these commenters were able to receive SAINT because they participated in clinical trials for the therapy or were able to afford the treatment even if it was not covered by health insurance. The commenters want us to ensure that SAINT will be affordable to patients who receive treatment, and that SAINT will be widely available throughout the United States, so those who have MDD are able to access this therapy.

Response: We thank commenters for their input, and we are committed to establishing appropriate payment for the services described by CPT codes 0890T, 0891T, and 0892T.

After consideration of the public comments we received, we are finalizing our proposal with modification for CY 2025 to assign CPT code 0899T to New Technology APC 1511 (New Technology—Level 11 ($901–$1000)) and SI of ''S'' and to assign CPT codes 0890T, 0891T and 0892T to New Technology APC 1525 (New Technology—Level 25 ($3501–$4000)) and SI of ''S''. The final New Technology APC and status indicator assignments for CPT codes 0889T, 0890T, 0891T, and 0892T for CY 2025 are found in Table 63. The CY 2025 payment rates can be found in Addendum B to this final rule with comment period via the internet on the CMS website. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

TABLE 63: FINAL CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR SERVICES ASSOCIATED WITH THE SAINT NEUROMODULATION SYSTEM

CPT Code	Long Descriptor	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
0889T	Personalized target development for accelerated, repetitive high-dose functional connectivity MRI–guided theta-burst stimulation derived from a structural and resting-state functional MRI, including data preparation and transmission, generation of the target, motor threshold–starting location, neuronavigation files and target report, review and interpretation	S	1511
0890T	Accelerated, repetitive high-dose functional connectivity MRI–guided theta-burst stimulation, including target assessment, initial motor threshold determination, neuronavigation, delivery and management, initial treatment day	S	1525
0891T	Accelerated, repetitive high-dose functional connectivity MRI–guided theta-burst stimulation, including neuronavigation, delivery and management, subsequent treatment day	S	1525
0892T	Accelerated, repetitive high-dose functional connectivity MRI–guided theta-burst stimulation, including neuronavigation, delivery and management, subsequent motor threshold redetermination with delivery and management, per treatment day	S	1525

D. Universal Low Volume APC Policy for Clinical and Brachytherapy APCs

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63743 through 63747), we adopted a policy to designate clinical and brachytherapy APCs as low volume APCs if they have fewer than 100 single claims that can be used for ratesetting purposes in the claims year used for ratesetting for the prospective year. For the CY 2025 OPPS/ASC proposed rule, CY 2023 claims are generally the claims used for ratesetting; and clinical and brachytherapy APCs with fewer than 100 single claims from CY 2023 that can be used for ratesetting would be low volume APCs subject to our universal low volume APC policy. As we stated in the CY 2022 OPPS/ASC final rule with comment period, we adopted this policy to reduce the volatility in the payment rate for those APCs with fewer than 100 single claims. Where a clinical or brachytherapy APC has fewer than 100 single claims that can be used for ratesetting, under our low volume APC payment adjustment policy, we determine the APC cost as the greatest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data. We excluded APC 5853 (Partial Hospitalization for CMHCs) and APC 5863 (Partial Hospitalization for Hospital-based PHPs) from our universal low volume APC policy given the different nature of policies that affect the partial hospitalization program. We also excluded APC 2698 (Brachytx, stranded, nos) and APC 2699 (Brachytx, non-stranded, nos) as our current methodology for determining payment rates for non-specified brachytherapy sources is appropriate.

Based on claims data available for the CY 2025 OPPS/ASC proposed rule, we proposed to designate six brachytherapy APCs and five clinical APCs as low volume APCs under the OPPS. The six brachytherapy APCs and five clinical APCs meet our criteria of having fewer than 100 single claims in the claims' year used for ratesetting (CY 2023 for the CY 2025 OPPS/ASC proposed rule). Nine of the 11 APCs were designated as low volume APCs in CY 2024. Based on data for the CY 2025 OPPS/ASC proposed rule, APC 2645 (Brachytx,

non-stranded, gold-198) and APC 5881 (Ancillary Outpatient Services When Patient Dies) met our criteria to be designated a Low Volume APCs; and we proposed to designate those APCs as such for CY 2025.

We did not receive any public comments on our proposal. Based on CY 2023 claims data available for this final rule with comment period, we are finalizing our proposal to designate six brachytherapy APCs and five clinical APCs as low volume APCs under the OPPS. Table 64 includes the CY 2023 claims available for ratesetting for each of the APCs we are designating as Low Volume APCs for CY 2025. The final cost statistics for our CY 2025 Low Volume APCs, such as the median, arithmetic mean, and geometric mean cost are available for download with this final rule with comment period on the CMS website. We refer readers to our website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*; click on the relevant regulation to download the low volume APC cost statistics under the comprehensive (OPPS) ratesetting methodology in the downloads section of the web page.

TABLE 64: FINAL LOW VOLUME APCS USING COMPREHENSIVE (OPPS) RATESETTING METHODOLOGY FOR CY 2025

APC	APC Description	CY 2023 Claims Available for Ratesetting
2632	Iodine I-125 sodium iodide	1
2635	Brachytx, non-str, HA, p-103	20
2636	Brachy linear, non-str, p-103	1
2642	Brachytx, stranded, c-131	95
2645	Brachytx, non-str, gold-198	96
2647	Brachytx, NS, Non-HDRIr-192	2
5244	Level 4 Blood Product Exchanges and Related Services	60
5494	Level 4 Intraocular Procedures	88
5495	Level 5 Intraocular Procedures	62
5496	Level 6 Intraocular Procedures	29
5881	Ancillary Outpatient Services When Patient Dies	75

E. APC-Specific Policies

1. Cardiac CT Services, CPT Codes 75572, 75573, and 75574 (APC 5572)

For the 2006 coding update, the AMA's CPT Editorial Panel established six Category III CPT codes to describe cardiac computed tomography angiography with contrast materials (cardiac CT services) effective January 1, 2006. The codes were active and separately payable under the OPPS between January 1, 2006, and December 31, 2009. The CPT Editorial Panel deleted the Category III CPT codes and replaced them with Category I CPT codes 75572 through 75574 effective January 1, 2010. With the deletion of the Category III CPT codes on December 31, 2009, we crosswalked the APC assignments from the Category III CPT codes (predecessor codes) to the new Category I CPT codes effective January 1, 2010. Since 2010, the Category I CPT codes describing cardiac CT services are CPT codes 75572, 75573, and 75574. The codes and their long descriptors are listed below.

- 75572: Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology (including 3D image postprocessing, assessment of cardiac function, and evaluation of venous structures, if performed).
- 75573: Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology in the setting of congenital heart disease (including 3D image postprocessing, assessment of left ventricular (LV) cardiac function, right ventricular (RV) structure and function and evaluation of vascular structures, if performed).
- 75574: Computed tomographic angiography, heart, coronary arteries and bypass grafts (when present), with contrast material, including 3D image postprocessing (including evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluation of venous structures, if performed).

Like the predecessor codes, CPT codes 75572, 75573, and 75574 have been paid separately under the OPPS since 2010. From CY 2015 through CY 2024, the OPPS payment rate, based on the geometric mean cost for the cardiac CT codes, has ranged between $175 and $265 for these codes, as listed in Table 65 below.

TABLE 65: CY 2015 - CY 2024 OPPS PAYMENT RATES FOR CPT CODES 75572 – 75574

CPT Codes	CY 2015	CY 2016	CY 2017	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
75572 - 75574	$216.05	$236.86	$265.02	$252.74	$201.74	$182.22	$178.55	$182.43	$180.34	$175.06

We note that the OPPS payment rate applies only to the hospital outpatient facility and does not include the physician service payment. Physician services are paid under Medicare's Physician Fee Schedule (PFS).

We update the OPPS payment rates on an annual basis consistent with the requirements set forth in section 1833(t)(9)(A) of the Act, which requires the HHS Secretary to review, not less often than annually, and revise the APC groups, the relative payment weights, and the wage and other adjustments to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. Because of the annual updates, OPPS payment rates for services may fluctuate from year to year. We note that we generally use the latest claims data available to set the annual payment rates. Payment rates for this CY 2025 OPPS/ASC final rule with comment period are based on claims with dates of service between January 1, 2023, and December 31, 2023, processed through June 30, 2024.

Over the years we have received comments noting that the payment for these codes has declined since 2017. Comments on previous OPPS proposed rules have indicated that the payment amount is insufficient to cover the cost of providing the service and have stated that the payment amount does not consider the hospital resources required to perform these services, including the use of the equipment, medication administration, staff time, and scanner time. We have maintained over the years that an analysis of our claims data for these three codes have shown geometric mean costs consistent with the geometric mean cost for APC 5571 (Level 1 Imaging with Contrast), the APC to which the cardiac CT codes have been assigned since 2015.

We have also received comments in the past urging CMS to allow hospitals the flexibility to submit charges for cardiac CT services with a revenue code other than CT scan (035X) and Radiology Diagnostic (032X) revenue codes, implying that MACs had applied edits to the cardiac CT codes that prevented hospitals from reporting a cardiology (048X) revenue code when appropriate. It is longstanding CMS policy that hospital outpatient facilities are responsible for reporting the appropriate cost centers and revenue codes on claims. As stated in section 20.5 in Chapter 4 (Part B Hospital) of the Medicare Claims Processing Manual, CMS ''does not instruct hospitals on the assignment of HCPCS codes to revenue codes for services provided under OPPS since hospitals' assignments of cost vary. Where explicit instructions are not provided, HOPDs should report their charges under the revenue code that will result in the charges being assigned to the same cost center to which the cost of those services are assigned in the cost report.'' We have consistently stated that hospital outpatient facilities must determine the most appropriate cost center and revenue code for the cardiac CT codes (87 FR 71849, 88 FR 81664).

After we issued the CY 2024 OPPS/ASC final rule, interested parties notified us of a specific claims edit that may have limited the revenue codes reported with the cardiac CT codes in prior years' claims data. CMS removed the revenue code edit in early December 2023 to allow for the cardiac CT codes to be billed with any appropriate revenue code. We informed the public of our findings and the changes that we made in the January 2024 OPPS Update (Transmittal 12421, Change Request 13488), dated December 21, 2023. We believe the edit may have prevented some providers from reporting the cardiology revenue code (048X), which maps to the cardiology cost center (03140), when billing for cardiac CT services. In the past, commenters have indicated that the cardiology cost center has a higher cost-to-charge ratio (CCR) than the imaging cost centers, and they believe the inability to report the cardiology revenue code has resulted in a lower payment rate for cardiac CT services. Since the OPPS ratesetting process utilizes the applicable cost center's CCR to reduce the charges on the claim to estimated cost, utilizing cost centers with lower CCRs results in a lower OPPS payment compared to utilizing cost centers with higher CCRs. With the edit no longer in place, hospitals may bill for cardiac CT services with whichever revenue code they believe appropriate for CY 2024, including cardiology revenue code 048X, and the CY 2026 OPPS payment rates (which most likely will be based on CY 2024 claims) will reflect those updated revenue code billing patterns. We note that for CY 2025, based on our standard ratesetting methodology using claims submitted during CY 2023, our analysis reveals that the angiocardiography and CT scan revenue codes were reported with CPT codes 75572 through 75574, which were mapped to angiography and CT scan cost centers, as shown in Table 66.

TABLE 66: STANDARD OPPS RATESETTING METHODOLOGY –REVENUE CODES AND COST CENTERS REPORTED WITH THE CARDIAC COMPUTED TOMOGRAPHY (CT) CPT CODES 75572, 75573, AND 75574

Revenue Code	Revenue Code Description (applicable to CY 2023 claims)	Used in CY 2025 OPPS Ratesetting (Based on CY 2023 claims)	Primary Cost Center	Primary Cost Center Description
0321	Radiology - Diagnostic	Y	03030	Angiocardiography
0350	Computed tomographic (CT scan) - general	Y	05700	CT Scan
0351	Computed tomographic (CT scan) – head scan	Y	05700	CT Scan
0352	Computed tomographic (CT scan) – body scan	Y	05700	CT Scan
0359	Computed tomographic (CT scan) – other CT scans	Y	05700	CT Scan

Because we wanted to determine whether the revenue edit could have affected the geometric mean costs for CPT codes 75572 through 75574, we conducted studies prior to the CY 2025 proposed rule and during the comment period to calculate HCPCS geometric mean costs for these codes based on a simulation that assumed that differing numbers of HOPDs (specifically 25 percent, 50 percent, and 75 percent of the total number of HOPDs billing for these services) would have assigned these services to the cardiology revenue code (048X) and cardiology cost center (03140). Based upon the results of the studies, we found that if 50 percent or more of HOPDs had billed these services with the cardiology revenue code (048X) and cardiology cost center (03140), the geometric mean cost for these codes would have increased and would have resulted in a revised APC assignment from APC 5571 (Level 1 Imaging with Contrast) to APC 5572 (Level 2 Imaging with Contrast). As noted in Table 67, under our standard ratesetting methodology, the geometric mean cost for the cardiac CT codes would be approximately $182, which maps to APC 5571, while an assumption that 50 percent of HOPDs billed with the cardiology revenue code (048X) and cardiology cost center (03140) on CY 2023 claims would result in a geometric mean cost of about $386, which maps to APC 5572.

We also reviewed the limited CY 2024 claims data for cardiac CT services available to determine the percentage of HOPDs that are utilizing the cardiology revenue code (048X) and cardiology cost center (03140) with the understanding that many HOPDs may still be updating their current billing practices. We did not find any appreciable change in current billing practices.

TABLE 67: STANDARD OPPS RATESETTING METHODOLOGY VS. SIMULATED 50 PERCENT OF HOPDS UTILIZING THE CARDIOLOGY REVENUE CODE AND CARDIOLOGY COST CENTER

Code	Number of Claims Used for Ratesetting	Standard OPPS Methodology GMC	Standard OPPS Methodology Ambulatory APC	50 percent HOPD GMC	50 percent HOPD Methodology APC
75572	26,879	$148.88	APC 5571	$240.70	APC 5572
75573	647	$182.26	GMC	$278.20	GMC
75574	69,377	$185.98	$181.72	$299.80	$386.46

Because the RTP edit associated with the cardiac CT codes may have affected the CY 2023 data we have available to establish the CY 2025 OPPS payment rates for these services, in the CY 2025 OPPS/ASC proposed rule, we requested information on the following topics regarding hospitals' billing practices for cardiac CT services:

(1) Where are cardiac CT services performed in a hospital? Are cardiac CT services performed in a dedicated cardiology department, radiology department, or some other hospital outpatient department?

(2) What factors determine the revenue code assignment for cardiac CT services (*i.e.,* the department in which the service is performed, the type of service that is performed, or some other factor)?

(3) What revenue codes are HOPDs reporting for these services in CY 2024? Are HOPDs using the cardiology revenue code on claims for cardiac CT services now that they are no longer restricted from using this revenue code?

We stated in the CY 2025 OPPS/ASC proposed rule that we would use the comments received and the information from the CY 2024 claims data to help us identify whether the current OPPS payment is appropriate for the cardiac CT codes, or whether we should revise the payment methodology for the CY 2025 OPPS. We received a significant number of comments in response to our Request for Information. While a major portion of the comments were part of a large write-in campaign, commenters provided information specific to their experiences in their facilities. We appreciate all the feedback and address the comments below.

Comment: We received a significant number of comments in response to our Request for Information about cardiac CT services and the billing practices for these services. Commenters ranged from specialty societies to healthcare providers who practice in a variety of settings of different sizes and in various locations throughout the United States.

In terms of where cardiac CT services are performed, commenters shared that cardiac CT services may be performed in a radiology department, an interventional radiology department, a cardiology department, or a clinic setting. Resources to furnish the services, such as staff, are utilized from both the cardiology and radiology departments. Many commenters described the test being performed in radiology departments utilizing cardiology nursing staff to prepare the patient, administer medications (such as IV beta blockers and nitroglycerin), and monitor the patient during and after the procedure.

In terms of the factors that determine the revenue code assignment for cardiac CT services, most commenters stated that the resources used for these services are very similar to other cardiac procedures such as cardiac stress tests or even cardiac catheterizations, which are assigned to the cardiology revenue code. Commenters described cardiac CT services as resource intensive, stating that the cross-department coordination between cardiology and radiology, the skill level of staff (technicians, nurses, and physicians), the expense of up-to-date CT equipment, and the amount of testing time involved is comparable to other more expensive and invasive cardiac tests.

In response to our request for the revenue codes hospital outpatient departments are reporting with cardiac CT services now that there is not an edit in place prohibiting them from using the cardiology revenue code, commenters stated that they want to use the cardiology revenue code when billing cardiac CT services, but they are unable to due to third-party edits (billing and payer) in place from clearinghouses, billing companies, or billing software companies. Some stated that they have continued to use the radiology revenue codes to prevent receiving claims denials. Another commenter stated their coding staff expressed compliance concerns with assigning cardiac CT services to a cardiology revenue code versus the CT revenue code. Commenters requested that CMS provide education about revenue code use for providers, healthcare facilities, clearinghouses, and health plans and indicated that explicit education would facilitate use of the cardiac revenue code with cardiac CT services.

Many commenters shared how many cardiac CT services are completed per year at their facilities. They expressed concern about the declining payment for such a complex, resource-intensive test that is used to accurately diagnose and manage coronary artery disease and the impact that insufficient payment could have on beneficiary access. Commenters noted that cardiac CT has been identified by the American College of Cardiology as a first line approach to manage patients with chest pain and asserted that cardiac CT is more clinically useful than more expensive, invasive tests such as cardiac catheterizations.

Response: We thank the commenters for their feedback regarding the clinical value cardiac CT services provide for clinicians diagnosing and managing patients with chest pain and coronary artery disease. We also thank commenters for describing the process of cardiac CT tests and all the resources used in providing those services and sharing information about selection of revenue code assignment when billing for CT services.

We acknowledge commenters' concerns that, even with the revenue code edit removed for CY 2024, there are a number of procedural and logistical hurdles to providers billing with the cardiology revenue codes in CY 2024 and that it would not be realistic to expect a majority of providers to be billing with the cardiology revenue codes at this point due to those issues. We acknowledge that process changes often happen slowly and that it may take time for facilities to update their billing practices, even if the majority of providers would prefer to bill these codes with the cardiology revenue code.

We appreciate commenters sharing their concerns about third-party edits that are still affecting the billing process and understand their request for additional guidance from CMS. We remind readers that we informed the public of our findings and the changes that we made in the January 2024 OPPS Update (Transmittal 12421, Change Request 13488), dated December 21, 2023. Specifically, we stated the following: ''We recently identified an outdated return-to-provider (RTP) Healthcare Common Procedure Coding System-to-revenue code edit that resulted in certain claims submissions being limited to specific revenue codes for CPT codes 75572, 75573, and 75574. These claims were returned to the providers for resubmission. The outdated edit has been removed; and providers, when appropriate, may begin billing these codes with any appropriate revenue code.'' We have also stated in section 20.5 in Chapter 4 (Part B Hospital) of the Medicare Claims Processing Manual, CMS ''does not instruct hospitals on the assignment of HCPCS codes to revenue codes for services provided under OPPS since hospitals' assignments of cost vary. Where explicit instructions are not provided, HOPDs should report their charges under the revenue code that will result in the charges being assigned to the same cost center to which the cost of those services are assigned in the cost report.'' We have consistently stated that hospital outpatient facilities must determine the most appropriate cost center and revenue code for the cardiac CT codes (87 FR 71849, 88 FR 81664). While we believe that this information should suffice for education to third parties who may have edits in place that affect the selection of a cardiology

revenue code when billing for cardiac CT services and for other interested parties who have compliance concerns, we will be providing public education and instruction through the CMS Medicare Learning Network (MLN).

We are persuaded after a review of the comments submitted that a majority of providers who bill these codes would prefer to bill them with the cardiology revenue code but have not been able to do so due to the prior revenue code edit and remaining procedural hurdles that flow from the prior revenue code edit. As stated above, if there had not been a systems edit in place preventing providers from choosing the cardiology revenue code (048X) and cardiology cost center (03140) and 50 percent or more of HOPDs had billed these services with the cardiology revenue code and cardiology cost center, the geometric mean cost for these codes would have increased and would have resulted in a revised APC assignment from APC 5571 (Level 1 Imaging with Contrast) to APC 5572 (Level 2 Imaging with Contrast). Therefore, for CY 2025, we are using our equitable adjustment authority under section 1833(t)(2)(E) of the Act to utilize an alternative methodology to calculate the payment for the cardiac CT services in CY 2025 and subsequent years. Specifically, we are finalizing a temporary reassignment of the cardiac CT codes (CPT code 75572 through 75574) to APC 5572 (Level 2 Imaging with Contrast). See Table 68 for the CY 2025 Proposed and Final OPPS SI and APC assignments for CPT codes 75572 through 75574. We anticipate that it may take 3 to 4 years to see an impact from changes in billing practices from providers based on the comments we received on the proposed rule. If we do not see a significant change in the geometric mean costs after several years, we would revert payment for these services to the standard OPPS payment methodology and assign the cardiac CT codes to appropriate APCs based on their geometric mean costs. We note that this APC reassignment will not involve reprocessing of claims with dates prior to January 1, 2025.

TABLE 68: CY 2025 PROPOSED AND FINAL OPPS SI AND APCS FOR CPT CODES 75572, 75573, and 75574

CPT Code	Long Descriptor	Proposed CY 2025 APC	Proposed CY 2025 SI	Final CY 2025 APC	Final CY 2025 SI
75572	Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology (including 3D image postprocessing, assessment of cardiac function, and evaluation of venous structures, if performed).	5571	S	5572	S
75573	Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology in the setting of congenital heart disease (including 3D image postprocessing, assessment of left ventricular (LV) cardiac function, right ventricular (RV) structure and function and evaluation of vascular structures, if performed).	5571	S	5572	S
75574	Computed tomographic angiography, heart, coronary arteries and bypass grafts (when present), with contrast material, including 3D image postprocessing (including evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluation of venous structures, if performed).	5571	S	5572	S

The final CY 2025 payment with rates for the cardiac CT CPT codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI definitions for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

2. Neurostimulator and Related Procedures (APCs 5461 Through 5465)

In the CY 2021 OPPS/ASC final rule with comment period, we finalized a five-level APC structure for the Neurostimulator and Related Procedures series (85 FR 85968 through 85970). For a detailed discussion of the history of neurostimulators policy, we refer readers to the CY 2015, CY 2020, CY 2021, CY 2023, and CY 2024 OPPS/ASC final rules with comment period (79 FR 66807 through 66808; 84 FR 61162 through 6116, 85 FR 85968 through 85970; 87 FR 71869; 88 FR 81645 through 81658).

In the CY 2024 OPPS/ASC final rule with comment period, we did not make any changes to the 5 level APC structure for the Neurostimulator and Related Procedures series. However, we made temporary changes to services previously assigned to the neurostimulator APCS: reassigning HCPCS code 33276 (Insertion of phrenic nerve stimulator system (pulse generator and stimulating lead[s]), including vessel catheterization, all imaging guidance, and pulse generator initial analysis with diagnostic mode activation, when performed), with predecessor code 0424T, and 33287 (Removal and replacement of phrenic nerve stimulator, including vessel

catheterization, all imaging guidance, and interrogation and programming, when performed; pulse generator), from New Technology APC 1581 to New Technology APC 1580 (88 FR 81645 through 81647) and assigning HCPCS code 0266T (Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)) to New Tech APC 1580 (88 FR 81658).

For the CY 2025 OPPS/ASC proposed rule, we proposed to maintain the 5 level APC structure for the Neurostimulator series. We proposed to assign HCPCS codes 0266T and 33276 to the APC 5465 (Level 5 Neurostimulator and Related Procedures), given the cost and coding changes associated with those codes. We noted that while we have claims data available for HCPCS codes in the neurostimulator APC series that are no longer active, there would also be cost and coding changes associated with new CPT codes as their claims data become available.

While we continued to believe that a five-level structure for the Neurostimulator and Related Procedures APC series remained appropriate, we also solicited comments from interested parties in CY 2025 OPPS/ASC proposed rule on the need for a Level 6 APC, given the clinical and estimated cost characteristics of the services currently assigned to APC 5465 (Level 5 Neurostimulator and Related Procedures).

In summary, for the CY 2025 OPPS, we proposed to maintain the current 5-level structure for the Neurostimulator and Related Procedure APC series, assign HCPCS codes 0266T and 33276 to APC 5465, and solicited comment creating an additional Level 6 Neurostimulator APC.

See Table 69 for the services that we proposed to reassign to the Level 5 APC and Table 70 below for the proposed CY 2025 Neurostimulator and Related Procedures APCs.

TABLE 69: PROPOSED CY 2025 APC AND STATUS INDICATOR ASSIGNMENTS

HCPCS Code	HCPCS Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
0266T	Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)	J1	5465
33276	Insertion of phrenic nerve stimulator system (pulse generator and stimulating lead[s]), including vessel catheterization, all imaging guidance, and pulse generator initial analysis with diagnostic mode activation, when performed	J1	5465

TABLE 70: PROPOSED CY 2025 NEUROSTIMULATOR AND RELATED PROCEDURES APCS

APC	Group Title	SI	Proposed CY 2025 APC Geometric Mean Cost
5461	Level 1 Neurostimulator and Related Procedures	J1	$3,653.12
5462	Level 2 Neurostimulator and Related Procedures	J1	$6,779.89
5463	Level 3 Neurostimulator and Related Procedures	J1	$13,472.02
5464	Level 4 Neurostimulator and Related Procedures	J1	$21,777.61
5465	Level 5 Neurostimulator and Related Procedures	J1	$31,222.52

At the August 26, 2024, HOP Panel Meeting, several presenters provided information to the Panel regarding HCPCS codes 33276 (Insertion of phrenic nerve stimulator system (pulse generator and stimulating lead[s]), including vessel catheterization, all imaging guidance, and pulse generator initial analysis with diagnostic mode activation, when performed), 64568 (Open implantation of cranial nerve (*e.g.,* vagus nerve) neurostimulator electrode array and pulse generator), and 0266T (Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)). The presenters advised the Panel to request that CMS either create a new Level 6 Neurostimulator and Related Procedures APC and consider including the three codes mentioned above in the Level 6 Neurostimulator APC, or alternatively assign the three codes mentioned above to New Technology APC 1580 (New Technology—Level 43 ($40,001–$50,000)). The HOP Panel agreed with the presenter and made that recommendation.

Comment: Many commenters requested the creation of a Level 6 Neurostimulator and Related Procedures APC, noting that creating an additional APC would align payment more closely with costs incurred while maintaining access to services assigned to that APC. Many of these commenters requested that if a Level 6 APC could not be created, that HCPCS code 0266T be maintained in New Technology APC 1580 for an additional year. Other commenters asked that CMS reconsider the proposed assignment of HCPCS code 33276 to APC 5465 and place the code in an APC consistent with the resources required for the procedure. One of those commenters specifically requested an APC assignment to New Technology APC 1580 until a more permanent solution to address disparity between payment and resource costs could be determined. Some commenters requested that HCPCS code 64568 be moved from APC 5465 (Level 5 Neurostimulator and Related Procedures) to New Technology APC 1580. Two commenters supported maintaining the current 5 level APC structure for the Neurostimulator series. One of those commenters recommended that HCPCS codes 33276 and 0266T continue to be assigned to New Technology APC 1580 to maintain beneficiary access while additional claims data are collected, while the other recommended more broadly that New Technology APCs be used for similar scenarios where codes had high cost but low volume. One commenter believed that HCPCS code 64568 should remain assigned to APC 5465 (Level 5 Neurostimulator and Related Procedures) since it is a long-established procedure and would not be expected to have changes in cost or volume the way ''new'' technologies would.

Response: We appreciate the thoughtful responses commenters have provided with regard to the proposed policy and our requests for comments. While we understand the concerns and issues commenters have raised, we believe that the 5 level APC structure for the series continues to remain appropriate in grouping together procedures with similar cost and clinical characteristics. Therefore, we are finalizing the 5 level APC structure for the Neurostimulator and Related Procedures APCs.

However, we also recognize the concerns commenters have raised regarding HCPCS codes 0266T and 33276 and in particular, the request that we return those codes to their current New Technology APC placements should we establish a final policy of not creating an additional APC level. Thus, we are assigning these codes to New Tech APC 1580, the same APC these codes were assigned to in CY 2024, in this CY 2025 OPPS/ASC final rule with comment period.

For HCPCS code 64568, we believe its current assignment to the Level 5 APC remains appropriate. The code has been assigned to the Neurostimulator and Related Procedures APC series for many years and the claims volume we have for the procedure allow for an estimate of the associated resource costs. Therefore, we do not believe a New Tech APC assignment is appropriate at this time, as New Technology APC placements are typically used when insufficient cost and claims data are available to make appropriate clinical APC assignments. We will continue to monitor the data as additional claims become available for these codes.

After consideration of the public comments we received, we are finalizing our proposal with modification. We are finalizing the

proposed 5 level APC structure for the Neurostimulator and Related Procedures APC series. However, we are continuing to assign HCPCS codes 33276 and 0266T to New Technology APC 1580 (New Technology—Level 43 ($40,001–$50,000)) in CY 2025 rather than finalizing our proposal to assign them to APC 5465. See Table 71 for the status indicators and APC assignments for HCPCS codes 0266T and 33276. We note that we have previously discussed the placement of these codes in New Technology APCs until such time that sufficient claims data were available to assign those codes to clinical APCs (87 FR 81769, 88 FR 81645 through 81647, 88 FR 81658). We will continue to monitor the data as more claims for these codes become available. Finally, we are maintaining the APC assignment of HCPCS code 64568 to APC 5465 (Level 5 Neurostimulator and Related Procedures). Please see Table 74 for the final CY 2025 OPPS APC and SI assignments for HCPCS codes 0266T and 33276.

TABLE 71: FINAL CY 2025 APC AND STATUS INDICATOR ASSIGNMENTS

HCPCS Code	HCPCS Long Descriptor	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
0266T	Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)	S	1580
33276	Insertion of phrenic nerve stimulator system (pulse generator and stimulating lead[s]), including vessel catheterization, all imaging guidance, and pulse generator initial analysis with diagnostic mode activation, when performed	S	1580

3. Focal Laser Ablation, CPT Code 0655T (APC 5375)

Focal laser ablation is an MRI directed and image guided, minimally invasive procedure that targets prostate cancer tissue. The focal laser ablation procedure, represented by CPT code 0655T (Transperineal focal laser ablation of malignant prostate tissue, including transrectal imaging guidance, with mr-fused images or other enhanced ultrasound imaging), became effective July 1, 2021, and describes the destruction of localized prostate cancer tissue with the high energy source of focal laser radiation. The procedure utilizes real-time intraoperative prostate ultrasound fused with MRI guidance to allow the surgeon to plan the ablation and guide the laser targeting as well as providing real-time feedback to minimize changes to the tissues outside of the targeted ablation zone. This procedure offers another therapy option for select patients with localized intermediate risk prostate cancer.

For the CY 2025 OPPS/ASC proposed rule, we reviewed the CY 2023 claims submitted between January 1, 2023, through December 31, 2023, that were processed on or before December 31, 2023, for CPT code 0655T and found seven single frequency claims available for ratesetting, with a resulting geometric mean cost of $12,777. Additionally, for the CY 2025 OPPS/ASC proposed rule, we examined the procedures assigned to the Urology Procedures APCs. Based on our examination of the procedures assigned to Urology and Related Procedures APCs and the available CY 2023 claims data, we stated that we believe it is appropriate to move CPT code 0655T to APC 5375 (Level 5 Urology and Related Services) from APC 5374 (Level 4 Urology and Related Services) because 0655T shares more resource cost and clinical homogeneity with procedures in APC 5375. Specifically, we explained that we believe CPT code 0655T shares resources and is clinical homogeneous with CPT code 0714T (Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance), and CPT code 52648 (Laser vaporization of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed)). We noted that the seven available CY 2023 single frequency claims for CPT code 0655T would not significantly impact the geometric mean cost calculations for APC 5374 and APC 5375. Therefore, for CY 2025, we proposed to reassign CPT code 0655T from APC 5374 (Level 4 Urology and Related Services) to APC 5375 (Level 5 Urology and Related Services).

Comment: One commenter supported our proposal to reassign CPT code 0655T from APC 5374 (Level 4 Urology and Related Services) to APC 5375 (Level 5 Urology and Related Services), citing the clinical and resource homogeneity with CPT codes 52648 and 0714T. Furthermore, the commenter suggested we monitor the impact of the

reassignment on the geometric mean cost for APCs 5374 and 5375 to ensure payment stability.

Response: We thank the commenter for the support. Based on evaluation of their clinical and resource similarities, and taking into account updated claims data for this final rule with comment period, we continue to believe it is appropriate to reassign CPT code 0655T to APC 5375.

After consideration of the public comment we received, we are finalizing our policy without modification for CPT code 0655T. Please refer to Table 72 below for the final OPPS APC and status indicator assignments for HCPCS code 0655T for CY 2025. The final CY 2025 payment rates can be found in Addendum B to this final rule with comment period via the internet on the CMS website.

TABLE 72: FINAL CY 2025 OPPS APC ASSIGNMENT AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODE 0655T

CPT Code	Long Descriptor	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
0655T	Transperineal focal laser ablation of malignant prostate tissue, including transrectal imaging guidance, with mr-fused images or other enhanced ultrasound imaging	J1	5375

4. Bone Mass Measurement: Biomechanical Computed Tomography (BCT) Analysis With and Without Vertebral Fracture Assessment, CPT Codes 0554T–0558T, 0743T (APCs 5521, 5523, and 5731)

CPT code 0743T (Bone strength and fracture risk using finite element analysis of functional data and bone mineral density (BMD), with concurrent vertebral fracture assessment, utilizing data from a computed tomography scan, retrieval and transmission of the scan data, measurement of bone strength and BMD and classification of any vertebral fractures, with overall fracture-risk assessment, interpretation and report) became effective January 1, 2023. This code describes the service associated with biomechanical computed tomography (BCT) analysis with concurrent vertebral fracture assessment (VFA).

In the CY 2023 OPPS/ASC final rule (87 FR71844 through 71846), we stated that, based on our review and understanding of the service, BCT analysis does not meet Medicare's definition of bone mass measurement, as specified in § 410.31(a), which specifies the coverage of, and payment for, bone mass measurements for Medicare beneficiaries. Therefore, we assigned the BCT codes (CPT codes 0554T–0558T) and CPT code 0743T to status indicator ''E1'' to indicate that these codes are not covered by Medicare, and not paid by Medicare when submitted on outpatient claims (any outpatient bill type). The complete long descriptors for the codes can be found below:

0554T: Bone strength and fracture risk using finite element analysis of functional data and bone-mineral density utilizing data from a computed tomography scan; retrieval and transmission of the scan data, assessment of bone strength and fracture risk and bone-mineral density, interpretation and report.

0555T: Bone strength and fracture risk using finite element analysis of functional data and bone-mineral density utilizing data from a computed tomography scan; retrieval and transmission of the scan data.

0556T: Bone strength and fracture risk using finite element analysis of functional data and bone-mineral density utilizing data from a computed tomography scan; assessment of bone strength and fracture risk and bone mineral density.

0557T: Bone strength and fracture risk using finite element analysis of functional data and bone-mineral density utilizing data from a computed tomography scan; interpretation and report.

0558T: Computed tomography scan taken for the purpose of biomechanical computed tomography analysis.

In the CY 2024 OPPS/ASC proposed rule, we proposed to continue to assign the codes to status indicator ''E1'' to indicate non-coverage and non-payment for the services. (See Addendum B for CY 2024/ASC proposed rule via the internet on the CMS website.) However, as discussed in the CY 2024 OPPS/ASC final rule with comment period (88 FR 81660 through 81661), based on comments received and further review of the issue, we did not finalize our proposal. We instead assigned CPT code 0555T to APC 5731 (Level 1 Minor Procedures) and SI of ''S,'' (Procedure or Service, Not Discounted When Multiple; Paid under OPPS; separate APC payment), CPT code 0556T to APC 5523 (Level 3 Imaging without Contrast) and SI of ''S,'' and CPT code 0558T to APC 5521 (Level 1 Imaging without Contrast) with SI of ''S,'' which were the same APC assignments for the codes between CY 2019 and CY 2022. In addition, we assigned CPT codes 0554T, 0557T, and 0743T to SI of ''M'' (Items and Services Not Billable to the MAC. Not paid under OPPS) to indicate that these codes are not payable under the OPPS because they describe physician-only services. The final payment rates for these codes were listed in the OPPS Addendum B that was released with the CY 2024 OPPS/ASC final rule via the internet on the CMS website.

For the CY 2025 OPPS/ASC proposed rule, we proposed to assign CPT codes 0554T and 0557T to status indicator of ''M'' as the codes include or describe a professional component of the service

that is provided by a physician as evidenced by ''interpretation and report'' in the descriptor. It is important to note that CPT code 0554T is a comprehensive code (or ''parent code'') that includes both technical and professional components. Because there are additional CPT codes (''child codes'') that facilities can use to describe the technical components of BCT analysis, we explained that we believed it was appropriate for the comprehensive code that includes the professional component to be assigned a SI of ''M''. In addition, we proposed to assign CPT code 0555T to APC 5731 (Level 1 Minor Procedures) and a SI of ''S,'' CPT code 0556T to APC 5523 (Level 3 Imaging without Contrast) and a SI of ''S,'' and CPT code 0558T to APC 5521 (Level 1 Imaging without Contrast) with a SI of ''S.''

For the CY 2025 OPPS/ASC proposed rule, we explained that we believe the service described by CPT code 0743T is a comprehensive code and involves both a technical component and a professional component that are performed by hospital outpatient facilities. Unlike CPT 0554T, there are no additional codes to describe the technical component(s) of this service (BCT analysis and VFA) and there is a parenthetical note instructing facilities to not report the BCT analysis codes (0554T–0557T) with CPT code 0743T. Consequently, we proposed to assign CPT code 0743T to APC 5523 (Level 3 Imaging without Contrast) and we proposed to change the status indicator for 0743T from ''M'' to ''S'' (Procedure or Service, Not Discounted When Multiple; Paid under OPPS; separate APC payment) for CY 2025. See Table 73 below.

Comment: We received several comments describing support for the use of BCT services to assess bone strength, bone mineral density, and fracture risk indicating that these services were cost-effective and provided valuable clinical information. Commenters noted the significant impact that osteoporosis has on Medicare beneficiaries, especially women. They shared that BCT is effective in clinical practice when determining use and approval of anti-osteoporotic medications that are dependent on bone density assessments. They also noted that DXA (dual-energy X-ray absorptiometry) scans (most common test used to measure bone mineral density) may be difficult to do when patients have scoliosis or extensive degenerative diseases and thus prefer to use BCT.

Response: We appreciate the feedback supporting BCT services.

Comment: We received one comment requesting that we assign payable status indicators for CPT codes 0554T and 0557T.

Response: We thank the commenter for their request. As stated above, we proposed to continue to assign CPT codes 0554T and 0557T a status indicator of ''M'' as the codes include or describe a professional component of the service that is provided by a physician as evidenced by ''interpretation and report'' in the descriptor. CPT code 0554T is a comprehensive code (or ''parent code'') that includes both technical and professional components. Because there are additional CPT codes (''child codes'') that facilities can use to describe the technical components of BCT analysis, it is appropriate for the comprehensive code that includes the professional component to be assigned a SI of ''M''. CPT code 0557T describes only the professional component of the BCT analysis code and therefore, is appropriately assigned a SI of ''M''.

Comment: We received several comments expressing support for the proposed APC and status indicator assignments.

Response: We thank the commenters for their support.

Comment: Several commenters believe that Medicare has limited access to some BCT services in the hospital outpatient setting by assigning non-payable status indicators. Consequently, they are requesting that the pertinent codes be allowed through national coverage.

Response: We appreciate these comments. In Transmittal 2362 dated September 19, 2019, we note the BCT codes, specifically CPT codes 0554T, 0555T, 0556T, 0557T, and 0558T were listed as covered effective July 1, 2019 under NCD 150.3 Bone Mineral Density Studies. These services were added in error and were retracted due to ''added in error'' in Transmittal 11952 dated April 12, 2023. We apologize for the confusion this has caused and the mistaken belief that ''coverage was revoked'' when in fact these services had not been approved for national coverage.

While CMS further considers the issue of national coverage, we will finalize our proposed status indicator and (if applicable) APC assignments for CPT codes 0554T–0558T and CPT code 0743T as listed in Table G42 below.

The regulation at 42 CFR 410.31(f) (Bone mass measurement: Conditions for coverage and frequency standards) recognizes that CMS may use the Medicare National Coverage Determination (NCD) process to examine additional BMM systems for coverage. The public may request an NCD for a particular item or service by following the procedures established at 78 FR 48164 (August7, 2013). The commenter may request a new NCD (or seek reconsideration of an existing NCD). As a reminder to our readers, National Coverage Determinations do not include coding and payment decisions.

In summary, after consideration of the public comments, we are finalizing our proposed status indicator and (if applicable) APC assignments for CPT codes 0554T–0558T and CPT code 0743T without modification. The final payment rates for the separately payable codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

TABLE 73: FINAL CY 2024 AND CY 2025 OPPS APC & STATUS INDICATOR ASSIGNMENTS FOR BCT CODES 0554T – 0558T, 0743T

CPT Codes	Long Descriptors	FINAL CY 2024 OPPS/ASC SI	FINAL CY 2024 OPPS/ASC APC	FINAL CY 2025 OPPS/ASC SI	FINAL CY 2025 OPPS/ASC APC
0554T	Bone strength and fracture risk using finite element analysis of functional data and bone-mineral density utilizing data from a computed tomography scan; retrieval and transmission of the scan data, assessment of bone strength and fracture risk and bone-mineral density, interpretation and report.	M		M	
0555T	Bone strength and fracture risk using finite element analysis of functional data and bone-mineral density utilizing data from a computed tomography scan; retrieval and transmission of the scan data.	S	5731	S	5731
0556T	Bone strength and fracture risk using finite element analysis of functional data and bone-mineral density utilizing data from a computed tomography scan; assessment of bone strength and fracture risk and bone mineral density.	S	5523	S	5523
0557T	Bone strength and fracture risk using finite element analysis of functional data and bone-mineral density utilizing data from a computed tomography scan; interpretation and report.	M		M	
0558T	Computed tomography scan taken for the purpose of biomechanical computed tomography analysis.	S	5521	S	5521
0743T	Bone strength and fracture risk using finite element analysis of functional data and bone mineral density (BMD), with concurrent vertebral fracture assessment, utilizing data from a computed	M		S	5523

CPT Codes	Long Descriptors	FINAL CY 2024 OPPS/ASC SI	FINAL CY 2024 OPPS/ASC APC	FINAL CY 2025 OPPS/ASC SI	FINAL CY 2025 OPPS/ASC APC
	tomography scan, retrieval and transmission of the scan data, measurement of bone strength and BMD and classification of any vertebral fractures, with overall fracture-risk assessment, interpretation and report				

5. 3D Contour Simulation, CPT Code 0944T (APC 5523)

CAS-One® IR is Software as a Service (SaaS) that assists a physician or other qualified health care professional during percutaneous liver ablation treatments by providing 3D images that allow the physician to visualize the liver lesions, as well as define suitable margins and pathways to perform the ablation procedure. The AMA CPT Editorial Panel established CPT code 0944T effective January 1, 2025:

The long descriptor for CPT code 0944T is as follows: 3D contour simulation of target liver lesion(s) and margin(s) for image-guided percutaneous microwave ablation.

In the CY 2025 OPPS/ASC proposed rule with comment period, we proposed to assign 0944T to status indicator ''E1'' to indicate that the code is not payable by Medicare when submitted on outpatient claims because the service had not received FDA clearance at the time of the assignment.

Comment: We received one comment from the manufacturer. The commenter states that the 3D simulation is always performed with CPT code 47382 (Ablation, 1 or more liver tumor(s), percutaneous, radiofrequency) which is assigned to APC 5361 (Level 1 Laparoscopy and Related Services) and has a payment rate of approximately $5,800. The manufacturer asserts the costs for the 3D simulation service are approximately $3,000 which include a CT of the abdomen with contrast, utilization of the CAS-One® system, sterile accessories (patient markers, instrument markers, drapes, and marker templates), and annual services for the system (including maintenance, warranty, software subscription, and clinical support). They have requested that we reassign CPT code 0944T to APC 5362 (Level 2 Laparoscopy and Related Service) with a payment rate of approximately $10,400 and a status indicator of J1, representing a comprehensive service that includes both the ablation procedure (CPT code 47382) and the 3D simulation service (CPT code 0944T).

Response: We thank the commenter for their input. We disagree that we should consider adding the costs of both the ablation procedure (CPT code 47382) and the 3D simulation service (CPT code 0944T) to determine the appropriate payment for the 3D simulation service. The ablation procedure (CPT code 47382) is a primary service as identified by the OPPS status indicator ''J1'' (Hospital Part B Services Paid Through a Comprehensive APC; Paid under OPPS). The ablation procedure can be done with or without 3D simulation services, but 3D simulation services are never provided without the primary ablation services. Under our C–APC policy, we designate a service described by a HCPCS code assigned to a C–APC as the primary service when the service is identified by OPPS status indicator ''J1''. Because the 3D simulation service is always performed with the ablation service, we believe the 3D simulation could be considered an adjunctive service. (See 78 FR 74865 and 79 FR 66799.) Payments for adjunctive services are generally packaged into the payments for the primary services.

After review of the procedure description for 3D simulation and input from our CMS medical officers, we do not believe it would be appropriate to always package the costs of the 3D simulation procedure into the ablation procedure. Based on the technology and its potential use in the HOPD setting, we used CPT code 75557 (Cardiac magnetic resonance imaging for morphology and function without contrast material) as a comparator code to determine an APC and status indicator assignment for CPT 0944T. While we realize that there are significant differences between these two codes, we believe that both codes use a type of imaging service to provide valuable information for the clinician to assist in further diagnosing and treating patients. CPT code 75557 is assigned to APC 5523 (Level 3 Imaging without Contrast) and a status indicator of ''Q1'' (STV-Packaged Codes; Paid under OPPS). We also note that the CAS-One® IR has received 510(k) Premarket Notification from the FDA and should no longer be assigned status indicator ''E1''.

In summary, we are revising the status indicator for CPT code 0944T from status indicator ''E1'' to status indicator ''Q1'' (STV-Packaged Codes; Paid under OPPS), indicating a conditionally packaged procedure. CPT code 0944T will be packaged when it is provided with a significant procedure but will be separately paid when the service appears on the claim without a significant procedure (see Table 74). We are assigning CPT code 0944T to APC 5523 (Level 3 Imaging without Contrast) with a final payment rate of around $240.00. Please refer to Table G43 for the code descriptor, APC assignment, and status indicator assignment for CPT code 0944T for CY 2025. The final payment rate for 0944T can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

TABLE 74: CY 2025 PROPOSED AND FINAL OPPS SI AND APC FOR CPT CODE 0944T

CPT Code	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
0944T	3D contour simulation of target liver lesion(s) and margin(s) for image-guided percutaneous microwave ablation	E1		Q1	5523

6. Administration of Lacrimal Ophthalmic Insert Into Lacrimal Canaliculus, CPT Code 68841(APC 5503)

Dextenza, which is described by HCPCS code J1096 (Dexamethasone, lacrimal ophthalmic insert, 0.1 mg), is a drug indicated for ''the treatment of ocular inflammation and pain following ophthalmic surgery'' and for ''the treatment of ocular itching associated with allergic conjunctivitis.'' [24] The drug manufacturer previously asserted that this drug is administered and described by CPT code 0356T (Insertion of drug-eluting implant (including punctal dilation and implant removal when performed) into lacrimal canaliculus, each). Interested parties also previously stated that Dextenza is inserted in a natural opening in the eyelid (called the punctum) and that the drug is designed to deliver a tapered dose of dexamethasone to the ocular surface for up to 30 days. CPT code 0356T was deleted December 31, 2021, and replaced with CPT code 68841 (Insertion of drug-eluting implant, including punctal dilation when performed, into lacrimal canaliculus, each), effective January 1, 2022.

Interested parties currently assert that the drug, Dextenza, is administered and described by CPT code 68841. We refer readers to the CY 2023 OPPS/ASC final rule with comment period for a detailed history of CMS payment assignments for CPT code 0356T and CPT code 68841 (87 FR 71840). See section XIII.F. of this final rule with comment period for the CY 2025 payment status of the drug, Dextenza, which may be described by HCPCS code J1096.

In the CY 2024 OPPS/ASC final rule with comment period (88 FR 81651 through 81653), we stated that based on the claims data available at the time, we continued to believe that the assignment of CPT code 68841 to APC 5503 (Level 3 Extraocular, Repair, and Plastic Eye Procedures) was appropriate based on the geometric mean costs. We also reiterated our reasoning that CPT code 68841 was appropriately assigned to an OPPS status indicator of ''Q1'' and ASC payment indicator of ''N1.'' We continued to believe that CPT code 68841 is mostly performed during ophthalmic surgeries, such as cataract surgeries. A status indicator ''Q1,'' indicating a conditionally packaged procedure, describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are generally packaged (payment indictor ''N1'') under the ASC payment system. Although stakeholders stated this is an independent surgical procedure and should not be packaged into the primary ophthalmic procedure in which the drug and drug administration are associated, we did not agree based on observed clinical patterns of how the drug is used. Based on CY 2024 claims data, out of over 7,000 total frequency claims, CPT code 68841 was used independently only about 2 percent of the time, meaning that the other 98 percent of the time CPT code 68841 had its payment packaged into the primary procedure with which it is associated.

These data reinforced our belief that Dextenza and CPT code 68841 are not furnished independently of a surgical procedure and should be packaged into the primary ophthalmic procedure with which the drug and drug administration are associated. While we recognized that there are some claims that may only include CPT code 68841 without a primary ophthalmic surgery on the claim, we did not believe that this is a frequent occurrence based on our claims data and clinical use patterns; as previously mentioned, our claims data showed that only 2 percent of claims are performed independently of another primary procedure.

For CY 2025, we proposed to continue to assign CPT code 68841 to APC 5503 (Level 3 Extraocular, Repair, and Plastic Eye Procedures). We also proposed to continue to assign CPT code 68841 to OPPS status indicator ''Q1'' and an ASC payment indicator of ''N1.'' The issue of payment for CPT code 68841 was brought to the Advisory Panel on Hospital Outpatient Payment (also known as HOP Panel) in 2024 for CY 2025 rulemaking. At the August 2024 meeting, based on the information presented, the Panel made no recommendation to CMS regarding changing the proposed status indicator assignment, Q1, for HCPCS code 68841 for CY 2025.

Comment: We received input from several interested parties contending that increased and separate payment for CPT code 68841, the code that can be used to describe the administration of the drug Dextenza, is required to ensure continued beneficiary access to Dextenza (HCPCS code J1096) in both the HOPD and ASC settings. Commenters emphasized that the lack of payment disproportionately and negatively affects the ASC setting. Several commenters pointed to the clinical importance of providing Dextenza to patients, noting that it reduces ocular pain and inflammation and reduces the burden of topical eyedrop application. Additionally, commenters stated that they usually perform the procedure to administer Dextenza in conjunction with ophthalmic surgeries.

Commenters generally did not disagree with the proposed APC assignment, but rather recommended CMS pay separately for the procedure.

[24] FDA Package Insert. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208742s007lbl.pdf.*

Many of these commenters recommended CMS assign CPT code 68841 to a status indicator of ''J1,'' indicating a comprehensive APC procedure. Commenters believed that ''J1'' would be the most accurate status indicator assignment and would generate consistency within APC 5503 (Level 3 Extraocular, Repair, and Plastic Eye Procedures), as all other codes in APC 5503 are assigned to status indicator ''J1.'' Commenters stated that CPT code 68841 required an additional 5 minutes of operating time and the assistance of an ophthalmic technician, and without payment for those costs, it was difficult to provide the drug to Medicare beneficiaries.

Commenters did not agree with CMS that the fact that CPT code 68841 was performed as a standalone procedure only two percent of the time was an adequate justification for assigning a ''Q1'' status indicator. They believed, and provided examples, that there are many other procedures that are performed independently at that frequency or a lower percentage of the time, that are assigned to a payable status indicator for hospital outpatient purposes and thus also are paid separately in the ASC setting. For example, commenters mentioned CPT code 64415 (Injection(s), anesthetic agent(s) and/or steroid; brachial plexus, including imaging guidance when performed) as an example of a procedure with a lower percentage of single frequency claims and that is assigned to a payable status indicator; a status indicator of ''T'' in this example. Commenters also believed that CPT code 68841 was similar to other procedures for introducing a product to the eye, such as CPT code 66020 (Injection, anterior chamber of eye (separate procedure); air or liquid) and should be paid in a similar manner. Commenters believed the procedure described by CPT code 68841 is a distinct surgical procedure that requires additional operating room time and resources. These commenters believed that the cataract surgery is conducted and concluded, and then the procedure described by CPT code 68841 begins.

Response: We thank commenters for their feedback. We have long maintained that Dextenza is a drug that functions as a surgical supply and should be packaged under our packaging policy at 42 CFR 419.2(b), which lists the types of items and services for which payment is packaged under the OPPS. Specifically, § 419.2(b)(16) includes drugs and biologicals that function as supplies when used in a surgical procedure as packaged costs. Historically, we have stated that we consider all items related to the surgical outcome and provided during the hospital stay in which the surgery is performed, including postsurgical pain management drugs, to be part of the surgery for purposes of our drug and biological surgical supply packaging policy (79 FR 66875). As such, the drug administration procedure, CPT code 68841, is also supporting the main ocular procedure being performed. CPT code 68841 should, therefore, be packaged as an intraoperative service under § 419.2(b)(14).

Based on the rationale provided in the CY 2024 OPPS/ASC final rule with comment period, (88 FR 81651 through 81653), the procedure described by CPT code 68841 had its payment packaged into another procedure 98 percent of the time, meaning that it is not an independent surgical procedure as commenters assert. Rather, CPT code 68841 is used to support the primary procedure being performed and is a supportive intraoperative service that is a part of that primary procedure. We reiterate that both Dextenza and its administration impact the surgical outcome of the primary procedure and are provided during the hospital stay in which the surgery is performed, which we consider to be part of the surgery for purposes of our drug and biological surgical supply packaging policy. Although interested parties state this is an independent surgical procedure and should not be packaged into the primary ophthalmic procedure in which the drug and drug administration are associated, based on expected and observed clinical patterns as to how the drug is used, we do not agree.

When revaluating the claims data available for CY 2025, CPT code 68841 has 94 single frequency claims in the OPPS out of over 4200 total frequency claims, meaning that 98 percent of the time CPT code 68841 was furnished with another primary procedure into which CPT code 68841's payment was packaged. This confirms our belief that CPT code 68841 is a component of another primary procedure, supportive of that procedure, and should have its payment packaged into that procedure.

Additionally, as commenters were most concerned about a financial disincentive, we note that utilization has been increasing year over year based on utilization patterns of Dextenza in the ASC setting. For example, from claims year CY 2022 to claims year CY 2023, the number of units of Dextenza billed increased from approximately 260,000 to approximately 320,000 units, which reflects a nearly 20 percent year over year increase in utilization. Therefore, we do not believe that our packaging policies are hindering appropriate utilization as suggested by commenters. We note that HCPCS code J1096, which may be used to describe the drug, Dextenza, is a qualifying product for separate payment in both the OPPS and ASC under our policy to implement section 4135 of the CAA, 2023. Please see section XIII.F. of this final rule with comment period, for additional information.

For the reasons discussed, we continue to believe that it is appropriate to assign CPT code 68841 to a status indicator ''Q1,'' indicating a conditionally packaged procedure, which describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are generally packaged (payment indictor ''N1'') under the ASC payment system. We do not believe the HCPCS codes suggested by commenters that are not conditionally packaged are analogous to CPT code 68841. Therefore, our analysis was based on claims data specific to CPT code 68841 in order to confirm the appropriateness of the assignment to an OPP SI = ''Q1'' and ASC PI = ''N1.''

After consideration of the public comments, we are finalizing our proposal, without modification, to assign CPT code 68841 to APC 5503 with OPPS status indicator ''Q1'' (STV Packaged Codes) for CY 2025, which typically means there will be a packaged APC payment if this code is billed on the same claims as a HCPCS code assigned to status indictor ''S,'' ''T,'' or ''V'' (Clinic or Emergency Department Visit). In addition, based on the OPPS assignments, we are finalizing an ASC payment indicator of ''N1'' (Packaged service/item; no separate payment made) for CPT code 68841 for CY 2025.

For the final CY 2025 OPPS payment rates, we refer readers to OPPS Addendum B to this final rule with comment period. In addition, we refer readers to OPPS Addendum D1 to this final rule with comment period for the status indicator definitions for all codes reported under the OPPS. For the final CY 2025 ASC payment rates and payment indicators, we refer readers to Addendum AA and Addendum BB for the ASC payment rates, and Addendum DD1 for the ASC payment indicator and their definitions. The OPPS Addenda B and D1 and ASC Addenda AA, BB, and

DD1 are available via the internet on the CMS website.

Please refer to Table 75 for the code descriptor, APC assignment, status indicator assignment, and payment indicator assignment for CPT code 68841 for CY 2025.

TABLE 75: FINAL CY 2025 OPPS AND ASC PAYMENT ASSIGNMENTS FOR CPT CODE 68841

CPT Code	Long Descriptor	Final CY 2025 OPPS APC	Final CY 2025 OPPS SI	Final CY 2025 ASC PI
68841	Insertion of drug-eluting implant, including punctal dilation when performed, into lacrimal canaliculus, each	5503	Q1	N1

7. Application of Rigid Total Contact Leg Cast, CPT Code 29445 (APC 5102)

CPT code 29445 describes the procedure of applying a rigid leg cast. This code specifically refers to the process of immobilizing a leg fracture or injury by encasing the affected area in a hard cast, which helps to stabilize the bone and promote healing.

In the CY 2025 OPPS/ASC proposed rule, we proposed to continue to assign CPT code 29445 to APC 5102 (Level 2 Strapping and Cast Application) with status indicator ''T'' (Procedure or service, multiple procedure reduction applies; with a separate APC payment under OPPS) and proposed payment rate of $266.86.

Payment for CPT code 29445 was brought to the Advisory Panel on Hospital Outpatient Payment (also known as HOP Panel) at the August 2024 meeting. Based on the information presented, the HOP Panel recommended that ''CMS consider HCPCS code 29445, (Application of rigid total contact leg cast), a separately payable code when performed concurrently on the same date of service as any of the following: HCPCS codes 11402, 11403,11404, 11405, 11406, 11407, 97597, 97598, 15271, 15272, 15273, 15274, 15275, 15276, 15277, 15278.''

We received two public comments endorsing the recommendation of the HOP Panel.

Comment: One commenter requested that CMS ensure that hospital outpatient departments are able to receive separate payment for the CPT code 29445 when a debridement or graft is performed on the same date of service, which they are currently are unable to do because of a National Correct Coding Initiative (NCCI) edit that has been put in place.

Another commenter stated that if a wound debridement is performed (codes 11042–11047, 97597–97598), any primary or secondary dressing materials used to cover the wound would be included in the debridement and would not be separately reported. However, a TCC is not considered a wound dressing and is not included in the debridement procedure. Therefore, the commenter believed the cast application should be reported in addition to the code for the appropriate level of debridement, if performed, and should be mapped to APC 5102.

Response: We thank the commenters for providing this information related to CPT code 29445. We will take commenters' suggestions into consideration for the future rulemaking.

8. Aquabeam Waterjet Ablation Procedure, CPT Code 0421T (APC 5376)

CPT code 0421T (Transurethral waterjet ablation of prostate, including control of post-operative bleeding, including ultrasound guidance, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included when performed) describes the Aquabeam waterjet ablation procedure. According to the manufacturer, Aquabeam is for treating lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH) by using a high-velocity water stream to ablate and remove tissue from enlarged prostates.

For the CY 2025 proposed rule, we estimated the geometric mean cost for CPT code 0421T to be $10,438 based on 4,743 single claims and proposed to assign the service to APC 5376 (Level 6 Urology and Related Services), which has a geometric mean cost of $9,356.

Comment: One commenter supported our proposal to assign CPT code 0421T to APC 5376 due to the clinical and resource similarities to other procedures assigned to APC 5376.

Response: We appreciate the commenter's feedback on CPT code 0421T and we agree with the commenter's recommendation to finalize the APC assignment.

After consideration of the public comment we received, we are finalizing our proposal without modification to assign CPT code 0421T to APC 5376. Please refer to Table 76 below for the final OPPS APC and status indicator assignment for HCPCS code 0421T for CY 2025. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 76: FINAL CY 2025 OPPS APC STATUS INDICATOR ASSIGNMENTS FOR CPT CODE 0421T

CPT Code	Long Descriptor	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
0421T	Transurethral waterjet ablation of prostate, including control of post-operative bleeding, including ultrasound guidance, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included when performed	J1	5376

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9. Aqueous Shunt to Extraocular Plate Reservoir Procedure, CPT Code 66180 (APC 5493)

For CY 2024, we assigned CPT code 66180 (Aqueous shunt to extraocular equatorial plate reservoir, external approach; with graft) to APC 5492 (Level 2 Intraocular Procedures). For CY 2025, as shown in OPPS Addendum B that was released with the CY 2025 OPPS/ASC proposed rule with comment period, we proposed to maintain the APC assignment to APC 5492 with a payment rate of $3,873.90 for CPT code 66180.

Comment: We received two comments requesting that we reassign CPT code 66180 to APC 5493 (Level 3 Intraocular Procedures) due to the code's similarity to CPT code 66179 (Aqueous shunt to extraocular equatorial plate reservoir, external approach; without graft), which we proposed to assign to APC 5493 for CY 2025. The commenters explained that the procedures are the same except that CPT code 66180 requires additional clinical work, time, and resources, associated with suturing a patch graft to the eye. The commenters also explained that the available claims data from the CY 2025 OPPS/ASC proposed rule support assigning CPT code 66180 to APC 5493. For example, per the commenters, the geometric mean cost for CPT code 66180 ($5,026.75) is closer to the geometric mean cost of APC 5493 ($5,298.63) than the geometric mean cost of APC 5492 ($4,159.32).

Response: We agree with the commenters that APC 5493 is a more appropriate placement for CPT code 66180 due to the additional clinical work and resources utilized to furnish the service due to its similarity to CPT code 66179. We also agree with the commenters that the geometric mean cost of CPT code 66180 confirms that the resources necessary to furnish the service more closely match the geometric mean cost of APC 5493 than APC 5492.

After consideration of the public comments received, we are finalizing an APC assignment for CPT code 66180 to APC 5493 for CY 2025. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

10. Arteriovenous Fistula (AVF) Creation Procedures, CPT Codes 36836 and 36837 (APC 5194)

CPT codes 36836 (Percutaneous arteriovenous fistula creation, upper extremity, single access of both the peripheral artery and peripheral vein, including fistula maturation procedures (*e.g.,* transluminal balloon angioplasty, coil embolization) when performed, including all vascular access, imaging guidance and radiologic supervision and interpretation) and 36837 (Percutaneous arteriovenous fistula creation, upper extremity, separate access sites of the peripheral artery and peripheral vein, including fistula maturation procedures (*e.g.,* transluminal balloon angioplasty, coil embolization) when performed, including all vascular access, imaging guidance and radiologic supervision and interpretation) describe a percutaneous arteriovenous fistula creation of an upper extremity. CPT code 36836 replaced HCPCS codes C9754 and G2170, while CPT code 36837 replaced HCPCS codes C9755 and G2171.

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61246 through 61247), in response to public comment, input from our medical advisors, and the available claims data, we reassigned C9754 and C9755 from APC 5193 to APC 5194. In the CY 2021 OPPS/ASC final rule with comment period (85 FR 85954 through 95955), we used our equitable adjustment authority to maintain the assignment of HCPCS codes G2170 and G2171 to APC 5194 (Level 4 Endovascular Procedures), given that both procedures are for ESRD patients that need dialysis, the predecessor codes had very similar median costs, and there were low claims data available. We continued the assignment of CPT codes 36836 and 36837 to APC 5194, with commenter support, for CY 2022.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 71863 through 71864), we assigned the newly established [25] CPT codes 36836 and 36837 to APC 5194 based on our assessment of the CY 2023 geometric mean cost of predecessor codes HCPCS codes G2170 ($12,055.90) and G2171 ($13,486.08) and their APC assignment. For CY 2024, we continued assignment to APC 5194 for HCPCS codes G2170 and G2171, with commenter support.

For CY 2025, we proposed to continue assignment of both CPT codes 36836 and 36837 to APC 5194 (Level 4 Endovascular) with a proposed payment rate of around $17,956. For the CY 2025 proposed rule, CPT code 36836 had227 single claims for ratesetting, a geometric mean cost (GMC) of around $11,234, and CPT code 36837 had 121 single claims for ratesetting and a GMC of around $16,770.

Comment: A few commenters supported our assignment of CPT code 36837 to APC 5194.

Response: We thank the commenters for their support.

Comment: Several commenters requested that we avoid a proposed payment reduction for CPT code 36837 by maintaining its CY 2024 APC assignment.

Response: We note that for CY 2025 we proposed to maintain the assignment

[25] The AMA's CPT Editorial Panel established CPT codes 36836 and 36837 during the January 2023 update and CMS deleted HCPCS codes G2170 and G2171, effective January 1, 2023.

of CPT code 36837 to APC 5194 and did not propose to reassign CPT code 36837 to a lower-paying APC.

Comment: Several commenters indicated that CPT codes 36836 and 36837 do not have similar resource costs and that CPT code 36836 would be more appropriately assigned to APC 5193, which had a proposed payment rate of $11,478.26, as opposed to continuing to assign the code to APC 5194, which had a proposed payment rate of $18,167.36. A commenter further suggested that the volume of current claims data is sufficient to support reassigning CPT code 36836 to APC 5193. The commenter believed that the proposed rule geometric mean cost data illustrated distinct differences in required resources to perform the procedures described CPT code 36836 (GMC: $10,123.79) and CPT code 36837 (GMC: $16,849.60) and that CPT code 36836 is significantly overpaid in APC 5194 and would be overpaid in APC 5193, but to a lesser degree.

Response: We thank the commenters for their comments. We reiterate that we review, on an annual basis, the APC assignments for all services and items paid under the OPPS based on our analysis of the latest claims data and review of the clinical characteristics of the procedure. After further clinical review, we continue to believe that CPT code 36836 is more similar clinically to services in APC 5194, which includes more complex endovascular procedures, than those in APC 5193, which primarily contains less complex revascularization and embolization procedures. Further, while CPT code 36836 does have more available claims than what was available for the initial assignment of CPT code 36836 to APC 5194, we believe additional claims and clinical data would be useful before proposing to move this code to a different APC.

However, we note that we review the APC assignments for all items and services paid under the OPPS on an annual basis. We will reevaluate the APC assignment for CPT code 36836 in the next rulemaking cycle.

In summary, after consideration of the public comments we received, we are finalizing our proposal, without modification, to continue to assign CPT code 36836 and CPT code 36837 to APC 5194 for CY 2025. We refer readers to Addendum B of this final rule with comment period for the payment rate for all codes paid under the OPPS.

11. Arthroscopic Subacromial Balloon Implant, HCPCS Code C9781 (APC 5115)

HCPCS code C9781 describes the implantation of a subacromial spacer, such as a balloon, in the shoulder to treat a torn rotator cuff. The procedure may also include debridement, acromioplasty, subacromial decompression, and biceps tenodesis.

In the CY 2025 OPPS/ASC proposed rule, we proposed to continue to assign HCPCS code C9781 (Arthroscopy, shoulder, surgical; with implantation of subacromial spacer (*e.g.,* balloon), includes debridement (*e.g.,* limited or extensive), subacromial decompression, acromioplasty, and biceps tenodesis when performed) to APC 5115 (Level 5 Musculoskeletal Procedures) with a proposed payment rate of $12,755.58.

We received two comments in support of our proposal.

Comment: Both commenters endorsed our proposal to assign HCPCS code C9781, which describes InSpace™ Subacromial Tissue Spacer System, to APC 5115 for CY 2025. They encouraged CMS to maintain this assignment in the final rule.

Response: Based on our analysis of the latest CY 2023 claims data available for CY 2025 OPPS ratesetting, the geometric mean cost associated with HCPCS code C9781 is $12,757.71based on 493 single claims, which is consistent with the geometric mean cost of $13,022.88for APC 5115.

In summary, after consideration of the public comments we received, we are finalizing our proposal to assign HCPCS code C9781 to APC 5115 without modification. The final CY 2025 OPPS payment rate for this code can be found in Addendum B to this final rule with comment period.

12. Artificial Iris Insertion Procedures, CPT Code 66683 (APC 5496)

For the CY 2025 OPPS proposed rule, we proposed to assign placeholder CPT code 6X004 (Implantation of iris prosthesis, including suture fixation and repair or removal of iris, when performed) to APC 5496 (Level 6 Intraocular Procedures) with a payment rate of around $16,416. CPT code 66683 is the final code for 6X004 and will replace CPT code 0616T (Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; without removal of crystalline lens or intraocular lens, without insertion of intraocular lens); CPT code 0617T (Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with removal of crystalline lens and insertion of intraocular lens); and CPT code 0618T (Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with secondary intraocular lens placement or intraocular lens exchange).

Comment: One commenter supported our proposal to assign placeholder CPT code 6X004 (CPT code 66683) to APC 5496.

Response: We appreciate the support of the commenter for our proposal.

After consideration of the public comments we received, we are implementing our proposal without modification to assign CPT code 66683 to APC 5496 (Level 6 Intraocular Procedures). Table 77 shows the finalized status indicator and APC assignment for CPT code 66683. We refer readers to Addendum B of this final rule for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 77: FINAL CY 2025 OPPS APC STATUS INDICATOR ASSIGNMENT FOR CPT CODE 66683

CPT Code	Long Descriptor	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
66683	Implantation of iris prosthesis, including suture fixation and repair or removal of iris, when performed	J1	5496

13. Bronchoscopy With Needle Biopsy, CPT Code 31629 (APC 5154)

CPT code 31629 describes the use of diagnostic rigid or flexible bronchoscope to obtain one or more biopsies from the trachea, main stem, and/or lobar bronchus using a transbronchial needle aspiration technique. In the CY 2025 OPPS/ASC proposed rule, we proposed to continue to assign CPT code 31629 to APC 5154 (Level 4 Airway Endoscopy) with a proposed payment rate of $3,681.38.

Comment: We received one public comment that requested CMS reassign CPT code 31629 from APC 5154 (Level 4 Airway Endoscopy) to APC 5155 (Level 5 Airway Endoscopy) in the CY 2025 ASC/OPPS final rule. The commenter stated that CPT code 31629 is the highest cost significant procedure in APC 5154 with a geometric mean cost of $5,123.33. The geometric mean cost of CPT code 31629 exceeds the geometric mean cost of the lowest cost significant procedure in APC 5155, CPT code 31267 with a geometric mean cost of $5,031.74.

According to the commenter, given the intraoperative service time and physician skill level required for the procedure, this procedure is aligned with procedures already assigned to APC 5155 including balloon dilation and stenting procedures. The commenter stated that the reassignment of CPT code 31629 from APC 5154 to APC 5155 would better support resource homogeneity within the Airway Endoscopy Procedures APC series.

Response: Although the geometric mean cost of the CPT code 31629 is $1,300 higher than the geometric mean cost of APC 5154, it is $1,974 lower than the geometric mean cost of APC 5155. CPT code 31629 also does not violate the 2 times rule in its current assignment in APC 5154. In addition, we believe that CPT code 31629 fits appropriately in APC 5154 based on clinical similarity and resource homogeneity with the procedures in that APC.

Therefore, after consideration of the public comment we received, we are finalizing our proposal without modification, to assign CPT code 31629 to APC 5154 for CY 2025. We refer readers to Addendum B of this final rule with comment period for the CY 2025 final payment rate for this code. Addendum B is available via the internet on the CMS website.

14. CADScor System, CPT Code 0716T (APC 5733)

The CADScor System is intended as a diagnostic aid in symptomatic patients suspected of stable coronary artery disease (CAD) and is designed to help reduce invasive and costly diagnostic procedures. The CADScor System is a diagnostic aid that uses sensitive acoustics and advanced computational processing to analyze coronary blood flow to rule out obstructive CAD. CPT code 0716T describes the service that utilizes the CADScor System: Cardiac acoustic waveform recording with automated analysis and generation of coronary artery disease risk score. For CY 2025, we proposed to assign CPT 0716T to APC 5733—Level 3 Minor Procedures, with a payment rate of $59.07 and a status indicator of ''Q1'' (conditionally packaged).

Comment: Commenters disagreed with our proposal to assign CPT code 0716T to APC 5733 with a status indicator of ''Q1.'' Commenters suggested that CPT code 0716T should be assigned to APC 5722 based on clinical and resource homogeneity with other services assigned to APC 5722. Commenters also expressed that status indicator ''S'' (separately payable) would be most appropriate for CPT code 0716T. They contended that status indicator ''Q1'' essentially unconditionally packages the code because CPT code 0716T is never furnished without an emergency department visit.

Response: Although CPT code 0716T was effective July 1, 2022, we have no claims data for the code. The OPPS payment rates are proposed based on available CY 2023 claims data. Because we have no claims data, we believe that we should continue to assign CPT code 0716T to APC 5733 for CY 2024. We review, on an annual basis, the APC assignments for all services and items paid under the OPPS. As a result, we will reevaluate the APC assignment for CPT code 0716T for the next rulemaking cycle.

In addition, as listed in OPPS Addendum D1 of the CY 2025 OPPS/ASC proposed rule, codes assigned to status indicator ''Q1'' may be packaged, assigned to a composite APC, or paid separately under the OPPS. Specifically, a ''Q1'' status indicator may indicate a:

- Packaged APC payment if billed on the same claim as a HCPCS code assigned status indicator ''S'', ''T'', or ''V''; or
- Composite APC payment if billed with specific combinations of services based on OPPS composite-specific payment criteria. Payment is packaged into a single payment for specific combinations of services; or
- In other circumstances, payment is made through a separate APC payment

After reviewing the public comments, we believe that it is appropriate for the procedure described by CPT code 0716T to be paid separately. We agree with commenters that it is unlikely that CPT code 0716T would be furnished without an emergency department (ED) visit and should not be always be packaged with an ED visit. Therefore, we are revising the status indicator for the code from ''Q1'' (conditionally packaged) to ''S'' (Procedure or Service, Not Discounted When Multiple) to indicate that the service is paid separately.

In summary, after consideration of the public comments, we are finalizing the APC and status indicator assignment for

CPT code 0716T with modification. Specifically, we are finalizing the assignment of CPT code 0716T to APC 5733 and we are revising the status indicator assignment for CPT code 0716T to ''S'' (separately payable). Please refer to Table 78 for the code descriptor, APC assignment, status indicator assignment, and payment indicator assignment for CPT code 0716T for CY 2025.

TABLE 78: CY 2025 FINAL OPPS APC AND STATUS INDICATOR FOR CPT CODE 0716T

CPT Code	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
0716T	Cardiac acoustic waveform recording with automated analysis and generation of coronary artery disease risk score	Q1	5733	S	5733

15. Cardiac Magnetic Resonance Imaging Procedures, CPT Codes 75561 and 75563 (APCs 5572 and 5573)

CPT code 75561 (Cardiac magnetic resonance imaging for morphology and function without contrast material(s), followed by contrast material(s) and further sequences) and CPT code 75563 (Cardiac magnetic resonance imaging for morphology and function without contrast material(s), followed by contrast material(s) and further sequences; with stress imaging) both describe cardiac MRI procedures.

For CY 2024, we assigned CPT code 75561 to APC 5572 (Level 2 Imaging with Contrast), and CPT code 75563 to APC 5573 (Level 3 Imaging with Contrast). For the CY 2025 OPPS/ASC proposed rule, we proposed to maintain the current APC assignments for both cardiac MRI codes.

Comment: We received one comment requesting that we reassign CPT code 75561 to APC 5573 (Level 3 Imaging with Contrast). The commenter indicated that the other services in APC 5572 (Level 2 Imaging with Contrast) are not clinically similar or similar in resource use to the service described by CPT code 75561.

Response: We thank the commenter for their input. The OPPS payment rates are proposed based on available CY 2023 claims data. Our claims data show a geometric mean cost of about $450 for CPT code 75561 based on 27,543 single claims. We believe that the geometric mean cost of about $450 for CPT code 75561 is more consistent with the geometric mean cost of approximately $361 for APC 5572, than the geometric mean cost of approximately $800 for APC 5573. We continue to believe that the clinical and resource characteristics of CPT code 75561 are sufficiently like other procedures assigned to APC 5572 and should continue to be assigned to APC 5572.

Comment: The same commenter requested that CPT code 75563 (Cardiac magnetic resonance imaging for morphology and function without contrast material(s), followed by contrast material(s) and further sequences; with stress imaging) be reassigned to APC 5593 (Level 3 Nuclear Medicine and Related Services) because of lack of clinical homogeneity and resource utilization with other services currently assigned to APC 5573. The commenter notes that CPT code 75563 was previously assigned to the Nuclear Medicine APC family until the imaging services were restructured during a comprehensive review of the APC series that took place in CY 2016. The purpose of the restructuring of the OPPS APC groupings for imaging services was to improve the clinical and resource homogeneity of the services classified within the imaging APCs (80 FR 70392 and 81 FR 7928).

The commenter cites the following reasons to support the reassignment of 75563 to APC 5593:

(1) the clinical labor and resources (acquisition time, staffing, medications, and perfusion agents) are very similar to CPT code 78452 which describes myocardial perfusion imaging;

(2) both tests are indicated for patients with cardiac angina or coronary artery disease; and

(3) both tests provide the same clinical information.

We disagreed with a similar argument in the past (81 FR 79630) where commenters asserted that cardiac MRI with stress imaging is very similar to myocardial perfusion imaging because both tests are performed under a stress protocol and therefore should be assigned to APC 5593. APC 5593 contains procedures that describe nuclear medicine tests, and CPT code 75563 is a specific type of MRI and not a nuclear medicine test. Additionally, the geometric mean cost of CPT code 75563 is approximately $887 and the geometric mean cost of the APC to which it is assigned, APC 5573, is approximately $800. These geometric mean costs are very similar. However, the geometric mean cost of APC 5593 is approximately $1,321, which is significantly higher than the geometric mean cost of CPT code 75563. Therefore, assigning CPT code 75563 to APC 5593 would assign the procedure to an APC with clinically dissimilar nuclear medicine tests that have a geometric mean cost of $1,321 (as compared to the $887 geometric mean cost of CPT code 75563).

In summary, after consideration of the public comment, we are finalizing our proposal without modification to assign CPT code 75561 to APC 5572 and CPT code 75563 to APC 5573 for CY 2025. The final CY 2025 payment rates for the codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI definitions for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

16. CardioMEMS, HCPCS Code GMEM1, CPT Code 93264 (APCs 5724 and 5741)

The CardioMEMS Heart Failure System allows practitioners treating heart failure patients to wirelessly monitor and measure pulmonary artery pressure and heart rate in patients with heart failure and transmit the information to the physician to inform the treatment plan for the patient. The system includes two critical components: first, a miniaturized, wireless monitor, which is implanted into a patient's pulmonary artery, and second, a smart pillow (the CardioMEMS Patient Electronics System), which captures and transmits readings via safe radio frequency from the patient's implanted CardioMEMS Heart Failure System. The CardioMEMS Heart Failure System enables patients to transmit critical heart failure status information to clinicians regularly, potentially eliminating the need for frequent clinic or hospital visits. The CardioMEMS Heart Failure System is described by CPT code 33289 (Transcatheter implantation of wireless pulmonary artery pressure sensor for long-term hemodynamic monitoring, including deployment and calibration of the sensor, right heart catheterization, selective pulmonary catheterization, radiological supervision and interpretation, and pulmonary artery angiography, when performed).

Interested parties have met with CMS and highlighted the critical importance of the device for heart failure patients who require close monitoring of weight and blood pressure to prevent fluid buildup around the heart and have requested that CMS establish coding to describe when practitioners and hospitals incur costs during clinical scenarios when crucial components of the system require replacement. Given that these components are crucial for system functionality and there is no existing coding framework to address their replacement, we believe that establishing appropriate coding and payment mechanisms can facilitate the provision of these services more effectively in the office and hospital settings. In the CY 2025 Physician Fee Schedule (PFS) proposed rule, we proposed a new code, HCPCS code GMEM1 (Provision of replacement patient electronics system (for example, system pillow) for home pulmonary artery pressure monitoring including provision of materials for use in the home and reporting of test results to physician or qualified health care professional). The CY 2025 PFS proposed rule (89 FR 61956) sought comment from interested parties regarding direct costs from invoices for the replacement component referenced above, utilization estimates, and potential indicators.

CPT Code 93264 (Remote monitoring of a wireless pulmonary artery pressure sensor for up to 30 days, including at least weekly downloads of pulmonary artery pressure recordings, interpretation(s), trend analysis, and report(s) by a physician or other qualified health care professional) can be used by hospitals to bill for the ongoing analysis and monitoring performed with CardioMEMS.

While we did not discuss the GMEM1 code in the CY 2025 OPPS proposed rule preamble it was included in Addendum B with an assignment to APC 5741 (Level 1 Electronic Analysis of Devices) with a payment rate of $36.90 and assigned a status indicator of Q1. CPT code 93264 was included in Addendum B with a status indicator of ''M'' to indicate that this code is not payable under the OPPS.

The issue of payment for GMEM1 was brought to the Advisory Panel on Hospital Outpatient Payment (also known as HOP Panel) in 2024 for CY 2025 rulemaking. At the August 2024 meeting, based on the information presented, the Panel did not make any recommendations on GMEM1.

We note that HCPCS code G0555 is replacing the placeholder code GMEM1.

Comment: In their comment letters on the CY 2025 OPPS proposed rule, commenters indicated that the G0555 (placeholder codeGMEM1) code descriptor proposed in the CY 2025 PFS proposed rule introduces confusion by also referencing reporting test results to the physician, which is a separate function furnished by a different party than the replacement Patient Electronics System (PES). Commenters requested that CMS revise the proposed code descriptor for G0555 (placeholder code GMEM1) to clarify that it is for the replacement PES only and remove the following language from the descriptor: ''and reporting of test results to physician or qualified health care professional''). Commenters requested that if the code is finalized under OPPS (and PFS) with the revised descriptor, that CMS assign it to APC 1528, New Technology—Level 28 ($5001-$5500), which they believe is reflective of the cost of the replacement PES.

Response: We agree that assignment to APC 5741 is likely not reflective of the cost of the replacement PES. However, assignment to New Technology APCs usually occurs when there is no existing clinical APC that is appropriate in terms of clinical similarity or resources. Based on the nature of the procedure, we believe that the service associated with GMEM1 is more appropriately in APC 5724 (Level 4 Diagnostic Tests and Related Services). We believe that the service described by HCPCS code G0555 (placeholder code GMEM1) shares similar resource costs and clinical characteristics with services included in APC 5724. Assignment to APC 5741 may not have sufficiently covered the cost of the replacement of the PES. Therefore, for CY 2025, we are revising the assignment for HCPCS code G0555 (placeholder code GMEM1) to APC 5724, with a status indicator of ''S''.

Comment: Commenters recommend that CMS revise the OPPS status indicator for CPT 93264, which CMS proposed to designate as ''M'' (not payable under the OPPS). They argued that this classification is contrary to CMS's treatment of similar monitoring procedures (*e.g.,* CPT codes 93297 and 93298), which have status indicator ''Q1'' and are assigned to APC 5741 (Level 1 Electronic Analysis of Devices).

Response: As listed in OPPS Addendum D1 of the CY 2025 OPPS/ASC proposed rule, codes assigned to status indicator ''Q1'' may be packaged, assigned to a composite APC, or paid separately under the OPPS. Specifically, a ''Q1'' status indicator may indicate a:

- Packaged APC payment if billed on the same claim as a HCPCS code assigned status indicator ''S'', ''T'', or ''V''; or
- Composite APC payment if billed with specific combinations of services based on OPPS composite-specific payment criteria. Payment is packaged into a single payment for specific combinations of services; or
- In other circumstances, payment is made through a separate APC payment

After reviewing the public comments, we agree with commenters that it is appropriate for the procedure described by CPT code 93264 to be assigned to status indicator Q1(conditionally packaged). Therefore, we are revising the status indicator for the code from ''M'' (not payable under the OPPS'') to ''Q1'' (conditionally packaged). The conditional packaging of this code supports our overarching goal to make payments for all services paid under the OPPS and ASC payment system more consistent with those of a prospective payment system and less like those of a per-service fee schedule. We believe that packaging encourages efficiency and is an essential component of a prospective payment system, and that packaging payments for items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service is a

fundamental part of the OPPS. We therefore believe packaging of CPT code 93264 is appropriate.

Because CPT code 93264 was assigned status indicator ''M'' (not payable under the OPPS) we have no claims data to use for making an APC assignment for CPT code 93264 in CY 2025. We agree with commenters that the code is similar in clinical and resource use to CPT codes 93297 and 93298. Therefore, we will be assigning CPT code 93264 to APC 5741 (Level 1 Electronic Analysis of Devices) for CY 2025.

In summary, after consideration of the public comment, we are finalizing the APC assignment for HCPCS code G0555 (placeholder code GMEM1) with modification. Specifically, we are revising the APC assignment for HCPCS code G0555 (placeholder code GMEM1) to APC 5724 and assigning the code to status indicator ''S'' for CY 2025. We are revising the status indicator for CPT 93264 and assigning a status indicator of ''Q1'' for CY 2025. Lastly, we are assigning CPT 93264 to APC 5741 for CY 2025. The final CY 2025 OPPS payment rate for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addendum D1 is available via the internet on the CMS website.

We refer readers to Table 79 for the code descriptor, APC assignment, status indicator assignment, and payment indicator assignment for CPT codes G0555 (placeholder code GMEM1) and 93264 for CY 2025.

TABLE 79: CY 2025 PROPOSED OPPS APC AND STATUS INDICATOR FOR HCPCS CODE G0555 AND CPT CODE 93264

HCPCS Code	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
G0555 (placeholder code GMEM1)	Provision of replacement patient electronics system (for example, system pillow) for home pulmonary artery pressure monitoring including provision of materials for use in the home	S	5741	S	5724
93264	Remote monitoring of a wireless pulmonary artery pressure sensor for up to 30 days, including at least weekly downloads of pulmonary artery pressure recordings, interpretation(s), trend analysis, and report(s) by a physician or other qualified health care professional	M		Q1	5741

17. Caregiver Training Services, HCPCS Codes GCTD1, GCTD2, and GCTD3 (APC 5731)

The CY 2025 Physician Fee Schedule (PFS) proposed rule (89 FR 61956) proposed to establish new coding and payment for caregiver training for direct care services and supports. The topics of training could include, but would not be limited to, techniques to prevent decubitus ulcer formation, wound dressing changes, and infection control. Unlike other caregiver training codes that are currently paid under the PFS, the caregiver training codes for direct care services and supports focus on specific clinical skills aimed at the caregiver effectuating hands-on treatment, reducing complications, and monitoring the patient when the patient is not capable to do so themselves. Three new HCPCS codes were proposed: GCTD1 (*Caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound dressing changes, and infection control) (without the patient present), face-to-face; initial 30 minutes*), GCTD2 (*Caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound dressing changes, and infection control) (without the patient present), face-to-face; each additional 15 minutes (List separately in addition to code for primary service) (Use GCTD2 in conjunction with GCTD1)*), and GCTD3 (*Group caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent*

decubitus ulcer formation, wound dressing changes, and infection control) (without the patient present), face-to-face with multiple sets of caregivers)). We did not propose APC or status indicator assignments for these G codes in the CY 2025 OPPS proposed rule (89 FR 59186).

We note that the HCPCS codes G0541, G0542, and G0543 are replacing their respective placeholder codes GCTD1, GCDT2, and GCTD3.

Comment: We received several comments related to the CY 2025 Physician Fee Schedule (PFS) proposal suggesting that we begin providing payment for Caregiver Training Services (CTS) G0541, G0542, and G0543placeholder codes GCTD1, GCTD2, and GCTD3) under the OPPS. Commenters asked for clarification on whether these codes would be given the OPPS status indicator ''A,'' which would limit their use for outpatient hospital payment purposes to therapists only, or whether CMS will assign separately payable status indicators to those codes. Commenters stated that assigning separately payable status would recognize the different types of hospital staff that can render appropriate CTS. Commenters requested that CMS make the newly proposed CTS codes G0541, G0542, and G0543 (placeholder codes GCTD1, GCTD2, and GCTD3) payable under the OPPS.

Response: HCPCS codes G0541, G0542, and G0543 (placeholder codes GCTD1, GCTD2, and GCTD3) will be effective on January 1, 2025. Based on our evaluation of these new codes, we are proposing an interim assignment of HCPCS codes G0541, G0542, and G0543 (placeholder codes GCTD1, GCTD2, and GCTD3) to status indicator ''A'' to indicate that these codes are payable under a fee schedule or payment system other than the OPPS. These services are covered Medicare services and will be assigned payable indicators under the Physician Fee Schedule (PFS). While these services are not payable under the OPPS, they are payable under the PFS; therefore, we are proposing to assign them status indicator of ''A.'' Sections 1834(k) and 1833(a)(8) of the Act require that payment be made for outpatient therapy services (physical therapy, speech language pathology, and occupational therapy) furnished by providers of therapy services, including a hospital (to its outpatients and inpatients not under a Part A stay), be made under the PFS.

In summary, we are proposing an interim assignment of HCPCS codes G0541, G0542, and G0543 (placeholder codes GCTD1, GCTD2, and GCTD3) to status indictor ''A'' to indicate that the code is payable under a fee schedule or payment system other than the OPPS. Because we were not able to propose APC and status indicator assignments in the CY 2025 OPPS proposed rule, we will be assigning HCPCS codes G0541, G0542, and G0543 (placeholder codes GCTD1, GCTD2, and GCTD3) comment indicator ''NI'' in Addendum B of this final rule. This comment indicator is for new HCPCS codes that will be effective January 1, 2025, to indicate that we are assigning them an interim status indicator and APC assignment, which is subject to public comment. We invite public comment on the interim proposed status indicators for HCPCS codes G0541, G0542, and G0543 (placeholder codes GCTD1, GCTD2, and GCTD3), which will then be finalized in the CY 2026 OPPS/ASC final rule with comment period.

Please refer to Table 80 below for the proposed interim status indicator assignments for HCPCS codes G0541, G0542, and G0543 (placeholder codes GCTD1, GCTD2, and GCTD3) for CY 2025.

TABLE 80: INTERIM CY 2025 SI FOR THE CAREGIVER TRAINING SERVICES HCPCS CODES EFFECTIVE JANUARY 1, 2025

HCPCS Code	Long Descriptor	Interim CY 2025 OPPS SI	Comment Indicator
G0541 (placeholder code GCTD1)	Caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound dressing changes, and infection control) (without the patient present), face-to-face; initial 30 minutes)	A	N1
G0542 (placeholder code GCTD2)	Caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound dressing changes, and infection control) (without the patient present), face-to face; each additional 15 minutes (List separately in addition to code for primary service) (Use GCTD2 in conjunction with GCTD1)	A	N1
G0543 (placeholder code GCTD3)	Group caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound dressing changes, and infection control) (without the patient present), face-to face with multiple sets of caregivers))	A	N1

18. Chimeric Antigen Receptor Therapy (CAR–T), CPT Codes 0537T, 0538T, 0539T, and 0540T (APC 5694)

Chimeric Antigen Receptor T-Cell (CAR T-cell) therapy is a cell-based gene therapy in which T-cells are collected and genetically engineered to express a chimeric antigen receptor that will bind to a certain protein on a patient's cancerous cells. The CAR T-cells are then administered to the patient to attack certain cancerous cells, and the individual is observed for potential serious side effects that would require medical intervention. We refer readers to previous discussions in the OPPS/ASC final rules with comment period for background regarding the specific CAR T-cell products, in both the CY 2020 OPPS/ASC final rule with comment period (84 FR 61231 through 61234) and the CY 2019 OPPS/ASC final rule with comment period (83 FR 58904 through 58908). In addition, for discussion about CY 2022 OPPS payment policies for separately paid drugs with pass-through status expiring or continuing in CY 2022, please see sections V.A.4 and V.A.5 of this final rule with comment period. The AMA created four Category III CPT codes that are related to CAR T-cell therapy, effective January 1, 2019. As discussed in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58904 through 58908), the CY 2020 OPPS/ASC final rule with comment period (84 FR 61231 through 61234), and the CY 2021 OPPS/ASC final rule with comment period (85 FR 85949 through 85951) we finalized our proposal to assign procedures described by CPT codes 0537T, 0538T, and 0539T to status indicator ''B'' (Codes that are not recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and 13x)) to indicate that the services are not paid under the OPPS. The procedures described by CPT codes 0537T, 0538T, and 0539T describe the various steps required to collect and prepare the genetically modified T-cells, and Medicare does not generally pay separately for each step used to

manufacture a drug or biological. We also finalized that the procedures described by CPT code 0540T would be assigned status indicator ''S'' (Procedure or Service, Not Discounted when Multiple) and APC 5694 (Level 4 Drug Administration) for CY 2019 through CY 2024 and made no proposal to change the assignment for CY 2025. Additionally, the National Uniform Billing Committee (NUBC) established CAR T-cell-related revenue codes and a value code to be reportable on Hospital Outpatient Department (HOPD) claims effective for claims received on or after April 1, 2019.

Category III CPT codes 0537T, 0538T, 0539T, and 0540T are being replaced by Category I CPT codes 38225, 38226, 38227, and 38228, which were previously represented by placeholder codes 3X018, 3X019, 3X020, and 3X021. As such, we made no specific proposal related to the CAR T-cell preparation codes but proposed to apply the existing APC and status indicator assignments for the predecessor Category III CPT codes to the replacement Category I CPT codes.

As listed in Addendum B of the CY 2025 OPPS/ASC proposed rule, we proposed to continue to assign procedures described by these CPT codes, 3X018, 3X019, and 3X020, to status indicator ''B'' (Codes that are not recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and 13x)) to indicate that the services are not paid under the OPPS. We proposed to continue to assign CPT code 3X021 to status indicator ''S'' (Procedure or Service, Not Discounted when Multiple) and APC 5694 (Level IV Drug Administration).

Comment: Some commenters provided input on the proposed policies in the physician office setting regarding the dose preparation procedures associated with CAR T-cell therapy and other billing topics in the office setting, such as the expansion of digits on MAC claims processing screens for physician office claims.

Response: Comments related to the CY 2025 PFS payment policies are out of scope.

Comment: Several commenters opposed our proposal to continue to assign status indicator ''B'' to CPT codes 38225, 38226, and 38227, for CY 2025. Many commenters provided alternate status indicator assignment recommendations, such as ''S'', as well as APC assignment recommendations. Commenters stated that by allowing these codes to be billable and paid, CMS could use claims data collected to assign the codes to more accurate APCs. Some commenters explained that CMS's overall practice and billing process should be reevaluated, with some recommending revisions to, or the retirement of, MLN Matters Number SE19009 [26] which they believed caused confusion, raised numerous program integrity concerns, including confusion regarding what can be included in ASP reporting, increased inconsistencies with Medicare requirements for under arrangement services and with charges reported and hospital billing, and commenters believed the elimination of this guidance, including separate payment of 38225, 38226, and 38227, would reduce hospital burden. One commenter raised the concern that some manufacturers will pay hospitals for the dose preparation services, while other manufacturers will not. In their view, this raises potential program integrity concerns and could influence medical decision making.

Commenters stated that the cell collection required as part of the CAR T-cell therapy process is done by leukapheresis, a costly and labor-intensive procedure in commenters' view. Commenters also communicated that the hospital in which the preparation procedure occurs is not always the same facility in which the final infusion of the therapy occurs. In their view, this could disincentivize hospitals from providing the preparation procedures if they are not the hospital ultimately providing the final product. A few commenters emphasized that manufacturers do not provide these services, hospitals do. Commenters believed ''under-arrangements'' made between hospitals were infeasible long term given the likely growth in the volume of these therapies and the costs incurred. Commenters also discussed that the preparation procedures could occur months apart from the final administration of the product.

Many of these commenters also stated that 10–15 percent of the time a finalized CAR T-cell therapy product is never administered to a beneficiary, which could occur for a multitude of reasons, such as a manufacturing failure, or disease progression potentially resulting in death or ineligibility for treatment while the CAR T-cell therapy product is being manufactured.

Commenters also recommended CMS revise the product specific Q-codes to remove ''leukapheresis and dose preparation procedures'' and they believe it is inappropriate for these services to be described by the HCPCS Level II codes when they can be described by Level I HCPCS codes. Additional commenters recommended CMS transition the product specific Q-codes to permanent J-codes.

Several commenters discussed other therapies, such as stem cell transplant, and therapies such as those described by HCPCS codes J3394 (Injection, lovotibeglogene autotemcel, per treatment) and J3393 (Injection, betibeglogene autotemcel, per treatment), which in commenter's view is similar to CAR T-cell therapy and requires similar dose preparation procedures.

Commenters supported the 2024 Advisory Panel on Hospital Outpatient Payment recommendation to assign CPT code 38225/3X018, *Chimeric antigen receptor T-cell therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR–T cells, per day,* an SI of S and place the code in APC 5242, *Level 2 Blood Product Exchange and Related Services.* The Panel further recommended that CMS assign CPT code 38226/3X019, *Chimeric antigen receptor T-cell therapy; preparation of blood-derived T lymphocytes for transportation (e.g., cryopreservation, storage);* and CPT code 38227/3X020, *Chimeric antigen receptor T-cell therapy; receipt and preparation of CAR–T cells for administration;* an SI of S and place these codes in APC 5241, *Level 1 Blood Product Exchange and Related Services.*

Response: We thank the commenters for their feedback. CMS continues to believe that the procedures described by CPT codes 0537T, 0538T, and 0539T and replacement CPT codes 38225, 38226, and 38227, describe the various steps required to collect and prepare the genetically modified T-cells, and Medicare does not generally pay separately for each step used to manufacture a drug or biological product. Therefore, CMS does not believe that separate or packaged payment under the OPPS is necessary for the procedures described by CPT codes 38225, 38226, and 38227, for CY 2025. However, we thank commenters for providing their unique perspectives and experiences in situations where the manufacturing process does not result in a final product being administered to a beneficiary.

We note that the current HCPCS coding for the currently approved CAR T-cell therapies include leukapheresis and dose preparation procedures, as these services are included in the manufacturing of these biologicals. Therefore, payment for these services is

[26] *https://www.cms.gov/regulations-and-guidance/guidance/transmittals/2019-transmittals-items/se19009.*

incorporated into the drug codes. CMS is not revising the descriptors for the Q-codes to remove leukapheresis and dose preparation procedures nor are we transitioning the Q-codes to J-codes at this time.

We note that, although there is no payment associated with CPT codes 38225, 38226, and 38227, for reasons stated previously, these codes can still be reported to CMS for tracking purposes. We thank commenters for their feedback and for raising concerns related to our guidance contained in MLN Matters Article SE19009. We are not revising this document at this time as we believe these instructions are consistent with our longstanding policies, but we understand the feedback provided. Accordingly, we are not accepting the recommendations at this time to revise the status indicators for procedures described by CPT codes 38225, 38226, and 38227. We will continue to evaluate and monitor payment for CAR T-cell therapies. In summary, after consideration of the public comments we received, we are finalizing our proposal to assign status indicator ''B'' to CPT codes 38225, 38226, and 38227 for CY 2025 without modification.

Additionally, we are continuing our policy from CY 2019 to assign status indicator ''S'' to CPT code 38228 for CY 2025. Table 81 shows the final SI and APC assignments for HCPCS codes 38225, 38226, 38227, and 38228 for CY 2025. For more information on CY 2025 OPPS final status indicators, APC assignments, and payment rates for HCPCS codes, including the CAR T-cell drug codes, we refer readers to Addendum B to this final rule with comment period. In addition, the status indicator definitions can be found in Addendum D1 (OPPS Payment Status Indicators for CY 2025) to this final rule with comment period. Both Addendum B and D1 are available via the internet on the CMS website.

TABLE 81. FINAL CY 2025 STATUS INDICATORS AND APCS FOR CATEGORY I AND III CPT CODES FOR THE PREPARATION OF CAR T-CELL THERAPY

CPT Code	Long Descriptor	Finalized CY 2025 Status Indicator	Finalized CY 2025 APC
0537T	Chimeric antigen receptor t-cell (car-t) therapy; harvesting of blood-derived t lymphocytes for development of genetically modified autologous car-t cells, per day	D	N/A
0538T	Chimeric antigen receptor t-cell (car-t) therapy; preparation of blood-derived t lymphocytes for transportation (e.g., cryopreservation, storage)	D	N/A
0539T	Chimeric antigen receptor t-cell (car-t) therapy; receipt and preparation of car-t cells for administration	D	N/A
0540T	Chimeric antigen receptor t-cell (car-t) therapy; car-t cell administration, autologous	D	5694
3X018/38225	Chimeric antigen receptor t-cell (car-t) therapy; harvesting of blood-derived t lymphocytes for development of genetically modified autologous car-t cells, per day	B	N/A
3X019/38226	Chimeric antigen receptor t-cell (car-t) therapy; preparation of blood-derived t lymphocytes for transportation (e.g., cryopreservation, storage)	B	N/A
3X020/38227	Chimeric antigen receptor t-cell (car-t) therapy; receipt and preparation of car-t cells for administration	B	N/A
3X021/38228	Chimeric antigen receptor t-cell (car-t) therapy; car-t cell administration, autologous	S	5694

19. Complex Bunion Correction Procedure CPT Code 28297 (APC 5115)

CPT code 28297 describes a surgical procedure to correct a bunion, or hallux valgus, in the foot. The procedure involves:

- Removing the bunion
- Realigning the big toe
- Correcting the bony prominence at the base of the toe

- Fusing the joint between the first metatarsal bone and the medial cuneiform bone
- Removing the sesamoid bones, which are pea-shaped bones under the big toe joint

In the CY 2025 OPPS/ASC proposed rule, we proposed to move CPT code 28297 (Correction, hallux valgus with bunionectomy, with sesamoidectomy when performed; with first metatarsal and medial cuneiform joint arthrodesis, any method) from APC 5114 (Level 4 Musculoskeletal Procedures) to APC 5115 (Level 5 Musculoskeletal Procedures) with the proposed payment rate of $12,755.58.

We received several comments supporting the proposed reassignment of CPT code 28297 from APC 5114 (Level 4 Musculoskeletal Procedures) to APC 5115 (Level 5 Musculoskeletal Procedures).

Comment: One commenter stated that CPT code 28297 clearly meets the criteria for reassignment. The total frequency of CPT code 28297 exceeded the significance threshold of 1,000 procedures. The geometric mean cost of CPT code 28297 exceeded two times the geometric mean cost of the lowest significant procedure in APC 5114 (Level 4 Musculoskeletal Procedures). Furthermore, the geometric mean cost of CPT code 28297 was nearly equal to the geometric mean cost of APC 5115 (Level 5 Musculoskeletal Procedures). Several other commenters also supported assigning CPT code 28297 to APC 5114 ((Level 5 Musculoskeletal Procedures).

Response: We agree with the commenters, and we thank them for their support. In summary, after consideration of the public comments that we received, we are finalizing our proposal without modification and are assigning CPT code 28297 to APC 5115 (Level 5 Musculoskeletal Procedures) for CY 2025. The final CY 2025 payment rate for this code can be found in Addendum B of this final rule with comment period.

20. Computational Electrocardiogram (ECG) Analysis System (vMap), CPT Code 0897T (APC 5724)

CPT code 0897T (Noninvasive augmentative arrhythmia analysis derived from quantitative computational cardiac arrhythmia simulations, based on selected intervals of interest from 12-lead electrocardiogram and uploaded clinical parameters, including uploading clinical parameters with interpretation and report) utilizes ECG data to identify potential arrhythmia focal points for patients. The vMap provides augmented information which enables physicians to characterize arrhythmia and assists in triage and treatment of abnormal rhythm. CPT code 0897T became effective July 1, 2024 and since its establishment, the code has been assigned to APC 5724 (Level 4 Diagnostic Tests and Related Services) for CY 2024. Because this is a new code for CY 2024, there are no claims available. For CY 2025, we proposed to maintain the assignment to APC 5724, with a payment rate of $1,012.27.

Comment: One commenter supported our proposal to assign CPT code 0897T to APC 5724, due to the resource similarity of this technology to other procedures assigned to APC 5724.

Response: We appreciate the commenter's feedback on CPT code 0897T and we agree with the commenter's recommendation to finalize the APC assignment.

After consideration of the public comment we received, we are finalizing our proposal without modification for CPT code 0897T. Please refer to Table 82 below for the final OPPS APC and status indicator assignment for HCPCS code 0897T for CY 2025. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 82: FINAL CY 2025 OPPS APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODE 0897T

CPT Code	Long Descriptor	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
0897T	Noninvasive augmentative arrhythmia analysis derived from quantitative computational cardiac arrhythmia simulations, based on selected intervals of interest from 12-lead electrocardiogram and uploaded clinical parameters, including uploading clinical parameters with interpretation and report	S	5724

21. Computed Tomographic Colonography, CPT Code 74263 (APC 5523)

For CY 2024, we assigned CPT code 74263 (Computed tomographic (CT) colonography, screening, including image postprocessing) to status indicator ''E1'' indicating that the service was not covered and not payable by Medicare under the OPPS. For the CY 2025 OPPS/ASC proposed rule, we proposed to assign CPT code 74263 to APC 5522 (Level 2 Imaging without Contrast) and a status indicator of ''S'' (Procedure or Service, Not Discounted When Multiple. Paid under OPPS; separate APC payment) to indicate that the code is separately payable under OPPS based on the proposed coverage changes for the colorectal cancer screening. (We refer our readers to section X.E. of this final rule with comment period for a full discussion of the coverage changes for colorectal cancer screening services.)

For the CY 2025 OPPS/ASC proposed rule, we believed the time and resources associated with performing a screening virtual colonoscopy is similar to those necessary to furnish a diagnostic virtual colonoscopy, which is described by CPT code 74261 (Computed tomographic (ct) colonography, diagnostic, including image postprocessing; without contrast material). Consequently, we proposed to

assign CPT code 74263 to APC 5522 (Level 2 Imaging without Contrast) based on its clinical and resource homogeneity to CPT code 74261, which is assigned to the same clinical APC.

Comment: We received one comment requesting to reassign CPT code 74263 to APC 5571 (Level 1 Imaging with Contrast). The commenter is concerned that the proposed payment for the screening CT colonography is insufficient to cover the costs of providing the service. The commenter believed that other services within that APC family such as CT abdomen with contrast have greater clinical homogeneity with CPT code 74263.

Response: We thank the commenter for their input. We disagree with the commenter that CPT code 74263 should be placed in APC 5571 (Level 1 Imaging with Contrast) as it is a procedure that is completed without contrast. However, we do believe that this newly covered screening test for colorectal cancer should be assigned to an APC where payment is more comparable to the purported resource costs. Given that any claims data in CY 2023 would be from before the service was payable in the OPPS, it would be difficult to rely on the claims data to determine the APC assignment for this code. Based on our review of the service (CT colonography) compared to other services assigned to the Imaging without Contrast APC series, we believe CPT code 74176 (Computed tomography, abdomen and pelvis; without contrast material) is an appropriate crosswalk code for CPT code 74263.

In summary, after consideration of the public comment, we are finalizing our proposal with modification to assign CPT code 74263 to APC 5523 (Level 3 Imaging without Contrast) and a status indicator of ''S'' for CY 2025. The final CY 2025 payment with rates for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI definitions for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

22. Concurrent Optical and Magnetic Stimulation (COMS) Therapy, CPT Codes 0906T and 0907T (APC 5051)

On June 20, 2023, CMS approved for Medicare coverage the Category B Investigational Device Exemption (IDE) study associated with concurrent optical and magnetic stimulation (Study Title: [27] Concurrent Optical and Magnetic Stimulation (COMS) for Treatment of Refractory Diabetic Foot Ulcer; a Prospective Randomized, Sham-controlled, Double-blinded, Pivotal Clinical Trial; NCT number NCT05758545; IDE number G220277 [28]). For the July 2024 update, the AMA CPT Editorial Panel established 0906T (placeholder code XX18T) (Concurrent optical and magnetic stimulation therapy, wound assessment and dressing care; first application, total wound(s) surface area less than or equal to 50 sq cm) and 0907T (placeholder code XX37T) (Concurrent optical and magnetic stimulation (COMS) therapy, wound assessment and dressing care; each additional application, total wound(s) surface area less than or equal to 50 sq cm (List separately in addition to code for primary procedure)) for COMS, effective January 1, 2025.

For the CY 2025 OPPS/ASC proposed rule, CMS proposed to assign the SIs and APCs listed in Table 83 below for the new codes based on the clinical characteristics of the procedures.

TABLE 83: PROPOSED CY 2025 OPPS APC AND STATUS INDICATORS FOR CPT CODES 0906T AND 0907T

CPT Code	Long Descriptor	Proposed 2025 OPPS SI	Proposed 2025 OPPS APC	Proposed CY 2025 OPPS APC Title	Proposed CY 2025 Payment Rate
0906T	Concurrent optical and magnetic stimulation therapy, wound assessment and dressing care; first application, total wound(s) surface area less than or equal to 50 sq cm	S	5051	Level 1 Skin Procedures	$201.14
0907T	Concurrent optical and magnetic stimulation (COMS) therapy, wound assessment and dressing care; each additional application, total wound(s) surface area less than or equal to 50 sq cm (List separately in addition to code for primary procedure)	N	N/A	N/A	N/A

We note that at the August 28, 2024, HOP Panel Meeting, a presentation was made requesting the reassignment to APC 5053 for CPT code 0906T (placeholder code XX18T). Based on the information presented at the meeting, the Panel made no recommendation on the APC assignment for the code.

[27] *ClinicalTrials.gov*. ''Trial to Evaluate the Safety and Effectiveness of Treatment With COMS One Device in Subjects With Diabetic Foot Ulcers (Mavericks).'' Accessed September 24, 2024. *https://clinicaltrials.gov/study/NCT05758545*

[28] Approved IDE Studies- ''G220277–NCT05758545.'' Accessed September 24, 2024. *https://www.cms.gov/medicare/coverage/ide/approved-ide-studies/683545095/g220277-nct05758545*

Comment: We received a comment from the manufacturer of COMS on our proposed assignments for the codes listed in Table 83. The commenter stated that the COMS procedures include extensive wound examination, wound bed preparation, and dressing management. With the inclusion of standard wound care administered before and after each active COMS device treatment, the commenter estimates that the total time required for a COMS procedure is 35–50 minutes, during which considerable medical supplies and facility resources are utilized. The manufacturer suggested that the total resource code for CPT code 0906T is $627, with $392 in hospital facility resource costs and $235 specifically for the COMS device-associated costs. The commenter maintains that the assignment to APC 5051, which has a proposed CY 2025 payment rate of $201.14, does not cover the costs of the procedure.

The commenter claims that CPT code 0906T is sufficiently similar in terms of resources and time to CPT codes 11043 (Debridement, muscle and/or fascia (includes epidermis, dermis, and subcutaneous tissue, if performed); first 20 sq cm or less) and 12044 (Repair, intermediate, wounds of neck, hands, feet and/or external genitalia; 7.6 cm to 12.5 cm), both assigned to APC 5053 ((Level 3 Skin Procedures, proposed CY 2025 payment rate of $619.63), to warrant the reassignment of CPT code 0906T to APC 5053. The commenter further stated that assigning these procedures to APC 5053 would align with other wound care procedures with similar resource costs and procedural time.

Response: We thank the commenter for their input. We have no claims data for CPT code 0906T available for this final rule. However, based on this code's similarity to CPT code 0521T (Extracorporeal shock wave for integumentary wound healing, including topical application and dressing care; initial wound) and CPT code 97610 (Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day) which are both assigned to APC 5051, we continue to believe CPT code 0906T has clinical and resource similarities to procedures assigned to APC 5051. Therefore, for CY 2025, we are finalizing our proposal without modification and assigning CPT code 0906T to APC 5051. Table 84 lists the final CY 2025 OPPS payment rate for 0906T and 0907T.

In summary, after consideration of the public comment that we received, we are finalizing the APC and SI assignments for CPT codes 0906T to APC 5051. As we do every year, we will reevaluate the APC assignments for these codes in the next rulemaking cycle. We remind hospitals that we review, on an annual basis, the APC assignments for all items and services paid under the OPPS. The final payment rates for the codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

TABLE 84: FINAL CY 2025 OPPS APC AND SI ASSIGNMENT FOR CPT CODES 0906T AND 0907T

CPT Code	Short Descriptor	Proposed CY 2025 SI	Proposed CY 2025 APC	Final CY 2025 SI	Final CY 2025 APC
XX18T/ 0906T	Concurrent optical and magnetic stimulation therapy, wound assessment and dressing care; first application, total wound(s) surface area less than or equal to 50 sq cm	S	5051	S	5051
XX37T/ 0907T	Concurrent optical and magnetic stimulation (COMS) therapy, wound assessment and dressing care; each additional application, total wound(s) surface area less than or equal to 50 sq cm (List separately in addition to code for primary procedure)	N	N/A	N	N/A

23. Cystourethroscopy With Temporarily Implanted Nitinol Device Procedure, HCPCS Code C9769 (APC 5376)

Cystourethroscopy temporarily implanted nitinol device (iTIND) is a minimally invasive surgery to treat bothersome lower urinary tract symptoms (LUTS) caused by benign prostate enlargement. The iTIND serves to re-model the bladder neck and the prostatic urethra. The HCPCS Code C9769 (Cystourethroscopy, with insertion of temporary prostatic implant/stent with fixation/anchor and incisional struts) became effective October 1, 2020.

For CY 2025, the proposed OPPS payment rates are based on available CY 2023 claims data. For CY 2025, based on our analysis of claims data, we found a total of 96 single frequency claims and a geometric mean cost of approximately $4,902 for HCPCS code C9769. For CY 2025, we proposed to continue to assign HCPCS code C9769 to APC 5376 (Level 6 Urology and Related Services) with a proposed payment rate of approximately $9,209.

Comment: One commenter pointed out that the AMA CPT created a new code, CPT code 5XX05 effective January 1, 2025, to describe the cystourethroscopy with iTIND service represented by HCPCS code C9769. CPT code 5XX05 (Cystourethroscopy with insertion of temporary device for ischemic remodeling (*i.e.,* pressure necrosis) of bladder neck and prostate) becomes effective January 1, 2025. The commenter stated that CMS may either sunset HCPCS code C9769 and reassign the underlying claims to CPT code 5XX05 or maintain HCPCS code C9769 active and assign CPT code 5XX05 to a non-payable status in the OPPS.

Response: We thank the commenter for pointing out that CPT code 5XX05 (53865) will become effective January 1, 2025. We note that we will replace HCPCS code C9769 with CPT code 5XX05 (53865) effective January 1, 2025, as well as assign the underlying claims associated with HCPCS code C9769 to CPT code 5XX05 (53865). Therefore, for CY 2025, we are reassigning CPT code 5XX05 (53865) to Level 6 Urology and Related Services (APC 5376). We note that we will continue to evaluate and monitor the cost for CPT code 5XX05 (53865) for future rulemaking.

After consideration of the public comment we received, we are finalizing our policy to assign CPT code 5XX05 (53865) to APC 5376 (Level 6 Urology and Related Services) and we will be sunsetting HCPCS code C9769. Please refer to Table 85 for the final OPPS APC and status indicator assignment for CPT code 5XX05 (53865) for CY 2025. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 85: FINAL CY 2025 OPPS APC STATUS INDICATOR ASSIGNMENTS FOR CPT CODE 5XX05 (53865)

CPT Code	Long Descriptor	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
5XX05 (53865)	Cystourethroscopy with insertion of temporary device for ischemic remodeling (i.e., pressure necrosis) of bladder neck and prostate	J1	5376

24. Dental Alveoloplasty and Exostosis Removal Procedures, CDT Codes D7320, D7321, and D7471 (APCs 5163, 5164)

Effective January 1, 2024, we made 229 additional dental codes payable under the OPPS when payment and coverage requirements are met, as provided in the relevant PFS payment rules regarding Medicare Part B payment for dental services (88 FR 81540–82185). For CY 2025, we did not propose to make additional dental codes payable under the OPPS. As a result, we proposed to continue to assign many dental services to non-payable status indicators, including CDT codes D7320 (Alveoloplasty not in conjunction with extractions—four or more teeth or tooth spaces, per quadrant), D7321(Alveoloplasty not in conjunction with extractions—one to three teeth or tooth spaces, per quadrant), and D7471 (Removal of lateral exostosis (maxilla or mandible), which we proposed to assign to status indicator ''B,'' indicating the service is not paid under OPPS, for CY 2025.

Comment: We received a comment from an association representing oral and maxillofacial surgeons requesting that we make CDT codes D7320, D7321, and D7471 payable under the OPPS. The commenter stated that these codes may contribute to the elimination of an oral or dental infection. The commenter explained that alveoloplasty and the removal of lateral exostosis are often necessary procedures for medically compromised patients undergoing tooth removal prior to radiation treatment. Failure to perform these procedures, per the commenter, can put patients at risk for osteoradionecrosis following radiation therapy. In addition, the commenter explained that not performing an alveoloplasty or removing the exostosis when clinically indicated may impede the patient's ability to receive a removable prosthesis due to the risk of tissue trauma. The procedures may also be required to address common sequelae following dental extractions. Per the commenters, excluding the services described by CDT codes D7320, D7321, and D7471 from OPPS payment places patients at considerable risk and diminishes the effectiveness of initial treatments aimed at eliminating oral or dental infections. Finally, the commenters stated that there are existing CPT codes that describe these procedures. Specifically, per the commenters, CPT code 41874 (Alveoloplasty, each quadrant (specify)) may describe alveoloplasty procedures and CPT code 41823 (Excision of osseous tuberosities, dentoalveolar structures) may describe the removal of exostosis.

Response: We appreciate the commenter's input. We note that the commenter submitted a similar public comment to the CY 2024 OPPS/ASC final rule to assign several codes, including CDT codes D7320, D7321, and

D7471, to APCs for CY 2024. In the CY 2024 OPPS/ASC final rule, we agreed to assign to clinical APCs the codes for which we agreed with the commenter may be considered medically necessary diagnostic and treatment services immediately necessary to eliminate or eradicate an oral or dental infection prior to, or contemporaneously with certain Medicare-covered medical services specified in the CY 2023 PFS final rule (42 CFR 411.15). We also specified we needed more information on how certain codes the commenter recommended for APC assignment, including CDT codes D7320, D7321, and D7471, were consistent with existing dental payment polices.

The comment to the CY 2025 OPPS/ASC proposed rule provided additional information regarding how dental surgical procedures including surgical interventions to facilitate tooth eruption, alveoloplasty or ridge preparation and removal of lateral exostosis of the jaw may contribute to the elimination of an oral or dental infection. Based on the additional information provided, we agree with the commenter that t CDT codes D7320, D7321 and D7471 should be assigned to clinical APCs for CY 2025 as we believe there may be instances where these services may be considered medically necessary diagnostic and treatment services immediately necessary to eliminate or eradicate an oral or dental infection prior to, or contemporaneously with, certain Medicare-covered medical services specified in the CY 2023 and CY 2024 PFS final rules. For CY 2025, we are assigning CDT codes D7320 and D7321 to APC 5163 (Level 3 ENT Procedures), based on clinical and resource similarities to other alveoloplasty codes currently assigned to the same clinical APC, specifically CDT codes D7310 (Alveoloplasty in conjunction with extractions—four or more teeth or tooth spaces, per quadrant) and D7311 (Alveoloplasty in conjunction with extractions—one to three teeth or tooth spaces, per quadrant). We are also assigning CDT code D7471 to APC 5164 (Level 4 ENT Procedures) based on clinical and resource similarities to other exostosis services assigned to the same clinical APC, specifically CPT codes 21031 (Remove exostosis mandible) and 21032 (Remove exostosis maxilla).

We note that Medicare Part B does not pay for removable prostheses, such as dentures. While we understand that services like alveoloplasty and the removal of the exostosis can improve the fit and stability of dentures and other dental prosthetics as the commenter explained, we are not finalizing APC assignments for CPT codes D7320, D7321 and D7471 so that these services may be furnished in preparation for a patient's denture or dental implant, and billing Medicare for that purpose would not meet our payment and coverage requirements. As we have consistently stated in past rules (87 FR 71879) and quarterly change requests to assign new codes to APCs (see, *e.g.,* Pub 100–04 Medicare Claims Processing, Transmittal 11937), the fact that a drug, device, procedure or service is assigned a HCPCS code and a payment rate under the OPPS does not imply coverage by the Medicare program, but indicates only how the product, procedure, or service may be paid if covered by the program. Medicare Administrative Contractors (MACs) determine whether a drug, device, procedure, or other service meets all program requirements and conditions for coverage and payment. Accordingly, we emphasize that HOPDs would only receive payment for a dental service assigned to an APC when the appropriate MAC determines that the service meets the relevant conditions for coverage and payment.

After consideration of the public comment received, for CY 2025, we are finalizing clinical APC assignments for CDT codes D7320, D7321, and D7471. Please refer to Table 86for the final APC assignments and status indicators for CDT codes D7320, D7321, and D7471. We refer readers to Addendum D1 to this final rule with comment period for a complete list of status indicators and their definitions. Addendum D1 is available via the internet on the CMS website.

TABLE 86: FINAL CY 2025 OPPS APC AND STATUS INDICATORS FOR CDT CODES D7320, D7321, D7471

CDT Code	Long Descriptor	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
D7320	Alveoloplasty not in conjunction with extractions - four or more teeth or tooth spaces, per quadrant	J1	APC 5163 (Level 3 ENT Procedures)
D7321	Alveoloplasty not in conjunction with extractions - one to three teeth or tooth spaces, per quadrant	J1	APC 5163 (Level 3 ENT Procedures)
D7471	Removal of lateral exostosis (maxilla or mandible)	J1	APC 5164 (Level 4 ENT Procedures)

25. Digital Mental Health Treatment Devices, HCPCS Codes GMBT1, GMBT2, and GMBT3 (APC 5012)

In CY 2025 Medicare Physician Fee Schedule proposed rule (89 FR 61956) we stated that we recognize that digital therapeutics may offer innovative means to access certain behavioral health care services. We noted that given nationwide behavioral health workforce shortages combined with increasing demand for behavioral health care services, some Medicare beneficiaries may have limited access to these services. To that end, we proposed to create three new HCPCS codes for Digital Mental Health Treatment Devices (DHMT): GMBT1 (*Supply of digital mental health treatment device and initial education and onboarding, per course of treatment that augments a behavioral therapy plan*) for furnishing a DMHT device; GMBT2 (*First 20*

minutes of monthly treatment management services directly related to the patient's therapeutic use of the digital mental health treatment (DMHT) device that augments a behavioral therapy plan, physician/other qualified health care professional time reviewing data generated from the DMHT device from patient observations and patient specific inputs in a calendar month and requiring at least one interactive communication with the patient/caregiver during the calendar month) and GMBT3 (*Each additional 20 minutes of monthly treatment management services directly related to the patient's therapeutic use of the digital mental health treatment (DMHT) device that augments a behavioral therapy plan, physician/other qualified health care professional time reviewing data generated from the DMHT device from patient observations and patient specific inputs in a calendar month and requiring at least one interactive communication with the patient/caregiver during the calendar month*). We did not address the new proposed DMHT device G-codes or propose APC or Status Indicator assignments in the CY 2025 OPPS proposed rule (89 FR 59186).

The HCPCS codes G0552, G0553, and G0554 are replacing the respective placeholder codes GMBT1, GMBT2, and GMBT3.

Comment: We received several comments on the DHMT codes with different suggestions on how these codes be treated in the OPPS. One commenter recommended that CMS assign code G0552 (placeholder code GMBT1) to APC 1511—New Technology Level 11—with a CY 2025 proposed payment rate of $950.50. This commenter went on to say that CMS could then update the applicable APC assignment for DMHT devices over time after it obtains hospital claims data. Commenters who suggested CMS assign HCPCS code G0552 (placeholder code GMBT1) to a New Technology APC explained that this approach is similar to ones the agency has taken in the past—most notably for reimbursing for the technical/facility components of remote therapeutic monitoring (RTM) and remote physiological monitoring (RPM) codes. One commenter supported contractor pricing for HCPCS code G0552 (placeholder code GMBT1). Commenters urged CMS to establish a payment for the DMHT device supply in the hospital outpatient setting in the CY 2025 OPPS final rule.

Response: HCPCS codes G0552, G0553, and G0554 (placeholder codes GMBT1, GMBT2, and GMBT3) will be effective on January 1, 2025. Based on our evaluation of these new codes and in response to commenters' requests, we are proposing an interim assignment of HCPCS code G0552 (placeholder code GMBT1) to status indicator ''V'' (Clinic or Emergency Department Visit; Paid under OPPS; separate APC payment) and APC 5012 (Clinic Visits and Related Services). We are proposing an interim assignment of HCPCS code G0553 (placeholder code GMBT2) to status indicator ''V'' (Clinic or Emergency Department Visit; Paid under OPPS; separate APC payment) and APC 5012 (Clinic Visits and Related Services). Finally, we are proposing an interim assignment of HCPCS code G0554 (placeholder code GMBT3) to status indictor ''N'' to indicate that the code is packaged since it is an add-on service to the primary code, and payment for add-on codes is always packaged with their associated primary service codes under regulation at 419.2(b)(18).

Because we were not able to propose APC and status indicator assignments in the CY 2025 OPPS proposed rule, we will be assigning HCPCS codes G0552, G0553, and G0554 (placeholder codes GMBT1, GMBT2, and GMBT3) comment indicator ''NI'' in Addendum B of this final rule. This comment indicator is for new HCPCS codes that will be effective January 1, 2025, to indicate that we are assigning them an interim status indicator and APC assignment, which is subject to public comment. We invite public comment on the interim proposed status indicators and APC assignments for HCPCS codes G0552, G0553, and G0554 (placeholder codes GMBT1, GMBT2, and GMBT3), which will then be finalized in the CY 2026 OPPS/ASC final rule with comment period.

Please refer to Table 87 for the proposed interim APC and status indicator assignments for HCPCs codes G0552, G0553, and G0554 (placeholder codes GMBT1, GMBT2, and GMBT3) for CY 2025. The final CY 2025 payment rates can be found in Addendum B to this final rule with comment period.

TABLE 87: INTERIM CY 2025 APC, SI, AND COMMENT INDICATOR FOR THE DIGITAL MENTAL HEALTH TREATMENT DEVICES HCPCS CODES EFFECTIVE JANUARY 1, 2025

CPT Code	Long Descriptor	Interim CY 2025 OPPS SI	Interim CY 2025 OPPS APC	Comment Indicator
G0552 (placeholder code GMBT1)	Supply of digital mental health treatment device and initial education and onboarding, per course of treatment that augments a behavioral therapy plan	V	5012	N1
G0553 (placeholder code GMBT2)	First 20 minutes of monthly treatment management services directly related to the patient's therapeutic use of the digital mental health treatment (DMHT) device that augments a behavioral therapy plan, physician/other qualified health care professional time reviewing data generated from the DMHT device from patient observations and patient specific inputs in a calendar month and requiring at least one interactive communication with the patient/caregiver during the calendar month	V	5012	N1
G0554 (placeholder code GMBT3)	Each additional 20 minutes of monthly treatment management services directly related to the patient's therapeutic use of the digital mental health treatment (DMHT) device that augments	N		N1

26. Drug-Coated Balloon for Esophageal and Bowel Strictures, CPT Codes 0884T, 0885T, and 0886T (APC 5331)

ProTractX3™ TTS is a drug-coated balloon that is used to treat strictures in the esophagus, small intestine, and large intestine. For the CY 2025 OPPS proposed rule, we proposed to assign CPT code 0884T (Esophagoscopy, flexible, transoral, with initial transendoscopic mechanical dilation (*e.g.,* nondrug-coated balloon) followed by therapeutic drug delivery by drug-coated balloon catheter for esophageal stricture, including fluoroscopic guidance, when performed) with no claims data for CY 2025 to APC 5303 (Level 3 Upper GI Procedures) with a payment rate of around $3,805804. In addition, we proposed to assign both CPT code 0885T (Colonoscopy, flexible, with initial transendoscopic mechanical dilation (*e.g.,* nondrug-coated balloon) followed by therapeutic drug delivery by drug-coated balloon catheter for colonic stricture, including fluoroscopic guidance, when performed) and CPT code 0886T (Sigmoidoscopy, flexible, with initial transendoscopic mechanical dilation (*e.g.,* nondrug-coated balloon) followed by therapeutic drug delivery by drug-coated balloon catheter for colonic stricture, including fluoroscopic guidance, when performed) with no claims data for CY 2025 to APC 5313 (Level 3 Lower GI Procedures) with a payment rate of around $2,742.

Comment: One commenter, the manufacturer of the ProTractX3™ TTS, requested that the procedures described CPT codes 0884T–0886T be reassigned to APC 5331 (Complex GI Procedures) with a payment rate of around $5,953. The commenter stated that the cost of the ProTractX3™ TTS is $3,100. The commenter based their cost estimate for the ProTractX3™ TTS on similar drug-coated balloons used for other medical procedures. The commenter believes the cost of ProTractX3™ TTS should be added to the geometric mean cost of the existing procedures that correspond to the procedures described by CPT codes 0884T–0886T, but do not describe the use of a drug-coated balloon with the procedures. These procedures are CPT code 43220 (Esophagoscopy, flexible, transoral; with transendoscopic balloon dilation (less than 30 mm diameter) with a geometric mean cost of around $2,175 that corresponds to procedure described by CPT code 0884T; CPT code 45386 (Colonoscopy, flexible; with transendoscopic balloon dilation) with a geometric mean cost of around $1,662 that corresponds to the procedure described by CPT code 0885T; and CPT code 45340 (Sigmoidoscopy, flexible; with transendoscopic balloon dilation) with a geometric mean cost of around $1,518 that corresponds to the procedure described by CPT code 0886T. The commenter also noted that additional operating room time needed to use the drug-coated balloon adds another $806 to the cost of each of these procedures.

According to the commenter, when the cost of ProTractX3™ TTS drug-coated balloon and the cost of the additional operating room time to use the drug-coated balloon is added to the geometric cost of CPT code 43220, the estimated cost of CPT code 0884T is $6,081. The commenter performed similar calculations for CPT code 0885T reporting an estimated procedure cost of $5,568, and for CPT code 0886T, the commenter reported an estimated procedure cost is $5,424. The commenter made the case that these procedure costs are much closer to the payment rate of APC 5331 of $5,953, than the payment rate of $3,805 for APC 5303 where we proposed to assign CPT code 0884T. Likewise, the commenter showed that the procedure costs for CPT codes 0885T and 0886T are much closer to the payment rate of APC 5331 of $5,953, than the payment rate of APC 5313 of $2,742 where we had proposed to assign those CPT codes.

Response: We appreciate the detailed analysis by the commenter which demonstrated the additional costs of the ProTractX3™ TTS drug-coated balloon, as well as the use of the drug-coated

balloon when compared to the corresponding procedures where no drug-coated balloon is used. Based on the additional cost data provided by the commenter, we agree with the commenter that CPT codes 0884T–0886T should be assigned to APC 5331.

After consideration of the public comments we received, we are implementing our proposal with modification to assign CPT codes 0884T, 0885T, and 0886T to APC 5331 (Complex GI Procedures). Table 88 shows the finalized status indicator and APC assignment for all of the procedure codes. We refer readers to Addendum B of this final rule for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 88: FINAL CY 2025 OPPS APC STATUS INDICATOR ASSIGNMENTS FOR CPT CODES 0884T – 0886T

CPT Code	Long Descriptor	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
0884T	Esophagoscopy, flexible, transoral, with initial transendoscopic mechanical dilation (e.g., nondrug-coated balloon) followed by therapeutic drug delivery by drug-coated balloon catheter for esophageal stricture, including fluoroscopic guidance, when performed	J1	5331
0885T	Colonoscopy, flexible, with initial transendoscopic mechanical dilation (e.g., nondrug-coated balloon) followed by therapeutic drug delivery by drug-coated balloon catheter for colonic stricture, including fluoroscopic guidance, when performed	J1	5331
0886T	Sigmoidoscopy, flexible, with initial transendoscopic mechanical dilation (e.g., nondrug-coated balloon) followed by therapeutic drug delivery by drug-coated balloon catheter for colonic stricture, including fluoroscopic guidance, when performed	J1	5331

27. EchoGo Echocardiography Image Processing Service, HCPCS Code C9786 (APC 5743)

Effective July 1, 2023, based on a New Technology application received by CMS for an echocardiography image processing service, CMS established HCPCS code C9786 (Echocardiography image post processing for computer aided detection of heart failure with preserved ejection fraction, including interpretation and report) and assigned it to APC 5742 (Level 2 Electronic Analysis of Devices). In CY 2024, CMS reassigned HCPCS code C9786 to APC 5743 (Level 3 Electronic Analysis of Devices).

For CY 2025, CMS is deleting HCPCS code C9786 because the CPT Editorial Panel established new Category III CPT code, specifically, 0932T (Noninvasive detection of heart failure derived from augmentative analysis of an echocardiogram that demonstrated preserved ejection fraction, with interpretation and report by a physician or other qualified health care professional) to describe the same service, which will be effective January 1, 2025. Because the final CY 2025 CPT code number was not available when we published the CY 2025 OPPS/ASC proposed rule, the code was listed as placeholder code XX68T in the OPPS Addendum B of the CY 2025 OPPS/ASC proposed rule.

In the CY 2025 OPPS/ASC proposed rule, we proposed to assign CPT code XX68T (Noninvasive detection of heart failure derived from augmentative analysis of an echocardiogram that demonstrated preserved ejection

fraction, with interpretation and report by a physician or other qualified health care professional) to APC 5743 (Level 3 Electronic Analysis of Devices), the same APC to which HCPCS code C9786 is assigned.

We note that because both HCPCS code C9786 and CPT code 0932T describe the same service, effective January 1, 2025, CMS will delete HCPCS code C9786 and only CPT code 0932T will be used to bill for the service. We received one public comment in support of our proposal.

Comment: The commenter noted that the assignment of XX68T to APC 5743 appropriately reflects the resources required to perform this advanced artificial intelligence (AI) analysis, as well as the clinical value it provides. and stated that this APC assignment would help ensure adequate reimbursement for hospitals, supporting broader access to this important diagnostic tool for Medicare beneficiaries. The commenter appreciated CMS's consideration of this new technology and its potential impact on patient care.

Response: We thank the commenter for the support.

In summary, after consideration of the public comment we received, we are finalizing our proposal, without modification, to assign CPT code 0932T to APC 5743 for CY 2025. We note that the final CY 2025 payment rate for the code can be found in Addendum B of this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

28. Endoscopic Submucosal Dissection (ESD) Procedure, HCPCS Code C9779 (APC 5303)

CMS established HCPCS code C9779 (Endoscopic submucosal dissection (ESD), including endoscopy or colonoscopy, mucosal closure, when performed) effective October 1, 2021, to describe the endoscopic submucosal dissection (ESD) performed during an endoscopy or colonoscopy. HCPCS code C9779 was established based on a New Technology application that was submitted to CMS for New Technology consideration under the OPPS. Based on our assessment, we assigned the code to APC 5313 (Level 3 Lower GI Procedures) because we believed the ESD procedure had similar clinical characteristics and resource costs as the surgical procedures assigned to APC 5313. We announced the assignment to APC 5313 in the October 2021 OPPS quarterly update CR (Transmittal 10997, Change Request 12436, dated September 16, 2021). In CY 2022, we continued to assign the code to APC 5313.

For CY 2023, we assigned HCPCS code C9779 to APC 5303 (Level 3 Upper GI Procedures) after receiving public comments that stated that the ESD procedure's resource requirements and geometric mean cost were more similar to the resource requirements and geometric mean costs of procedures found in APC 5303. Further, commenters noted that the ESD procedure is technically more demanding, requires advanced skills to perform, and is clinically similar to CPT code 43497 (Lower esophageal myotomy, transoral (*i.e.,* peroral endoscopic myotomy [POEM])), which was assigned to APC 5303. For CY 2025, we proposed to maintain HCPCS code C9779 (with a geometric mean cost (GMC) of around $5,093) in APC 5303 (Level 3 Upper GI Procedures).

Comment: We received one comment requesting that we reassign HCPCS code C9779 from APC 5303 (Level 3 Upper GI Procedures) to APC 5361 (Level 1 Laparoscopy and Related Procedures). The commenter states that resource requirements for HCPCS code C9779 are well-aligned with other procedures in APC 5361, noting that the geometric mean cost of HCPCS code C9779 is higher than 4 procedures with significant volume assigned to APC 5361. The commenter believes that based on resource cost and clinical homogeneity, HCPCS code C9779 should be reassigned to APC 5361.

Response: We thank the commenter for their input. We disagree with the commenter that HCPCS code C9779 should be assigned to APC 5361. Specifically, we do not believe that endoscopic submucosal dissection is a laparoscopic procedure and should not be assigned to a laparoscopic APC family. Additionally, we believe HCPCS code C9779 is appropriately assigned, based on both clinical similarity and resource costs, to APC 5303 (Level 3 Upper GI Procedures).

In summary, after consideration of the public comment, we are finalizing our proposal without modification to assign HCPCS code C9779 to APC 5303 (Level 3 Upper GI Procedures). We note that we review, on an annual basis, the APC assignments for all services and items paid under the OPPS based on our analysis of the latest claims data. The final CY 2025 OPPS payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

29. Esophageal Balloon Distention Study, CPT Code 91040 (APC 5723)

Esophageal balloon distension studies are used to diagnose conditions of the esophagus and may be used to determine the source of certain types of pain, such as chest pain. The esophageal balloon study is often performed in conjunction with esophagogastroduodenoscopy procedures. For CY 2025, we proposed to assigned CPT code 91040 (Esophageal balloon distension study, diagnostic, with provocation when performed) to APC 5723 (Level 3 Diagnostic Tests and Related Services) with a proposed payment rate of around $530.

Comment: We received one public comment requesting that CPT code 91040 be reassigned from APC 5723 (Level 3 Diagnostic Tests and Related Services) to APC 5724 (Level 4 Diagnostic Tests and Related Services), stating that the costs of this procedure significantly exceed the APC 5723 assignment. The commenter suggested that a higher payment would more closely align with the costs of the resources utilized to perform this test.

Response: We thank the commenter for their input. We note that the geometric mean cost (GMC) for CPT code 91040 is around $1,500, and the GMC for APC 5723 is around $537. While this is a significant difference, our claims data show that approximately 70 percent of the costs for this procedure are made up of higher cost items (equipment, drugs, and supplies) that are packaged with the procedure costs.

In addition, claims data for CY 2025, show that out of all the claims billed with CPT code 91040 (3,429 total frequency), only 2.7 percent (approximately 95) of those claims were billed with only CPT code 91040. We believe that in addition to the higher costs of the items that are packaged, the costs from the other procedures that are performed with CPT code 91040 have driven up the GMC of CPT code 91040.

Based on review of the service and other services in the same APC family, input from CMS medical advisors, and the claims data, we believe that the clinical and resource characteristics of CPT code 91040 are sufficiently like other procedures assigned to APC 5723 and should continue to be assigned to APC 5723. For CY 2025, based on our evaluation, we are finalizing our proposal, without modification, to assign CPT code 91040 to APC 5723.

The final CY 2025 payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

30. Esophagogastroduodenoscopy With Optical Endomicroscopy, CPT Code 43252 (APC 5302)

An esophagogastroduodenoscopy is a procedure to view the esophagus, stomach, and duodenum by means of a flexible endoscope passed through the mouth. The provider uses an endomicroscopy system to evaluate the structures during this procedure. This procedure is reported with CPT code 43252 (Esophagogastroduodenoscopy, flexible, transoral; with optical endomicroscopy).

In the CY 2024 OPPS/ASC final rule with comment period (88 FR 81685), we reassigned CPT code 43252 from APC 5303 (Level 3 Upper GI Procedures) to APC 5302 (Level 2 Upper GI Procedures). In the 2025 OPPS/ASC proposed rule, we proposed to continue to assign this code to APC 5302 with a proposed payment rate of $1,884.11. We received two public comments that disagreed with our proposal.

Comment: Both commenters noted that the significant payment reduction for this service could impede access to this service for beneficiaries. One commenter noted that just a few hospital outpatient facilities are offering this procedure and that over 70 percent of cases are performed in ASCs.

One commenter stated that CPT code 43252 is similar in clinical intensity, resource utilization and costs to CPT code 0654T (Esophagogastroduodenoscopy, flexible, transnasal; with insertion of intraluminal tube or catheter) which is assigned to APC 5303. This commenter also claimed that some hospitals are underreporting their costs for CPT code 43252. Both commenters requested that CMS reassign CPT code 43252 to APC 5303.

Response: We note that the CY 2025 OPPS payment rates are proposed based on available CY 2023 claims data. Based on our latest review of the claims data, we found the geometric mean cost of approximately $1,839.38for CPT code 43252 based on 246 single claims, is consistent with the geometric mean cost of about $1,920.00for APC 5302. We note that the geometric mean cost of APC 5303 is approximately $3,850.67which is about $2,011 more than the geometric mean cost of CPT code 43252.

In summary, we are finalizing without modification our proposal to assign CPT code 43252 to APC 5302 for CY 2025. The CY 2025 final payment rate for this code can be found in Addendum B of this final rule with comment period.

31. Extracorporeal Shock Wave Lithotripsy (SWL), CPT Code 50590 (APC 5374)

Extracorporeal shock wave lithotripsy is a procedure used to break up stone in the urinary tract using directed shock wave therapy. Shock waves are generated by a lithotripter which is a machine and capital equipment for the provider. The procedure is described by CPT code 50590 (Lithotripsy, extracorporeal shock wave).

For CY 2025, the OPPS payment rates are proposed based on available CY 2023 claims data. For the CY 2025 OPPS/ASC proposed rule, we found a total of 26,669 single frequency claims and a geometric mean cost of approximately $3,536 for CPT code 50590. For CY 2025, we proposed to continue to assign CPT code 50590 to APC 5374 (Level 4 Urology and Related Services) with a proposed payment rate of approximately $3,438.

Comment: One commenter disagreed with our APC assignment of CPT code 50590 to APC 5374 (Level 4 Urology and Related Services) and suggested that CPT code 50590 should be assigned to APC 5375 (Level 5 Urology and Related Services) like CPT code 52353 (Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy (ureteral catheterization is included)) and CPT code 52356 (Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy including insertion of indwelling ureteral stent (*e.g.,* gibbons or double-j type)). The commenter stated that higher payment for CPT codes 52353 and 52356 has driven service volume toward those codes and away from CPT code 50590.

Response: We thank the commenter for the input. We note that, with over 25,000 single claims in CY 2025, the geometric mean cost of CPT code 50590 very closely aligns with the geometric mean cost of the APC to which it is assigned, APC 5374. Furthermore, CPT code's geometric mean cost is well below that of CPT code 52356, which is the primary driver of the geometric mean cost of APC 5375.

After consideration of the public comment we received, we are finalizing our proposal without modification for CPT code 50590. Please refer to Table 89 for the final OPPS APC and status indicator assignment for CPT code 50590 for CY 2025. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 89: FINAL CY 2025 OPPS APC STATUS INDICATOR ASSIGNMENTS FOR CPT CODE 50590

CPT Code	Long Descriptor	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
50590	Lithotripsy, extracorporeal shock wave	J1	5374

32. Female Intraurethral Valve-Pump, Insertion and Replacement, CPT Codes 0596T and 0597T (APC 5372)

For CY 2025, we proposed to assign CPT codes 0596T (Temporary female intraurethral valve-pump (*i.e.,* voiding prosthesis); initial insertion, including urethral measurement) and 0597T (Temporary female intraurethral valve-pump (*i.e.,* voiding prosthesis); replacement) to status indicator ''J1'', APC 5372 (Level 2 Urology and Related Services) with a proposed payment rate of $675.64.

Comment: Commenters shared support for the proposal to assign CPT code 0597T to APC 5372 and agreed that the proposed assignment to APC 5372 aligns with costs incurred by hospitals to perform this service.

Response: We thank commenters for their support.

Comment: Commenters, the manufacturer and a trade association, expressed concerns that the proposed assignment of CPT code 0597T to APC 5372 does not sufficiently consider the targeted device cost of $1,885 and is not appropriate from a resource perspective, which the commenters feel may limit access to the procedures. The commenters requested reassignment of CPT code 0596T to APC 5373 (Level 3 Urology and Related Services) with a proposed payment rate of $2,074.53 as they believe that APC 5373 would be appropriate from a clinical and resource perspective and would more appropriately reflect the device costs to hospitals to furnish the service.

Response: We thank the commenter for their comment. For this final rule with comment period, we have no claims data for CPT code 0596T for OPPS ratesetting purposes. We continue to believe that CPT code 0596T shares similar clinical characteristics and resource costs to the services assigned to APC 5372.

In summary, after consideration of the public comments we received, we are finalizing our proposal, without modification, to continue to assign CPT codes 0596T and 0597T to APC 5372 for CY 2025. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reported under the OPPS. In addition, we refer readers to Addendum A of this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Both Addendum A and Addendum B are available via the internet on the CMS website.

33. Fractional Flow Reserve (FFR) With 3D Coronary Mapping, CPT Code 0523T

The fractional flow reserve (FFR) with 3D coronary mapping procedure is described by CPT code 0523T (Intraprocedural coronary fractional flow reserve (ffr) with 3d functional mapping of color-coded ffr values for the coronary tree, derived from coronary angiogram data, for real-time review and interpretation of possible atherosclerotic stenosis(es) intervention (list separately in addition to code for primary procedure)). CPT code 0523T became effective January 1, 2019. For CY 2024, CPT code 0523T was assigned the status indicator ''N'' (packaged).

Comment: One commenter requested that the packaging exemption for SaaS add-on codes policy should be applied to CPT code 0523T. The commenter further requested that CPT code 0523T be assigned to status indicator ''J1'' (Comprehensive APC) and assigned to APC 5191 (Level 1 Endovascular Procedures) for CY 2025.

Response: We note that CPT code 0523T is an add-on code. Add-on codes represent services that are always performed in addition to the primary service or procedure and must never be reported as a stand-alone code. As specified under 42 CFR 419.2(b)(18), add-on codes are generally packaged under the OPPS, and payment for the codes are bundled with the primary codes. Consequently, CPT code 0523T is not paid separately under the OPPS, but instead, has its payment packaged into the payment for the primary code.

Under the packaging exemption for SaaS add-on codes (87 FR 72027 to 72035), we adopted a policy that services represented by SaaS add-on codes are not among the ''certain services described by add-on codes'' for which we package payment with the related procedures or services under the regulation at 42 CFR 419.2(b)(18). Specifically, the SaaS CPT add-on codes will be assigned to identical APCs and have the same status indicator assignments as their standalone SaaS codes. As such, the policy exempts SaaS add-on codes for which a standalone SaaS code is separately payable under the OPPS for the identical SaaS service furnished without concurrent imaging and described by the standalone CPT code. In summary, the packaging exemption for SaaS add-on codes policy only exempts SaaS add-on codes when the identical SaaS procedure is also represented by a standalone SaaS code and payable under the OPPS because the procedure requires the same resources regardless of whether it is furnished with or without the imaging service.

After consideration of the public comments we received, we are finalizing our proposal without modification for CPT codes 0523T. Please refer to Table 90 below for the final OPPS APC and status indicator assignment for CPT codes 0523T for CY 2025. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 90: FINAL CY 2025 OPPS APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODE 0523T

CPT Code	Long Descriptor	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
0523T	Intraprocedural coronary fractional flow reserve (ffr) with 3d functional mapping of color-coded ffr values for the coronary tree, derived from coronary angiogram data, for real-time review and interpretation of possible atherosclerotic stenosis(es) intervention (list separately in addition to code for primary procedure)	N	NA

34. Fractional Flow Reserve Derived From Computed Tomography (FFRCT), CPT Code 75580 (APC 5724)

Fractional Flow Reserve Derived from Computed Tomography (FFRCT), also known by the trade name HeartFlow®, is a noninvasive diagnostic service that allows physicians to measure coronary artery disease in a patient through the use of coronary CT scans. The HeartFlow® service is indicated for clinically stable symptomatic patients with coronary artery disease, and, in many cases, may avoid the need for an invasive coronary angiogram procedure. HeartFlow® uses a proprietary data analysis process performed at a central facility to develop a three-dimensional image of a patient's coronary arteries, which allows physicians to identify the fractional flow reserve to assess whether patients should undergo further invasive testing (that is, a coronary angiogram).

HeartFlow® is currently described by CPT code 75580 (Noninvasive estimate of coronary fractional flow reserve (FFR) derived from augmentative software analysis of the data set from a coronary computed tomography angiography, with interpretation and report by a physician or other qualified health care professional). On January 1, 2024, CPT code 75580 replaced CPT code 0503T ((Noninvasive estimated coronary fractional flow reserve (ffr) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; analysis of fluid dynamics and simulated maximal coronary hyperemia, and generation of estimated ffr model).

HeartFlow® was assigned to APC 5724 (Level 4 Diagnostic Tests and Related Services) for CY 2024, and we proposed for CY 2025 to continue to assign HeartFlow® (CPT code 75580) to APC 5724.

Comment: We received one comment stating that several of the Medicare Administrative Contractors (MACs) have an edit in place that prohibits the use of the cardiology revenue code (0480) when billing CPT code 75580 as evidenced by claims denials with ''Invalid Revenue Code'' errors. The commenter asked that we provide guidance that explicitly allows CPT code 75580 to be billed with any appropriate revenue code just as we did for cardiac CT services. (See January 2024 Update (Transmittal 12421, Change Request 13488, dated December 21, 2023.)

Response: Based on the information the commenter provided, we were able to identify the outdated edit and remove it. Facilities may bill CPT 75580 with any appropriate revenue code. As a reminder, it is longstanding CMS policy that hospital outpatient facilities are responsible for reporting the appropriate cost centers and revenue codes on claims. As stated in section 20.5 in Chapter 4 (Part B Hospital) of the Medicare Claims Processing Manual, CMS ''does not instruct hospitals on the assignment of HCPCS codes to revenue codes for services provided under OPPS since hospitals' assignment of cost vary. Where explicit instructions are not provided, HOPDs should report their charges under the revenue code that will result in the charges being assigned to the same cost center to which the cost of those services are assigned in the cost report.'' In addition to referring readers to the Medicare Claims Processing Manual, we will be providing public education and instruction through the CMS Medicare Learning Network (MLN).

Comment: Multiple commenters supported our proposal to continue to assign CPT code 75580 to APC 5724 for CY 2025.

Response: We thank the commenters for their input and for their support of our policy.

After consideration of the public comments we received, we are finalizing our proposal without modification. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

35. Gastric Electrophysiology Mapping With Simultaneously Validated Patient System Profiling (GEMS) Service, CPT Code 0868T (APC 5723)

Effective July 1, 2023, based on a New Technology application received by CMS for the GEMS service, CMS established HCPCS code C9787 (Gastric electrophysiology mapping with simultaneous patient symptom profiling) and assigned it to APC 5723 (Level 3 Diagnostic Tests and Related Services). Effective July 1, 2024, HCPCS code C9787 was deleted and replaced by CPT code 0868T (High-resolution gastric electrophysiology mapping with simultaneous patient symptom profiling, with interpretation and report). CMS assigned CPT code 0868T to APC 5723, the same APC to which its predecessor code, HCPCS code C9787, was assigned. For CY 2025, CMS proposed to continue to assign CPT code 0868T to APC 5723 with a proposed payment rate of $527.44 for CY 2025.

Comment: We received several comments, including a comment from the manufacturer, requesting that we reassign CPT code 0868T from APC 5723 to APC 1520 (New Technology—Level 20 ($1801–$1900)) with a payment rate of $1850.50, based on the purported cost of the technology and the

fact that it is a new service with a low volume of claims. The commenters explained that the proposed payment rate for CPT code 0868T would not cover the costs of the device, supplies, and clinical staff expenses. One commenter explained that the available claims data supports the conclusion that the proposed APC placement is inadequate. Specifically, the commenter pointed to one single frequency claim that shows a geometric mean cost of approximately $1,800 to demonstrate that CPT code 0868T should be assigned to APC 1520. The commenters suggested that if CMS did not agree to finalize an assignment to APC 1520, they would then suggest that CPT code 0868T be assigned to APC 5724 (Level 4 Diagnostic Tests and Related Services) with a proposed payment rate of approximately $1,000 or APC 5302 (Level 2 Upper GI Procedures) with a proposed payment rate of approximately $1,800 for CY 2025. Finally, one commenter drew differences between the clinical characteristics of CPT code 0868T and the other services assigned to APC 5723, including CPT code 0799T. For example, the commenter stated that CPT code 0799T involves a low-resolution electrode patch generating data comparable to traditional legacy electrogastrography, whereas C9787/0868T uses a high-resolution 64-lead array and sophisticated software to provide detailed multimodal diagnostic data.

Response: We appreciate the commenters' input. We disagree with the APC assignments recommended by commenters based on the purported costs of the service. Since we issued the proposed rule, additional claims data have been processed which, we believe, confirm that the proposed APC assignment is appropriate for HCPCS code C9787/CPT code 0868T for CY 2025. Our analysis of the available claims data demonstrates that the geometric mean cost for HCPCS code C9787 is approximately $310 based on 5 single frequency claims, which is below the geometric mean cost of $530 for APC 5723, but within the range of geometric mean costs of services assigned to APC 5723 which vary from approximately $150 to $2000. We note that given the effective date of payment, we have only one year of claims data for HCPCS code C9787/CPT code 0868T with an extremely low level of single frequency claims.

We will continue to monitor the claims data and adjust the APC placement for CPT code 0868T, based on the claims data in future rulemaking. Additionally, based on our review of the technology used as part of the service, input from CMS medical advisors, and review of all other information available to us, we continue to believe that CPT code 0868T is similar to services assigned to APC 5723. Based on the resource and clinical similarities to other services assigned to APC 5723, including CPT code 0779T (Gi myoelectrical actv study), as well as the available claims data, we believe that our proposal to assign CPT code 0868T is appropriate for CY 2025.

After consideration of the public comments, we are finalizing our proposal without modification to continue to assign CPT code 0868T to APC 5723. The final CY 2025 payment rate for the code can be found in Addendum B to this final rule with comment period. We also refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

36. Hernia Repair Procedures, CPT Codes 49593, 49595, and 49615 (APCs 5342 and 5361)

Effective January 1, 2023, the AMA created new abdominal hernia repair CPT codes 49593 (Repair of anterior abdominal hernia(s) (*i.e.,* epigastric, incisional, ventral, umbilical, spigelian), any approach (*i.e.,* open, laparoscopic, robotic), initial, including implantation of mesh or other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, reducible), 49595 (Repair of anterior abdominal hernia(s) (*i.e.,* epigastric, incisional, ventral, umbilical, spigelian), any approach (*i.e.,* open, laparoscopic, robotic), initial, including implantation of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, reducible), and 49615 (Repair of anterior abdominal hernia(s) (*i.e.,* epigastric, incisional, ventral, umbilical, spigelian), any approach (*i.e.,* open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, reducible). For CY 2023, we assigned these codes to APC 5341 (Level 1 Abdominal/Peritoneal/Biliary and Related Procedures). For CY 2025, we proposed to reassign these codes to APC 5342 (Level 2 Abdominal/Peritoneal/Biliary and Related Procedures) to resolve a 2-times violation for APC 5341.

Comment: We received two comments supporting the reassignment of CPT codes 49593, 49595, and 49615 to APC 5342 for CY 2025.

Response: We thank the commenters for their support.

Comment: The two commenters recommended that we also reassign CPT codes 49650 (Laparoscopy, surgical; repair initial inguinal hernia) and 49651 (Laparoscopy, surgical; repair recurrent inguinal hernia) from APC 5361 (Level 1 Laparoscopy and Related Services) to APC 5342. The commenters noted that with the addition of the three ventral hernia procedures, APC 5342 would now contain both open and laparoscopic surgical procedures.

Response: We thank the commenter for their suggestions. After further clinical review, we continue to believe that CPT codes 49650 and 49651 are still appropriately assigned to APC 5361 based on clinical and resource homogeneity to the procedures in the APC 5361.

After consideration of the public comment we received, we are finalizing our proposal without modification to reassign CPT codes 49593, 49595 and 49615 to APC 5342 (Level 2 Abdominal/Peritoneal/Biliary and Related Procedures). We are also finalizing our proposal without modification to continue to assign CPT codes 49650 and 49651 to APC 5361 (Level 1 Laparoscopy and Related Services). Table 91 shows the finalized status indicator and APC assignment for the procedure code. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 91: FINAL CY 2025 OPPS APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODES 49593, 49595, 49615, 49650 AND 49651

CPT Code	Long Descriptor	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
49593	Repair of anterior abdominal hernia(s) (i.e., epigastric, incisional, ventral, umbilical, spigelian), any approach (i.e., open, laparoscopic, robotic), initial, including implantation of mesh or other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, reducible	J1	5342
49595	Repair of anterior abdominal hernia(s) (i.e., epigastric, incisional, ventral, umbilical, spigelian), any approach (i.e., open, laparoscopic, robotic), initial, including implantation of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, reducible	J1	5342
49615	Repair of anterior abdominal hernia(s) (i.e., epigastric, incisional, ventral, umbilical, spigelian), any approach (i.e., open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, reducible	J1	5342
49650	Laparoscopy, surgical; repair initial inguinal hernia	J1	5361
49651	Laparoscopy, surgical; repair recurrent inguinal hernia	J1	5361

37. Imaging of Retina for Detection or Monitoring of Disease, CPT Code 92229 (APC 5733)

CPT code 92229 (Imaging of retina for detection or monitoring of disease; point-of-care autonomous analysis and report, unilateral or bilateral) is performed to screen patients with diabetes for signs of diabetic retinopathy and other eye diseases. The code was established on January 1, 2021 and assigned to APC 5733 (Level 3 Minor Procedures). The code was assigned to Level 3 Minor Procedures because the service had clinical and resource similarity to long-established CPT code 92227 (Imaging of retina for detection or monitoring of disease; with remote clinical staff review and report, unilateral or bilateral) which also is assigned to APC 5733 (Level 3 Minor Procedures).

In the CY 2023 claims data, there were 370 (single frequency) claims for CPT code 92229 and the geometric mean for the service was $28.53. For CY 2025, we proposed to maintain CPT code 92229 in APC 5733 (Level 3 Minor Procedures) and wait for more claims data to be available before adjusting the payment rates for this service.

Comment: We received several comments supporting our decision to maintain CPT 92229 in APC 5733 (Level 3 Minor Procedures). Commenters noted that this service provides potentially sight saving technology to beneficiaries with diabetes in rural and underserved communities.

Response: We thank the commenters for their input.

Comment: We received one comment requesting that CPT code 92229 be removed from the Deficit Reduction Act (DRA) cap.

Response: We thank the commenter for their input, but we note that this comment is out of scope for purposes of this CY 2025 OPPS/ASC final rule with comment period.

After consideration of the public comments we received, we are finalizing our proposal without modification to assign CPT code 92229 to APC 5733. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

38. Implantable Cardiac Alert System, CPT Codes 0525T and 0527T (APCs 5224 and 5222)

The implantable cardiac alert system is a cardiac monitoring and alerting device to detect acute coronary syndrome (ACS) events and alerts the patient to seek urgent medical attention. The CPT codes 0525T (Insertion or replacement of intracardiac ischemia monitoring system, including testing of the lead and monitor, initial system programming, and imaging supervision and interpretation; complete system (electrode and implantable monitor)) and 0527T (Insertion or replacement of intracardiac ischemia monitoring system, including testing of the lead and monitor, initial system programming, and imaging supervision and interpretation; implantable monitor only) became effective January 1, 2019.

For CY 2025, the OPPS payment rates are proposed based on available CY 2023 claims data. For the CY 2025 OPPS/ASC proposed rule, based on our

analysis of claims data, we found a total of 15 single frequency claims and an estimated geometric mean cost of $3,244 for CPT code 0525T and a total of three single frequency claims and an estimated geometric mean cost of $3,433 for CPT code 0527T. For CY 2025, we proposed to continue to assign CPT code 0525T to Level 3 Pacemaker and Similar Procedures (APC 5223) and CPT code 0527T to Level 2 Pacemaker and Similar Procedures (APC 5222).

Comment: One Commenter disagreed with our APC's assignments of CPT codes 0525T and 0527T, suggesting that we did not account for the cost of the device represented by HCPCS code C1833 in the proposed rule. The commenter also stated that we erroneously assigned the status indicator of ''H'' to HCPCS code C1833 in the CY 2025 OPPS/ASC proposed rule. The commenter noted the Transitional Pass-Through period for C1833 expires December 31, 2024, and that HCPCS code C1833 should have been assigned the status indicator of ''N'' for CY 2025.

Additionally, the commenter argued that the proposed payment rates for CPT codes 0525T and 0527T are insufficient to cover the procedures' cost because we did not account for the device cost in the proposed CY 2025 payment rates. They claimed that the procedures represented by 0525T and 0527T are similar procedures and should both be assigned to APC 5231 (Level 1 ICD and Similar Procedures).

Response: We appreciate the commenter pointing out that HCPCS code C1833's Transitional Pass-through Status expires December 31, 2024. Therefore, we are revising the HCPCS code C1833's status indicator to ''N'' (packaged) for CY 2025.

We agree with the commenter the CY 2025 proposed APC assignments for 0525T and 0527T erroneously omitted the device cost (HCPCS code C1833) associated with these procedures. With the updated final rule data including the HCPCS code C1833 device cost, the revised geometric mean cost for CPT code 0525T is approximately $15,167 and the geometric mean cost for 0527T is approximately $7,242. Therefore, we believe an appropriate APC assignment for CPT code 0525T would be APC 5224 (Level 4 Pacemaker and Similar Procedures); and an appropriate assignment for CPT code 0527T would be APC 5222 (Level 2 Pacemaker and Similar Procedures).

We disagree with the commenter that CPT code 0525T is similar clinically and in resource costs to CPT code 0527T. We note that CPT code 0525T is for insertion of the complete system while CPT code 0527T is for insertion of the implantable monitor only.

After consideration of the public comments we received, we are finalizing a revision to our proposed APC assignment for CPT code 0525T and assigning this code to APC 5224 (Level 4 Pacemaker and Similar Procedures). We are finalizing the assignment of CPT code 0527T to APC 5222 (Level 2 Pacemaker and Similar Procedures) as proposed. Please refer to Table 92 for the final OPPS APC and status indicator assignment for CPT codes 0525T, 0527T and C1833 for CY 2025. The final CY 2025 payment rates can be found in Addendum B to this final rule with comment period via the internet on the CMS website.

TABLE 92: FINAL CY 2025 OPPS APC ASSIGNMENT AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODES 0525T, 0527T, AND HCPCS CODE C1833

HCPCS Code	Long Descriptor	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
0525T	Insertion or replacement of intracardiac ischemia monitoring system, including testing of the lead and monitor, initial system programming, and imaging supervision and interpretation; complete system (electrode and implantable monitor)	J1	5224
0527T	Insertion or replacement of intracardiac ischemia monitoring system, including testing of the lead and monitor, initial system programming, and imaging supervision and interpretation; implantable monitor only	J1	5222
C1833	Monitor, cardiac, including intracardiac lead and all system components (implantable)	N	

39. Implantable Glucose Monitoring System, CPT Codes 0446T and 0448T (APC 5054)

In 2017, the AMA CPT Editorial Panel established CPT codes 0446T and 0448T. CPT code 0446T (Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training) and CPT code 0448T (Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation) describe an implantable glucose sensor for diabetic patients. The current codes are used to describe both 90-day and 180-day sensors. The FDA recently approved a 365-day sensor that is not currently on the market.

For CY 2025, we proposed to maintain both CPT codes in APC 5054 (Level 4 Skin Procedures) with a status indicator of ''T'' (Procedure or Service, Multiple Procedure Reduction Applies; Paid under OPPS; separate APC payment.).

Comment: We received one comment from the manufacturer requesting that we reassign CPT codes 0446T and 0448T from APC 5054 (Level 4 Skin Procedures) to APC 1531 (New Technology—Level 31 ($6501–$7000)) with a payment of $6,750.50 to reflect the increased expense of the implantable sensor that has quadrupled the life of the 90-day sensor. The manufacturer reiterated the value of the longer sensor duration, including fewer insertion and removal procedures and increased adherence to therapy.

Response: We appreciate the request of the commenter and understand the implicated value that a longer life sensor brings to Medicare beneficiaries. Because the current CPT codes do not designate the increased battery life of the sensor, we believe it is more appropriate to create 2 new HCPCS G codes effective January 1, 2025 to describe the implantable interstitial glucose sensor with a 365-day battery life than to make APC reassignments and potentially overpay for the current codes that could be used to describe the 90-day, 180-day, or 365-day sensor. Specifically, we created the following G codes to describe the 365-day sensor:

- G0564 (Creation of subcutaneous pocket with insertion of 365 day implantable interstitial glucose sensor, including system activation and patient training); and
- G0565 (Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new 365 day implantable sensor, including system activation).

The manufacturer asserts the supply costs of the 365-day system will be equivalent to two 180-day systems or four 90-day systems. While we agree that there would be inherently increased costs to the new technology of a 365-day system, we do not agree that those costs would be 4 times more than the 90-day system.

After reviewing the device and procedure and obtaining input from our medical officers, we are assigning HCPCS codes G0564 and G0565 to APC 1561 (New Technology—Level 24 ($3001–$3500)) with a payment rate of $3,250.50.

We currently have very little claims information available for CPT codes 0446T and 0448T as there has only been 1 single frequency claim for CPT 0448T (with a geometric mean cost of around $1,320) and no single frequency claims for 0446T. The geometric mean cost for APC 5054 (Level 4 Skin Procedures) is around $1,850 so we believe APC 5054 is an appropriate assignment. We will continue to monitor these codes as we gather adequate claim information and other relevant clinical information that would be useful in determining appropriate APC assignments.

In summary, after consideration of the public comment, we are finalizing our proposal, without modification, to assign CPT code 0446T and 0448T to APC 5054 (Level 4 Skin Procedures) for CY 2025 and finalizing APC assignments for G0564 and G0565. The final CY 2025 payment rate for these codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

40. Integrated Sacral Neurostimulators, CPT Code 0786T

Effective January 1, 2024, the CPT Editorial Panel separated integrated from non-integrated (*i.e.,* traditional) sacral neurostimulator procedure by establishing new CPT code, 0786T to report procedures using integrated sacral neurostimulator devices, while CPT code 64590 was updated to reflect the use of traditional technology:

- *0786T:* Insertion or replacement of percutaneous electrode array, sacral, with integrated neurostimulator, including imaging guidance, when performed.
- *64590:* Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver

In the CY 2025 OPPS/ASC proposed rule Addendum B, we proposed to continue to assign CPT code 0786T to APC 5463 (Level 3 Neurostimulator and Related Procedures) with a proposed payment rate of $13,029.81. We received several comments related to the proposal.

Comment: One commenter disagreed with our proposal. The commenter stated that the proposed assignment for this technology would reduce reimbursement and limit access for Medicare and Medicaid patients seeking care in the outpatient surgery setting. The commenter thought that this decision may have been based on the concept that the Neuspera system is an integrated system, requiring no intra-operative connection. Although physical connections are not required, they stated a considerable amount of time and effort is expended on creating wireless connections and re-positioning the device once partially deployed.

One commenter asserted that the integrated sacral neuromodulation system (SNM) represents a disruptive technology that should improve patient satisfaction, with similar efficacy, lower risk, and as a ''one and done'' procedure that will reduce the need for 2–3 devices per patient to only one Neuspera devices per patient. The commenter stated the lead placement takes the majority of the procedure time, while the implantable pulse generator (IPG) placement requires very little time and expertise. Given their claim that the integrated system is nearly identical to the current non-integrated systems, they requested it should be paid on par with the current non-integrated system.

Other commenters maintained that the integrated SNM system anticipated to reach the market in 2025 has time and resources substantially equivalent to those for traditional SNM systems. Given this, they noted keeping CPT code 0786T in a lower APC with a lower device-intensive designation than traditional SNM systems will create an economic barrier and restrict hospitals and ASCs from offering this new less invasive form of SNM to patients.

Several commenters urged CMS to reassign CPT code 0786T to APC 5464 (Level 4 Neurostimulator and Related Procedures) to reflect the most accurate procedure and cost information related to this novel sacral neuromodulation system. They stated that there is a high degree of parity and similarity in time, work, staffing, costs, and resources required for the Neuspera procedure, compared to traditional sacral neuromodulation systems, which are currently assigned to APC 5464. The commenters also pointed out that if CMS is not willing to reassign CPT code 0786T to APC 5464, status indicator ''E1'' may provide CMS the ability to postpone APC assignment until there is FDA cleared technology to make a decision. Currently no FDA approved ''integrated'' sacral neuromodulation system exists.

Response: We proposed to continue to assign CPT code 0786T to APC 5463 for CY 2025, based on input from our clinicians and based on our evaluation of the code. We inadvertently listed Neuspera integrated sacral nerve stimulation system as receiving FDA-approval. However, it is still pending FDA approval and therefore, we agree with most of the commenters who recommended to reassign CPT code 0786T to status indicator ''E1'' until FDA approval has been received.

In summary, after consideration of the public comments that we received, we are finalizing our proposal with modification and are reassigning CPT code 0786T from APC 5463 to status indicator ''E1'' (Not covered by any Medicare outpatient benefit category; Statutorily excluded by Medicare; Not reasonable and necessary; Not paid by Medicare when submitted on outpatient claims (any outpatient bill type)) for CY 2025 because this service is not yet FDA approved.

We refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Addendum D1 is available via the internet on the CMS website.

41. Laparoscopic Appendectomy, CPT Code 44970 (APC 5361)

CPT code 44970 (Laparoscopy, surgical, appendectomy) describes the procedure for laparoscopic appendectomy. Using CY 2023 claims data, CPT code 44970 had a geometric mean cost of $6,499.86 in the CY 2025 OPPS/ASC proposed rule. For CY 2025, we believed this was still appropriately assigned to APC 5361 (Level 1 Laparoscopy and Related Services), which had a proposed payment rate of $5,798.13. Therefore, we proposed to continue assigning CPT code 44970 to APC 5361.

Comment: We received one comment requesting that we reassign CPT code 44970 to APC 5342 (Level 2 Abdominal/Peritoneal/Biliary and Related Procedures). The commenter argued that CPT code 44970 had clinical homogeneity and resource utilization similar to CPT code 44950 (Appendectomy), which is currently assigned to APC 5342.

Response: We thank the commenter for their input. CPT code 44970 has an updated GMC of $6,404.30 in the final rule data. While this is closer to the payment rate for APC 5342, after clinical review of this procedure, we did not find APC 5342 to be the clinically appropriate APC family for CPT code 44970. We continue to believe that this procedure belongs in the Laparoscopy and Related Procedures family.

After consideration of the public comment we received, we are finalizing our proposal without modification to continue to assign CPT code 44970 to APC 5361 (Level 1 Laparoscopy and Related Services). Table 93 shows the

finalized status indicator and APC assignment for the procedure code. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 93: FINAL CY 2025 OPPS APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODE 44970

CPT Code	Long Descriptor	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
44970	Laparoscopy, surgical, appendectomy	J1	5361

42. Litholapaxy Procedure, CPT Code 52318 (APC 5374)

Litholapaxy is a procedure that involves crushing bladder stones and extracting the fragmented stones. CPT code 52318 (Litholapaxy: crushing or fragmentation of calculus by any means in bladder and removal of fragments; complicated or large (over 2.5 cm)) became effective January 1, 1985.

For CY 2025, OPPS payment rates are proposed based on available CY 2023 claims data. For CY 2025, based on our analysis of claims data, we found a total of 4,215 single frequency claims and a geometric mean cost of approximately $4,298 for CPT code 52318. For CY 2025, we proposed to continue to assign CPT code 52318 to Level 4 Urology and Related Services (APC 5374) with a proposed payment rate of approximately $3,438.

Comment: One commenter requested the APC assignment of CPT code 52318 to Level 5 Urology and Related Services (APC 5375). The commenter stated that the complexity and resources required for CPT code 52318 is comparable to CPT code 52601 (Transurethral electrosurgical resection of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included)), which is assigned to APC 5375. Moreover, the commenter alleged that CPT code 52318 is two times greater than the lowest geometric mean of CPT code 54670 (Suture or repair of testicular injury) in APC 5375, which is a two times rule violation.

Response: We appreciate the commenter's recommendation regarding the APC assignment of CPT code 52318, but we disagree that the complexity and resources required for CPT code 52318 are comparable to CPT code 52601. Based on the claims data, we believe that CPT code 52318 fits more appropriately in APC 5374, rather than in APC 5375, based on resource cost and clinical similarity to the procedures in APC 5374.

Furthermore, CPT codes 52318 and 54670 are currently assigned to APC 5374 (Level 4 Urology and Related Services). We note that APC 5374 does not currently have a 2 times rule violation in the final rule data. In addition, both CPT codes 52318 and 54670 do not meet the requirements for cost significance for 2 times rule violation purposes, under the requirements described in section III.B.2. of this final rule with comment period. We have reviewed the codes' geometric mean cost based on the available CY 2023 claims data within APC 5374 and believe that their current APC assignment continues to be appropriate.

After consideration of the public comment we received, we are finalizing our proposal without modification for CPT code 52318 to be reassigned to APC 5374 (Level 4 Urology and Related Services). Please refer to Table 94 for the final OPPS APC and status indicator assignment for CPT code 52318 for CY 2025. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 94: FINAL CY 2025 OPPS APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODE 52318

CPT Code	Long Descriptor	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
52318	Litholapaxy: crushing or fragmentation of calculus by any means in bladder and removal of fragments; complicated or large (over 2.5 cm)	J1	5374

43. LIXELLE® Apheresis

LIXELLE® β2-microglobulin Apheresis Column is indicated for use in the treatment of dialysis-related amyloidosis (DRA), a disease that affects people with end-stage renal disease (ESRD). DRA is a metabolic disorder from the failure of the kidney to filter and remove β2-microglobulin, typically from chronic hemodialysis (typically 5 years or longer). The LIXELLE® device is used in an apheresis procedure that selectively removes β2-microglobulin from circulating blood and is used pursuant to a physician prescription in conjunction with hemodialysis. It is intended to be used at each hemodialysis session (that is, frequency

of treatment is expected to be 3 times per week). In March 2015, FDA approved LIXELLE® as a Class III Humanitarian Use Device (HUD) with an approved Humanitarian Device Exemption (HDE). For CY 2025, there are currently no specific HCPCS or CPT codes that represent the LIXELLE® apheresis service.

Comment: We received one comment, from the manufacturer, requesting CMS provide reimbursement for LIXELLE® apheresis procedure under the ESRD payment system or the OPPS to benefit patients with DRA. Specifically, the commenter requested that CMS provide separate payment under the OPPS for the procedure, and offered the following options:

(1) establish a new HCPCS C code or G code for the LIXELLE® apheresis procedure and assign the code to APC 5242 (Level 2 Blood Product Exchange and Related Services); or

(2) pay separately for the apheresis procedure used with the LIXELLE® device through CPT code 36516 (Therapeutic apheresis with extracorporeal immunoadsorption, selective adsorption or selective filtration and plasma reinfusion), assigned to APC 5243 (Level 3 Blood Product Exchange and Related Services) for CY 2025, and require the use of a modifier or add-on code when the LIXELLE® apheresis procedure is billed to reduce the procedure payment APC 5242 (Level 2 Blood Product Exchange and Related Services) payment rate; or

(3) allow separate payment for the dialysis performed as part of LIXELLE® apheresis procedure through HCPCS code G0257 (Unscheduled or emergency dialysis treatment for an ESRD patient in a hospital outpatient department that is not certified as an ESRD facility), which is assigned to APC 5401 (Dialysis) for CY 2025 and require the use of a modifier or add-on code to provide additional payment beyond that provided for APC 5401; or

(4) assign CPT 90947 (Dialysis procedure other than hemodialysis (*e.g.,* peritoneal dialysis, hemofiltration, or other continuous renal replacement therapies) requiring repeated evaluations by a physician or other qualified health care professional, with or without substantial revision of dialysis prescription) to APC 5242 (Level 2 Blood Product Exchange and Related Services).

The commenter also noted the FDA has approved a clarification to the Instructions for Use (IFU) since last year's comment and rulemaking. The IFU for LIXELLE® expands the list of personnel who can supervise the patient while connected to the extracorporeal system to include not only a physician, but a qualified health care professional such as a physician assistant, nurse practitioner, or registered nurse who is qualified to supervise hemodialysis procedures.

Response: We appreciate the thoughtful recommendations and will consider them for future rulemaking. We note this complex, ongoing issue is still under consideration and continues to merit a thorough evaluation to ensure an appropriate Medicare benefit category and payment pathway for the service is determined.

44. Low Ejection Fraction AI–ECG Service, CPT Codes 0764T and 0765T (APC 5734)

The low ejection fraction AI–ECG Service is intended to aid in screening for Left Ventricular Ejection Fraction (LVEF) less than or equal to 40 percent in adults at risk for heart failure. The low ejection fraction AI–ECG Service is an algorithmic SaaS service that aims to detect hidden diseases using algorithms to enhance and improve interventional procedures through real-time AI insights. CPT codes 0764T (Assistive algorithmic electrocardiogram risk-based assessment for cardiac dysfunction (*e.g.,* low ejection fraction, pulmonary hypertension, hypertrophic cardiomyopathy); related to concurrently performed electrocardiogram (List separately in addition to code for primary procedure)) and 0765T (Assistive algorithmic electrocardiogram risk-based assessment for cardiac dysfunction (*e.g.,* low ejection fraction, pulmonary hypertension, hypertrophic cardiomyopathy); related to previously performed electrocardiogram) became effective January 1, 2023 and were assigned to status indicator ''E1'' (Not paid by Medicare when submitted on outpatient claims). For CY 2025, we proposed that CPT codes 0764T and 0765T continue to be assigned to status indicator E1.

Comment: One Commenter provided documentation that AI–ECG has been FDA approved on September 28, 2023. The commenter requested separate payment for the low ejection fraction AI–ECG service for CY 2025. In addition, the commenter referenced our CY 2023 packaging exemption for SaaS add-on codes policy and requested separate payment for the add-on CPT code 0764T.

Response: We appreciate the commenter providing the FDA documentation for the AI–ECG approval. We agree that CPT code 0765T should be payable for CY 2025. Consistent with our SaaS Add-on Codes policy, CPT code 0764T, the add-on code for the low ejection fraction AI–ECG service would be assigned to the identical APC and status indicator to CPT code 0765T, the standalone code for the same service.

After consideration of the public comments we received, we are finalizing revised status indicator and APC assignments for CPT codes 0764T and 0765T. Please refer to Table 95 for the final OPPS APC and status indicator assignment for HCPCS codes 0764T and 0765T for CY 2025. The final CY 2025 payment rates can be found in Addendum B to this final rule with comment period via the internet on the CMS website.

TABLE 95: FINAL CY 2025 OPPS APC ASSIGNMENT AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODES 0764T and 0765T

CPT Code	Long Descriptor	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
0764T	Assistive algorithmic electrocardiogram risk-based assessment for cardiac dysfunction (e.g., low-ejection fraction, pulmonary hypertension, hypertrophic cardiomyopathy); related to concurrently performed electrocardiogram (list separately in addition to code for primary procedure)	S	5734
0765T	Assistive algorithmic electrocardiogram risk-based assessment for cardiac dysfunction (e.g., low-ejection fraction, pulmonary hypertension, hypertrophic cardiomyopathy); related to previously performed electrocardiogram	S	5734

45. Lower Esophageal Myotomy (POEM), CPT 43497 (APC 5331)

CPT code 43497 (Lower esophageal myotomy, transoral (*i.e.,* peroral endoscopic myotomy [POEM]) describes a minimally invasive endoscopic procedure that treats swallowing disorders caused by muscle problems in the esophagus.

For CY 2025, we proposed to assign CPT code 43497 to APC 5331 (Complex GI Procedures) with a proposed payment rate of around $5,838.

Comment: We received one comment requesting that we reassign CPT code 43497 to APC 5361 (Level 1 Laparoscopy and Related Services) with a proposed payment of around $5,798. The commenter stated that the procedure utilizes techniques that are surgical in nature and that APC 5361 would be a more appropriate APC assignment, based on clinical homogeneity and resource utilization with other services in APC 5361.

Response: The OPPS is a prospective payment system that provides payment for groups of services that share clinical and resource use characteristics. Based on our understanding of the service and input from our medical advisors, we do not agree that CPT code 43497 has clinical and resource homogeneity to other services in APC 5361 such that it should be assigned to APC 5361.

In summary, after consideration of the public comment, we are finalizing our proposal, without modification, to assign CPT code 43497 to APC 5331 for CY 2025. The final CY 2025 payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

46. Magnetic Resonance Exam Safety Procedures, CPT Codes 76014 Through 76019 (APCs 5521, 5523, 5731, 5733, and 5742)

For CY 2025, the AMA CPT Editorial Panel created six codes to report magnetic resonance (MR) examination safety procedures, effective January 1, 2025. The new codes did not have a predecessor code or a one-to-one match to an existing code. When determining the proposed status indicators and APC assignments for CY 2025, we reviewed the clinical and resource characteristics of the procedures, considered input from our medical advisors, and reviewed existing APC classifications to identify similar and closely related procedures. The codes, their long descriptors, and their proposed CY 2025 OPPS status indicators and APC assignments are listed in Table 96.

We note that CPT codes 76014, 76015, 76016, 76017, 76018, and 76019 were listed as placeholder codes 7XX00, 7XX01, 7XX02, 7XX03, 7XX04, and 7XX05 respectively, in OPPS Addendum B and Addendum O that were released with the CY 2025 OPPS/ASC proposed rule. Because we had not received the final CPT code numbers from AMA for the new codes that would be effective January 1, 2025, in time for the publication of the proposed rule, we listed the new CPT codes with their respective placeholder codes in OPPS Addendum B and Addendum O.

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TABLE 96 PROPOSED CY 2025 OPPS SI AND APC FOR THE MR DIAGNOSTIC PROCEDURES CPT CODES 76014-76019

CPT Code	Placeholder Code	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
76014	7XX00	MR safety implant and/or foreign body assessment by trained clinical staff, including identification and verification of implant components from appropriate sources (e.g., surgical reports, imaging reports, medical device databases, device vendors, review of prior imaging), analyzing current MR conditional status of individual components and systems, and consulting published professional guidance with written report; initial 15 minutes	S	5731
76015	7XX01	MR safety implant and/or foreign body assessment by trained clinical staff, including identification and verification of implant components from appropriate sources (e.g., surgical reports, imaging reports, medical device databases, device vendors, review of prior imaging), analyzing current MR conditional status of individual components and systems, and consulting published professional guidance with written report; each additional 30 minutes (List separately in addition to code for primary procedure)	N	N/A
76016	7XX02	MR safety determination by a physician or other qualified health care professional responsible for the safety of the MR procedure, including review of implant MR conditions for indicated MR examination, analysis of risk vs clinical benefit of performing MR examination, and determination of MR equipment, accessory equipment, and expertise required to perform examination, with written report	S	5521
76017	7XX03	MR safety medical physics examination customization, planning and performance monitoring by medical physicist or MR safety expert, with review and analysis by physician or other qualified health care professional to prioritize and select views and imaging sequences, to tailor MR acquisition specific to restrictive requirements or artifacts associated with MR conditional implants or to mitigate risk of non-conditional implants or foreign bodies, with written report	S	5734
76018	7XX04	MR safety implant electronics preparation under supervision of physician or other qualified health care professional, including MR-specific programming of pulse generator and/or transmitter to verify device integrity, protection of device internal circuitry from MR electromagnetic fields, and protection of patient from risks of unintended stimulation or heating while in the MR room, with written report	S	5731
76019	7XX05	MR safety implant positioning and/or immobilization under supervision of physician or other qualified health care professional, including application of physical protections to secure implanted medical device from MR-induced translational or vibrational forces, magnetically induced functional changes, and/or prevention of radiofrequency burns from inadvertent tissue contact while in the MR room, with written report	S	5733

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Comment: Some commenters disagreed with the proposed assignments for the five separately payable codes and provided

recommendations for APC reassignments. They stated that the proposed APC assignments for the new codes would be insufficient to cover the cost of furnishing the procedures and would impact beneficiary access. Commenters detailed that the proposed APC assignments for CPT codes 76017, 76018, and 76019 did not reflect the facility costs associated with these procedures, including additional staff time, MR room time and clinical resources for planning, preparation, and patient positioning.

The commenters requested that CMS reassign CPT codes 76014 (placeholder code 7XX00) and 76016 (placeholder code 7XX05) to APC 5611(Level 1 Therapeutic Radiation Treatment Preparation) with a proposed payment rate of $89.12. Commenters requested that CMS reassign CPT codes 76017 (placeholder code 7XX03) and 76019 (placeholder code 7XX05) to APC 5612 (Level 2 Therapeutic Radiation Treatment Preparation; proposed payment rate of around $370). Commenters shared that CPT codes 76017 (placeholder code 7XX03) and 76019 (placeholder code 7XX05) require additional staff time and clinical resources for planning, preparation, and positioning which warrants reassignment to APC 5612.

One commenter requested that CMS reassign CPT code 76018 (placeholder code 7XX04) to APC 5612 (Level 2 Therapeutic Radiation Treatment Preparation; proposed payment rate of around $370), Another commenter requested a reassignment of CPT code 76018 to APC 5742 (Level 2 Electronic Analysis of Devices; proposed payment rate of around $92). The commenter stated that CPT code 76018 involves interrogation and programming of an implanted device to protect the device and patient against interactions with the MRI scanner and would therefore fit well within APC 5612.

Response: We thank the commenters for their feedback and recommendations. In determining the appropriate APC placement for new codes, we rely on input from a variety of sources, including, but not limited to, review of the resource costs and clinical similarity of the service to existing procedures; input from CMS medical advisors; and information from interested specialty societies. We evaluated the recommendations, modeled the suggestions, analyzed the cost results of the suggested APC reassignments, and received additional input from our medical advisors. Because we believe that the services assigned to the Therapeutic Radiation Treatment Preparation APC family have higher degrees of technicality, require higher levels of trained professional staff, and therefore have additional facility costs beyond those described by the CPT codes 76014 through 76019, we disagree with the commenter requests to assign these CPT codes to APCs 5611 and 5612. And while we recognize that there is not currently a one-to-one match to crosswalk to the new codes, we based the proposed APC assignments for CPT codes 76014, 76016, and 76019 on crosswalks to CPT codes that have similar service and resource elements, as well as required staff, to the new codes.

Specifically, we continue to believe that:

- CPT code 76014 is similar to the service described by CPT code 0521T (Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording, and disconnection per patient encounter, wireless cardiac stimulator for left ventricular pacing), which is assigned to APC 5731.
- CPT code 76016 is similar to the service described by CPT code 77091 (Trabecular bone score (tbs), structural condition of the bone microarchitecture; technical calculation only), which is assigned to APC 5521.
- CPT code 76019 is similar to CPT code 29520 (Strapping; hip), which is assigned to APC 5733.

After consideration of the public comments, our review of CPT code 76017 identified procedures in APC 5523 (Level 3 Imaging without Contrast) that we believe better align with the clinical characteristics and resources required for CPT code 76017, including CPT code 73718 (Magnetic resonance (*e.g.,* proton) imaging, lower extremity other than joint; without contrast material(s)). After further input from CMS medical advisors, we believe that it may be appropriate to assign CPT code 76017 to APC 5523.

Additionally, we believe that we have identified additional procedures in APC 5742 that share similar resource and clinical characteristics with CPT code 76018. Specifically, we believe that CPT code 76018 shares resource and clinical similarities to the service described by CPT code 29125 (Application of short arm splint (forearm to hand); static). Based on our assessment, we believe it appropriate to assign CPT code 76018 to APC 5742, based on shared resource and clinical characteristics.

In summary, we believe that the below assignment of the new codes in Table 97 are the most appropriate, in terms of clinical and resource homogeneity. We note that we review our claims data on an annual basis to establish the OPPS payment rates and we will reevaluate the status indicator and APC assignments annually.

After consideration of the public comments we received, we are finalizing our proposal with modification for CPT codes 76014 through 76019. Table 97 shows the finalized status indicators and APC assignments for all of the procedure codes. The final CY 2025 payment rates for these codes can be found in Addendum B to this final rule with comment period. We also refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

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TABLE 97: FINAL CY 2025 OPPS SI AND APC FOR THE MR DIAGNOSTIC PROCEDURES CPT CODES 76014-76019

CPT Code	Placeholder Code	Long Descriptor	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
76014	7XX00	MR safety implant and/or foreign body assessment by trained clinical staff, including identification and verification of implant components from appropriate sources (e.g., surgical reports, imaging reports, medical device databases, device vendors, review of prior imaging), analyzing current MR conditional status of individual components and systems, and consulting published professional guidance with written report; initial 15 minutes	S	5731
76015	7XX01	MR safety implant and/or foreign body assessment by trained clinical staff, including identification and verification of implant components from appropriate sources (e.g., surgical reports, imaging reports, medical device databases, device vendors, review of prior imaging), analyzing current MR conditional status of individual components and systems, and consulting published professional guidance with written report; each additional 30 minutes (List separately in addition to code for primary procedure)	N	N/A
76016	7XX02	MR safety determination by a physician or other qualified health care professional responsible for the safety of the MR procedure, including review of implant MR conditions for indicated MR examination, analysis of risk vs clinical benefit of performing MR examination, and determination of MR equipment, accessory equipment, and expertise required to perform examination, with written report	S	5521
76017	7XX03	MR safety medical physics examination customization, planning and performance monitoring by medical physicist or MR safety expert, with review and analysis by physician or other qualified health care professional to prioritize and select views and imaging sequences, to tailor MR acquisition specific to restrictive requirements or artifacts associated with MR conditional implants or to mitigate risk of non-conditional implants or foreign bodies, with written report	S	5523
76018	7XX04	MR safety implant electronics preparation under supervision of physician or other qualified health care professional, including MR-specific programming of pulse generator and/or transmitter to verify device integrity, protection of device internal circuitry from MR electromagnetic fields, and protection of patient from risks of unintended stimulation or heating while in the MR room, with written report	S	5742
76019	7XX05	MR safety implant positioning and/or immobilization under supervision of physician or other qualified health care professional, including application of physical protections to secure implanted medical device from MR-induced translational or vibrational forces, magnetically induced functional changes, and/or prevention of radiofrequency burns from inadvertent tissue contact while in the MR room, with written report	S	5733

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47. MindMotion GO Neurorehabilitative Remote Therapy Service, CPT Code 0733T (APC 1505)

Effective July 1, 2022, the AMA established CPT code 0733T (Remote real-time, motion capture-based neurorehabilitative therapy ordered by a physician or other qualified health care professional; supply and technical support, per 30 days) to describe the procedure associated with the use of MindMotion GO, which provides remote real-time, motion capture-based neurorehabilitative therapy. In the CY 2025 OPPS/ASC proposed rule, CMS proposed to continue to assign CPT code 0733T to APC 5741 (Level 1 Electronic Analysis of Devices) with a proposed payment rate of $36.90, due to its similarity to CPT code 98976 (Remote therapeutic monitoring (*e.g.,* therapy adherence, therapy response); device(s) supply with scheduled (*e.g.,* daily) recording(s) and/or programmed alert(s) transmission to monitor respiratory system, each 30 days).

Comment: We received one comment from the manufacturer of MindMotion GO requesting that CMS reassign CPT code 0733T to APC 1510 (New Technology—Level 10 ($801–$900)). The commenter stated that the resource costs of this service are $849 and that the MindMotion GO technology will not be commercially available until early 2025, so there is currently no claims data available to assign this service to a clinical APC. The commenter also believed that CPT code 0733T was not clinically homogeneous with APC 5741 as the procedures in the APC are for monitoring services, while CPT code 0733T also describes a device used primarily for treatment of neurological conditions.

Response: We thank the commenter for their input. We agree with the commenter that the current assignment of APC 5741 would result in too low of a payment for CPT code 0733T. After further review, we believe this procedure is similar to the procedure described by CPT code 0693T (Comprehensive full body computer-based markerless 3d kinematic and kinetic motion analysis and report), which describes technology for DARI Motion. CPT code 0693T is currently assigned to APC 1505 (New Technology—Level 5 ($301—$400)). Therefore, we are reassigning CPT code 0733T to APC 1505 until we are able to obtain claims data for this procedure.

After consideration of the public comment we received, we are finalizing our proposal with modification to reassign CPT code 0733T to APC 1505 (New Technology—Level 5 ($301–$400)). Table 98 shows the finalized status indicator and APC assignment for the procedure code. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 98: FINAL CY 2025 OPPS APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODE 0733T

CPT Code	Long Descriptor	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
0733T	Remote real-time, motion capture-based neurorehabilitative therapy ordered by a physician or other qualified health care professional; supply and technical support, per 30 days	S	1505

48. Musculoskeletal Procedures (APCs 5111 Through 5116)

Prior to the CY 2016 OPPS, payment for musculoskeletal procedures was primarily divided according to anatomy and the type of musculoskeletal procedure. As part of the CY 2016 reorganization to better structure the OPPS payments to utilize prospective payment packages, we consolidated these individual APCs so that they became a general Musculoskeletal APC series (80 FR 70397 and 70398).

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59300), we continued to apply a six-level structure for the Musculoskeletal APCs because doing so provided an appropriate distinction for resource costs at each level and provided clinical homogeneity. However, we indicated that we would continue to review the structure of these APCs to determine whether additional granularity would be necessary. In the CY 2019 OPPS proposed rule (83 FR 37096), we recognized that commenters had previously expressed concerns regarding the granularity of the current APC levels and, therefore, requested comment on the establishment of additional levels. Specifically, we solicited comments on the creation of a new APC level between the current Level 5 and Level 6 within the Musculoskeletal APC series. While some commenters suggested APC reconfigurations and requested changes to APC assignments, many commenters requested that we maintain the current six-level structure and continue to monitor the claims data as they become available. Therefore, in the CY 2019 OPPS/ASC final rule with comment period, we maintained the six-level APC structure for the Musculoskeletal Procedures APCs (83 FR 58920 and 58921).

For CY 2025, based on the claims data available for the CY 2024 OPPS/ASC proposed rule, we continued to believe that the six-level APC structure for the Musculoskeletal Procedures APC series is appropriate, and we proposed to maintain it for the CY 2025 OPPS update.

Comment: Several commenters supported the assignment of HCPCS code 0737T (Xenograft implantation into the articular surface) to APC 5115 (Level 5 Musculoskeletal Procedures) and recommended that we finalize the assignment in the CY 2025 OPPS.

Response: We appreciate the commenters' support of our proposal. We agree and are finalizing the proposed assignment of HCPCS code 0737T (Xenograft implantation into the articular surface) to APC 5115 (Level 5 Musculoskeletal Procedures). We refer

readers to section III.E.67 of this final rule with comment period for a detailed discussion of this issue.

Comment: A commenter supported the continued assignment of HCPCS code C9781 (Arthroscopy, shoulder, surgical; with implantation of subacromial spacer (*e.g.,* balloon), includes debridement (*e.g.,* limited or extensive), subacromial decompression, acromioplasty, and biceps tenodesis when performed) to APC 5115 (Level 5 Musculoskeletal Procedures).

Response: We appreciate the commenter's support of our proposal. We agree and are finalizing the proposed assignment of HCPCS code C9781 (Arthroscopy, shoulder, surgical; with implantation of subacromial spacer (*e.g.,* balloon), includes debridement (*e.g.,* limited or extensive), subacromial decompression, acromioplasty, and biceps tenodesis when performed) to APC 5115 (Level 5 Musculoskeletal Procedures). We refer readers to section III.E.11. of this final rule with comment period for a detailed discussion of this issue.

Comment: A few commenters recommended that CMS consider the creation of additional musculoskeletal APC levels. Commenters noted that additional APCs should be considered with the goal of reducing payment gaps and volatility, while aligning cost and clinical homogeneity in the APCs. One commenter recommended that an additional APC level be considered between the current levels 4 and 5 with costs ranging from $7,000 to $12,000. Another commenter requested that we create an additional Musculoskeletal APC level from codes currently in APC 5116 (Level 6 Musculoskeletal Procedures) with geometric mean costs above $22,000, while moving codes with geomean costs above $14,000 in the current level 5 APC to the level 6 APC.

Response: We appreciate the commenters' recommendations. We also appreciate the goal of developing APC levels that properly group procedures by clinical and resource similarity. At this time, we believe the six-level structure for the Musculoskeletal APCs that we proposed continues to provide an appropriate distinction between the resource costs at each level and clinical homogeneity and are therefore finalizing that six-level structure for the Musculoskeletal Procedures APC series in the CY 2025 OPPS. However, we will take these comments into consideration for future rulemaking and continue to monitor the claims data as they are available.

After consideration of the public comments, we are finalizing our proposal to maintain the six-level Musculoskeletal Procedures APC structure. We are also finalizing the assignment of HCPCS code 0737T (Xenograft implantation into the articular surface) to APC 5115 and HCPCS code C9781 (Arthroscopy, shoulder, surgical; with implantation of subacromial spacer (*e.g.,* balloon), includes debridement (*e.g.,* limited or extensive), subacromial decompression, acromioplasty, and biceps tenodesis when performed) to APC 5115 for the CY 2025 OPPS.

49. Noncontact Near-Infrared (NIR) Spectroscopy, CPT 0640T (APC 5732)

Effective CY 2024, there are three codes that describe the service related to NIR spectroscopy: CPT codes 0640T (Noncontact near-infrared spectroscopy (*e.g.,* for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation), other than for screening for peripheral arterial disease, image acquisition, interpretation, and report; first anatomic site, 0859T (Noncontact near-infrared spectroscopy (*e.g.,* for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation), other than for screening for peripheral arterial disease, image acquisition, interpretation, and report; each additional anatomic site (list separately in addition to code for primary procedure)), and 0860T (Noncontact near-infrared spectroscopy (*e.g.,* for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation), for screening for peripheral arterial disease, including provocative maneuvers, image acquisition, interpretation, and report, one or both lower extremities). Only CPT code 0640T is separately paid under the OPPS. For CY 2025, CMS proposed to assign CPT code 0640T to APC 5732 (Level 2 Minor Procedures) and status indicator ''S'' with a $39 payment rate.

Comment: We received one comment regarding the proposed APC assignment for CPT code 0640T. The commenter requested that we reassign 0640T to APC 5722 (Level 2 Imaging without contrast) with a proposed payment rate of approximately $310 for CY 2025 based on a crosswalk to CPT code 0598T (Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; first anatomic site (*e.g.,* lower extremity)). The commenter explained that CPT code 0598T is an appropriate crosswalk code because it yields diagnostic images without contrast, is newer, and utilizes a Category III CPT code.

Response: We thank the commenter for their input. First, we note that prior to the AMA's CPT Editorial Panel descriptor revision for CPT code 0640T, the technical service associated with NIR spectroscopy was described by CPT code 0641T, which was assigned to APC 5732 for CY 2023, prior to being deleted for CY 2024. Under the OPPS, the predecessor code for CPT code 0640T is CPT code 0641T. We note for CY 2025, OPPS payment rates are proposed based on available CY 2023 claims data. Based on our analysis of the claims data for this final rule with comment period, we found a geometric mean cost of about $16 for predecessor CPT code 0641T, based on 32 single frequency claims (out of 445 total claims). In contrast, we found a geometric mean cost of approximately $170 for CPT code 0598T based on 1109 single frequency claims (out of 2531 total claims). Based on the data, the resource cost associated with noncontact real-time fluorescence imaging (CPT code 0598T), is significantly higher compared to noncontact near-infrared (NIR) spectroscopy (CPT code 0640T/0641T). We disagree that the resource cost for NIR spectroscopy is similar to noncontact real-time fluorescence imaging. Therefore, we do not agree that both technologies should be placed in the same APC. We believe that the code describing NIR spectroscopy, specifically, CPT code 0640T, is appropriately placed in APC 5732.

In consideration of the public comment we received, we are finalizing our proposal without modification for CPT code 0640T. Specifically, for CY 2025, we are finalizing our proposal to assign CPT code 0640T to APC 5732. The final CY 2025 OPPS payment rate for all the codes payable under the OPPS can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addendum D1 is available via the internet on the CMS website.

50. Percutaneous Coronary Revascularization Services by Intracoronary Antiproliferative Drug Delivery, CPT Codes 0913T and 0914T (APC 5192)

For the July 2024 update, the AMA's CPT Editorial Panel established two Category III codes to describe percutaneous coronary revascularization services by intracoronary antiproliferative drug delivery, performed for occlusive disease of the coronary vessels (major coronary arteries, coronary artery branches) using

drug-delivery balloon (*e.g.,* drug-coated, drug-eluting) for intracoronary antiproliferative drug delivery:

- CPT code 0913T (placeholder code XX23T) (Percutaneous transcatheter therapeutic drug delivery by intracoronary drug-delivery balloon (*e.g.,* drug-coated, drug-eluting), including mechanical dilation by nondrug-delivery balloon angioplasty, endoluminal imaging using intravascular ultrasound (IVUS) or optical coherence tomography (OCT) when performed, imaging supervision, interpretation, and report, single major coronary artery or branch)); and,
- CPT code 0914T (placeholder code XX40T) (Percutaneous transcatheter therapeutic drug delivery by intracoronary drug-delivery balloon (*e.g.,* drug-coated, drug-eluting) performed on a separate target lesion from the target lesion treated with balloon angioplasty, coronary stent placement or coronary atherectomy, including mechanical dilation by nondrug-delivery balloon angioplasty, endoluminal imaging using intravascular ultrasound (IVUS) or optical coherence tomography (OCT) when performed, imaging supervision, interpretation, and report, single major coronary artery or branch (List separately in addition to code for percutaneous coronary stent or atherectomy intervention)).

In the CY 2025 OPPS/ASC proposed rule, we proposed to assign CPT code 0913T (placeholder code XX23T) to APC 5192 (Level 2 Endovascular Procedures; geometric mean cost of $5,771.29) based on clinical and resource similarity to other Percutaneous Coronary Intervention (PCI) procedures, including CPT code 92920 (Percutaneous transluminal coronary angioplasty; single major coronary artery or branch). Additionally, as an add-on code, we proposed to assign CPT code 0914T to status indicator ''N.''

We note that a transitional device pass-through application was submitted for the AGENT™ Paclitaxel-Coated Balloon Catheter for CY 2025 to request separate payment for the device under the OPPS, in addition to the surgical CPT codes. We direct readers to section IV.A (Pass-Through Payment for Devices) of this final rule with comment period for a more detailed discussion of the transitional device pass-through applications and the status of the CY 2025 device pass-through application for the AGENT™ Paclitaxel-Coated Balloon Catheter.

We also note that a presenter provided information to the Panel on the description of the service and the cost of the Agent™ device and procedure at the August 28, 2024, HOP Panel Meeting. At the conclusion of the presentation, the presenter asked the Panel to request that CMS reassign CPT code 0913T from APC 5192 to APC 5193 (Level 3 Endovascular Procedures). Based on the information presented at the HOP Panel meeting, the HOP Panel recommended reassigning CPT 0913T to APC 5193.

Comment: We received several comments from interested parties, including the manufacturer, a trade association, and several practitioners. One commenter reiterated information shared during the 2024 HOP Panel. Commenters stated that coronary drug-delivery by drug-coated balloon (DCB) is a clinically similar procedure to a drug-eluting stent (DES) implant, which is reported with HCPCS code C9600 (Percutaneous transcatheter placement of drug eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch) and is assigned to APC 5193 (Level 3 Endovascular Procedures). The manufacturer also provided a cost analysis of one facility's Medicare outpatient claims for coronary DCB. Their provided cost analysis included eleven claims and indicated that the geometric mean cost of those eleven claims was $18,935.69.

Response: We thank the commenters for their comments. After consideration of the public comments, we continue to believe that CPT code 0913T is appropriately assigned to APC 5192. We note that the long descriptor for CPT code 0913T describes a service similar to other codes in APC 5192. After review of the service and input from our CMS medical officers, we believe that CPT code 92920 (Percutaneous transluminal coronary angioplasty; single major coronary artery or branch) which is assigned to APC 5192 is a good crosswalk code for CPT code 0913T because it is clinically similar.

In summary, we are finalizing our proposal to assign CPT code 0913T to status indicator ''J1,'' and APC 5192. The final CY 2025 payment rate for CPT code 0913T can be found in Addendum B to this final rule with comment period. We also refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addendums B and D1 are available via the internet on the CMS website.

51. Potential Two-Times Rule Violations (APCs 5302, 5415, 5092, and 5114)

We received comments on the APC assignments we proposed in the CY 2025 OPPS/ASC proposed rule, which commenters believe result in 2-times rule violations.

Endoscopic Esophageal Procedures

CPT code 43254 (Esophagogastroduodenoscopy, flexible, transoral; with endoscopic mucosal resection) with a geometric mean cost of around $2,632; CPT code 43270 (Esophagogastroduodenoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)) with a geometric mean cost of around $2,985; and CPT code 43275 (Endoscopic retrograde cholangiopancreatography (ERCP); with removal of foreign body(s) or stent(s) from biliary/pancreatic duct(s)) with a geometric mean cost of around $2,886 describe endoscopic procedures that are performed on the esophagus. For the CY 2025 OPPS/ASC proposed rule, we proposed to assign all 3 procedures to APC 5302 (Level 2 Upper GI Procedures), which had a proposed a payment rate of around $1,884.

Comment: One commenter requested that we reassign CPT codes 43254, 43270, and 43275 to APC 5303 (Level 3 Upper GI Procedures) with a proposed payment rate of around $3,648, due to the geometric mean costs of these codes being more than 2 times that of CPT code 0653T (Esophagogastroduodenoscopy, flexible, transnasal; with biopsy, single or multiple). CPT code 0653T has a geometric mean cost of around $1,212.

Response: We appreciate the commenter's request. We did not identify a 2-times rule violation for APC 5302. Since the release of the CY 2025 OPPS proposed rule, we have updated our 2-times analysis of claims from CY 2023 that are used to set rates for CY 2025. Our updated claims data found CPT code 0653T has fewer than 100 claims and does not meet the significance threshold for the two times rule evaluation, and therefore is not considered the lowest cost significant procedure for APC 5302.

Vaginal Hysterectomy Procedures

CPT code 58260 (Vaginal hysterectomy, for uterus 250 g or less) with a geometric mean cost of around $6,083 and CPT code 58262 (Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s)) with a geometric mean cost of around $6,753 describe vaginal hysterectomy procedures. For the CY 2025 OPPS/ASC proposed rule, we proposed to assign both procedures to APC 5415 (Level 5 Gynecologic Procedures) with a

proposed payment rate of around $4,902.

Comment: A commenter requested that we reassign CPT codes 58260 and 58262 to APC 5416 (Level 6 Gynecologic Procedures) with a proposed payment rate of around $7,312, citing the geometric mean cost of CPT code 57550 (Excision of cervical stump, vaginal approach) which is around $1,879.

Response: We appreciate the commenter's request. We did not identify a 2-times rule violations for APC 5415. Our updated claims data found CPT code 57550 has fewer than 100 claims and does not meet the significance threshold for the 2-times rule evaluation, and therefore is not considered the lowest cost significant procedure for APC 5415.

Mastectomy Procedures

CPT code 19303 (Mastectomy, simple, complete) with a geometric mean cost of around $7,236 and CPT code 19307 (Mastectomy, modified radical, including axillary lymph nodes, with or without pectoralis minor muscle, but excluding pectoralis major muscle) with a geometric mean cost of around $7,412 describe mastectomy procedures. For the CY 2025 OPPS/ASC proposed rule, we proposed to assign both procedures to APC 5092 (Level 2 Breast/Lymphatic Surgery and Related Procedures) with a proposed payment rate of around $6,473.

Comment: Another commenter requested that we reassign CPT code 19303 and 19307 to APC 5093 (Level 3 Breast/Lymphatic Surgery and Related Procedures) with a proposed payment rate of around $9,417, citing the geometric mean cost of CPT code 38555 (Excision of cystic hygroma, axillary or cervical; with deep neurovascular dissection) which is around $3,475.

Response: We appreciate the commenter's request. We did not identify a 2-times rule violations for APC 5092. Our updated claims data found CPT code 38555 has fewer than 100 claims and does not meet the significance threshold for the two times rule evaluation and therefore is not considered the lowest cost significant procedure for APC 5092.

Arthrodesis Procedure

CPT code 28740 (Arthrodesis, midtarsal or tarsometatarsal, single joint), which has a geometric mean cost of around $11,058, describes an arthrodesis procedure performed in the foot. For the CY 2025 OPPS/ASC proposed rule, we proposed to assign this procedure to APC 5114 (Level 4 Musculoskeletal Procedures) with a proposed payment rate of around $7,090.

Comment: A commenter requested that CPT code 28740 be reassigned to APC 5115 (Level 5 Musculoskeletal Procedures) with a proposed payment rate of around $12,755, citing the geometric mean cost of CPT code 27385 which is around $5,616.

Response: We appreciate the commenter's request. Our updated claims data did not identify a 2-times rule violation for APC 5115. We also found that the geometric mean cost for CPT code 28740 is $11,074. This is less than two times the updated cost of the suggested code CPT code 27385, which is $5,616.

In summary, after consideration of these public comments, we are finalizing our proposal without modification to assign CPT codes 43254, 43270, and 43275 to APC 5302 (Level 2 Upper GI Procedures); CPT codes 58260 and 58262 to APC 5415 (Level 5 Gynecologic Procedures); CPT codes 19303 and 19307 to APC 5092 (Level 2 Breast/Lymphatic Surgery and Related Procedures); and CPT code 28740 to APC 5114 (Level 4 Musculoskeletal Procedures). We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

52. Prostate Laser Enucleation Procedure, CPT Code 52649 (APC 5375)

Prostate laser enucleation procedure utilizes laser to remove the prostate tissue to treat benign prostatic hyperplasia. The procedure is described by CPT code 52649 (Laser enucleation of the prostate with morcellation, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed)).

For CY 2025, the OPPS payment rates are proposed based on available CY 2023 claims data. For the CY 2025 proposed rule, based on our analysis of claims data, we found a total of 7,494 single frequency claims and a geometric mean cost of approximately $6,812 for CPT code 52649. For CY 2025, we proposed to continue to assign CPT code 52649 to Level 5 Urology and Related Services (APC 5375) with a proposed payment rate of approximately $5,057.

Comment: One commenter disagreed with the proposed APC assignment to APC 5375 (Level 5 Urology and Related Services) and requested the reassignment of CPT code 52649 to APC 5376 (Level 6 Urology and Related Services). The commenter argued that CPT code 52649 shared more clinical and resource similarities with CPT code 50562 (Renal endoscopy through established nephrostomy or pyelostomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with resection of tumor) and CPT code 55873 (Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring)), which are currently assigned to APC 5376. Moreover, the commenter argued that there is more work involved in CPT code 52649 than CPT code 52601 (Transurethral electrosurgical resection of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included)) which is currently assigned to APC 5375 (Level 5 Urology and Related Services).

Response: The CY 2025 OPPS payment rates were proposed based on available CY 2023 claims data. We analyzed the claims data for this final rule, and based on our review, we found a geometric mean cost of approximately $6,812 for CPT code 52649 based on 7,494 single claims (out of 7,564 total claims), is consistent with the geometric mean cost of about $5,145 for APC 5375, rather than the geometric mean cost of approximately $9,356 for APC 5376. Based on the claims data, we believe that CPT code 52649 fits more appropriately in APC 5375, rather than in APC 5376, based on resource cost and clinical similarity to CPT code 52601 in APC 5375. We note that we review, on an annual basis, the APC assignments for all services and items paid under the OPPS based on our analysis of the latest claims data.

We also disagree that CPT code 52649 is sufficiently clinically similar to CPT code 50562 because the latter code involves a surgical treatment of the kidney rather than the prostate. Furthermore, we disagreed that CPT code 52649 shares resource similarity with CPT code 55873, as cryosurgical ablation requires many more resources than the prostate laser enucleation procedure.

In summary, after consideration of the public comment, we are finalizing our proposal, without modification, to assign CPT code 52649 to APC 5375 for CY 2025. Please refer to Table 99 below for the final OPPS APC and status indicator assignment for HCPCS code 52649 for CY 2025. The final CY 2025 payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, we refer

readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

TABLE 99: FINAL CY 2025 OPPS APC ASSIGNMENT AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODE 52649

CPT Code	Long Descriptor	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
52649	Laser enucleation of the prostate with morcellation, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed)	J1	5375

53. Remote Uroflowmetry Service, CPT Code 0812T (APC 5721)

Remote uroflowmetry is a service that allows patients to measure urine output while remotely monitored by health professionals. This service aids in the diagnosis and management of lower urinary tract issues, such as benign prostatic hyperplasia. It is described by CPT code 0812T (Remote multi-day complex uroflowmetry (*e.g.,* calibrated electronic equipment); device supply with automated report generation, up to 10 days) which became effective January 1, 2024. For CY 2025, we proposed to assign CPT code 0812T to APC 5741 (Level 1 Electronic Analysis of Devices).

Comment: One commenter disagreed with our proposed APC assignment of APC 5741 (Level 1 Electronic Analysis of Devices), citing higher equipment and labor cost associated with the CPT code 0812T than services assigned to APC 5741. The commenter requested CPT code 0812T be reassigned to APC 5722 (Level 2 Diagnostic Tests and Related Services), citing resource similarity to CPT code 51741(Complex uroflowmetry (*e.g.,* calibrated electronic equipment)).

Response: We appreciate the commenter's recommendation regarding the APC assignment for CPT code 0812T. However, we disagree with the commenter that CPT code 51741 shares similar resource requirements with CPT code 0812T, although both CPT codes describe the uroflowmetry service. CPT code 51741 is a more complex procedure than CPT code 0812T, which is why we proposed to assign CPT code 51741 to APC 5722 (Level 2 Diagnostic Tests and Related Services)). However, we also believe CPT code 0812T shares more resource similarity with CPT code 51703 (Insertion of temporary indwelling bladder catheter; complicated (*e.g.,* altered anatomy, fractured catheter/balloon)) than CPT code 51741. Therefore, for CY 2025, we are reassigning CPT code 0812T to APC 5721 (Level 1 Diagnostic Tests and Related Services).

After consideration of the public comment we received, we are finalizing our proposal with modification and reassigning CPT code 0812T to APC 5721 (Level 1 Diagnostic Tests and Related Services). Please refer to Table 100 below for the final OPPS APC and status indicator assignment for CPT code 0821T for CY 2025. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 100: FINAL CY 2025 OPPS APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODE 0812T

CPT Code	Long Descriptor	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
0812T	Remote multi-day complex uroflowmetry (e.g., calibrated electronic equipment); device supply with automated report generation, up to 10 days	Q1	5721

54. Skin Cell Suspension Autograft (SCSA) Procedures, CPT Codes 15011 Through 15018 (APCs 5051, 5054, and 1567)

The RECELL System is a device used for skin cell suspension autograft (SCSA) procedures. Skin cell suspension autograft procedures treat acute thermal burn injuries by adhering skin cell solutions to the wound site without use of fixation. There are three steps to perform a SCSA procedure: (1) skin harvesting, (2) SCSA preparation (utilizing the RECELL System), and (3) SCSA application to the wound bed.

The RECELL System is on transitional pass-through (TPT) effective January 1, 2022, to December 31, 2024. While on TPT, each time the RECELL device is used, providers must bill device code HCPCS C1832 (Autograft suspension, including cell processing and application, and all system components) and either CPT code 15110 (Epidermal autograft, trunk, arms, legs; first 100 sq cm or less, or 1% of body area of infants and children) or CPT code 15115 (Epidermal autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or 1% of body area of infants and children),as provided in the January 2022 OPPS Change Request 12552 (Transmittal R11150CP).

While HCPCS code C1832 describes the RECELL System that prepares the SCSA, CPT codes 15110 and 15115 describe the autograft procedure, which includes both the skin harvesting and SCSA application components of the service. For CY 2024, CPT codes 15510 and 15115 were assigned to APC 5054 (Level 4 Skin Procedures), with a payment rate of approximately $1,800. HCPCS code C1832 can also be billed with CPT codes 15100 (Split-thickness autograft, trunk, arms, legs; first 100 sq cm or less, or 1% of body area of infants and children (except 15050)) or 15120 (Split-thickness autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or 1% of body area of infants and children (except 15050)), so long as it is billed with one of the two preceding codes (CPT codes 15110 or 15115).

In September 2023, AMA's CPT Editorial Panel created eight new Category 1 CPT codes to describe SCSA procedures, effective January 1, 2025. The eight new codes are provided in Table 101.

TABLE 101: CATEGORY I CPT CODES TO DESCRIBE SCSA PROCEDURES EFFECTIVE JANUARY 1, 2025

CPT Code	Long Descriptor
15011 (placeholder code 15XX1)	Harvest of skin for skin cell suspension autograft; first 25 sq cm or less
15012 (15XX2)	Harvest of skin for skin cell suspension autograft; each additional 25 sq cm or part thereof (List separately in addition to code for primary procedure)
15013 (15XX3)	Preparation of skin cell suspension autograft, requiring enzymatic processing, manual mechanical disaggregation of skin cells, and filtration; first 25 sq cm or less of harvested skin
15014 (15XX4)	Preparation of skin cell suspension autograft, requiring enzymatic processing, manual mechanical disaggregation of skin cells, and filtration; each additional 25 sq cm of harvested skin or part thereof (List separately in addition to code for primary procedure)
15015 (15XX5)	Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, trunk, arms, legs; first 480 sq cm or less
15016 (15XX6)	Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, trunk, arms, legs; each additional 480 sq cm or part thereof (List separately in addition to code for primary procedure)
15017 (15XX7)	Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 480 sq cm or less
15018 (15XX8)	Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 480 sq cm or part thereof (List separately in addition to code for primary procedure)

In creating these eight new CPT codes, the harvesting, preparation, and application components of the service are each split into separate codes. The harvesting of the skin is described by CPT codes 15011 and 15012, the preparation of the SCSA is described by CPT codes 15013 and 15014, and the application of the SCSA is described by CPT codes 15015 through 15018. While the RECELL System is on TPT, it is sufficient to bill the device code HCPCS C1832 and only one procedure code (either CPT code 15110 or CPT 15115) to describe all three components of the service. However, with the creation of the eight new CPT codes, at least three CPT codes will need to be billed each time the RECELL System is used for a SCSA procedure: CPT code 15011 with or without CPT code 15012 for the skin harvesting, CPT code 15013 with or without CPT code 15014 for the SCSA preparation, and CPT code 15015 with or without CPT code 15016 or CPT code 15017 with or without CPT code 15018 for the SCSA application.

For CY 2025, we proposed to assign the eight new CPT codes to various clinical APCs and status indicators provided in Table 102.

BILLING CODE 4120–01–P

TABLE 102: PROPOSED CY 2025 APC AND STATUS INDICATOR ASSIGNMENTS FOR NEW SCSA PROCEDURES

CPT Code	Long Descriptors	Proposed CY 2025 Status Indicator	Proposed CY 2025 APC Assignment
15011 (15XX1)	Harvest of skin for skin cell suspension autograft; first 25 sq cm or less	T	5054
15012 (15XX2)	Harvest of skin for skin cell suspension autograft; each additional 25 sq cm or part thereof (List separately in addition to code for primary procedure)	N	N/A
15013 (15XX3)	Preparation of skin cell suspension autograft, requiring enzymatic processing, manual mechanical disaggregation of skin cells, and filtration; first 25 sq cm or less of harvested skin	T	5051
15014 (15XX4)	Preparation of skin cell suspension autograft, requiring enzymatic processing, manual mechanical disaggregation of skin cells, and filtration; each additional 25 sq cm of harvested skin or part thereof (List separately in addition to code for primary procedure)	N	N/A
15015 (15XX5)	Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, trunk, arms, legs; first 480 sq cm or less	T	5054
15016 (15XX6)	Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, trunk, arms, legs; each additional 480 sq cm or part thereof (List separately in addition to code for primary procedure)	N	N/A
15017 (15XX7)	Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 480 sq cm or less	T	5054

BILLING CODE 4120–01–C

Comment: We received two comments requesting that we finalize our proposal to assign 15011, 15015, and 15017 to

APC 5054 (Level 4 Skin Procedures) for CY 2025.

Response: We thank the commenters for their support.

Comment: We received two comments, including one comment from the manufacturer of the RECELL System, requesting that we reassign CPT code 15013 from APC 5051 (Level 1 Skin Procedures) to APC 1575 (New Technology—Level 38 ($10,001–$15,000) with a payment rate of $12,500.50 for CY 2025. The commenters expressed concern that the proposed APC assignment for CPT code 15013 to APC 5051 does not accurately reflect the hospital-reported costs associated with the RECELL System. The commenters requested that we consider the hospital costs reported with device code C1832 during the TPT period when finalizing the APC assignment for CPT 15013. The comments estimated a combined total cost of $10,188.96 for CPT code 15013 by adding the purported mean cost for device code C1832 ($7,220) with supply and operating room time costs of approximately $2,900. Based on these estimates, the commenters believe assigning CPT code 15013 to APC 1575 with a payment rate of $12,500.50 would sufficiently pay for the preparation step of the SCSA procedure.

Response: We thank the commenters for their input. Under the OPPS, once pass-through status ends for a device, the cost of the device is packaged into its associated procedure. For the RECELL System, once TPT expires on December 31, 2024, the associated procedure will be CPT code 15013. We agree with the commenters that we need to use the claims data available while the RECELL System is on TPT to determine the appropriate APC placement for CPT code 15013.

However, given the restructuring of how SCSA procedures utilizing the RECELL System will be billed effective January 1, 2025, we also believe we need to consider the costs of the skin harvesting and application steps of the procedure, which are currently billed by only one procedure code (either CPT Code 15110 or CPT code 15115), paid at approximately $1,800, to determine the appropriate payment for the RECELL System and SCSA application step. In other words, we believe that the sum of the payment rates for the new codes describing the three steps of the SCSA procedure should approximate the cost of the RECELL System on TPT and CPT codes 15110 or 15115. Based on our review of the claims data for device code C1832 during the TPT period, as well as the payment rates for CPT codes 15110 and 15115, we believe assigning CPT code 15013 to APC 1567 (New Technology—Level 30 ($6001–$6500)) with a $6,250.50 payment rate would be appropriate for CY 2025, considering that it will be billed with additional procedure codes that describe the other steps of the SCSA procedure. Rather than assigning CPT code 15013 to APC 5051, as proposed, which has a payment rate of approximately $200 for CY 2025, we believe assigning CPT code 15013 to APC 1567 with a payment rate of $6,250.50 will more appropriately pay for the preparation part of the service, which uses the device. When the full service is performed, meaning that the harvesting, preparation, and application steps are performed, the total cost of the service for CY 2025 will be approximately $10,000, an amount that we believe is appropriate based on the data we have collected while the device has had transitional pass-through status.

In consideration of the public comments received, we are finalizing our proposal with modification. For CY 2025, we are finalizing the APC assignments for CPT codes 15011, 15015, and 15017 to APC 5054 (Level 4 Skin Procedures) as proposed. However, we are not finalizing our proposal to assign CPT code 15013 to APC 5051 (Level 1 Skin Procedures) as proposed. For CY 2025, we are assigning CPT code 15013 to APC 1567 ((New Technology—Level 30 ($6001–$6500)).

The final 2025 payment rates for the codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

55. Surgical Pathology Examination, CPT Code 88309 (APC 5674)

CPT code 88309 describes a level VI examination of a surgical pathology specimen performed by the physician, typically a pathologist. The examination includes accessioning the specimen into the lab, which involves formally receiving the specimen, examining gross and microscopic features of the specimen, and reporting findings.

In the CY 2025 OPPS/ASC proposed rule, we proposed to reassign CPT code 88309 from APC 5674 (Level 4 Pathology) to APC 5673 (Level 3 Pathology) with a proposed payment rate of $356.00.

Comment: Three commenters asked CMS to maintain the assignment of CPT code 88309 in APC 5674.

One commenter recommended that CMS maintain the current assignment of CPT 88309 (Level VI—Surgical pathology, gross and microscopic examination) in APC 5674, (Level 4 Pathology), rather than assigning the code to APC 5673, (Level 3 Pathology), to promote resource and clinical cohesion.

Two commenters stated that the proposed reassignment is based on claims data that do not reflect the actual costs of performing the test. They stated that the CY 2025 geometric mean cost for this code is over 25% lower than the geometric mean cost for the prior calendar years and that the complexity of specimens and technical work associated with these services requires the maintenance of the code in APC 5674. Therefore, to ensure resource cohesion within the clinical APCs, the commenters asked CMS to maintain the assignment of CPT code 88309 to APC 5674 for CY 2025 and to not finalize an APC reassignment that would result in a greater than 56% reduction in the payment rate for this important service for Medicare beneficiaries.

Response: We thank the commenters for their input. We acknowledge a significant drop in the geometric mean cost for CPT code 88309, which is almost 25% lower than the geometric mean cost in previous years.

For this final rule with comment period, we once again reviewed the available CY 2023 claims data and observed a wide variation in claims used for ratesetting purposes for CY 2025. We note that the claims included in ratesetting for this code reflect a wide range of estimated costs and providers furnishing this service along with their associated clinical patterns. We believe these claims are an accurate reflection of those changing costs. However, we are sympathetic to commenters' concerns regarding the 25% reduction in the proposed payment rate for CPT code 88309 from CY 2024 to CY 2025. Therefore, we will use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to continue to assign CPT code 88309 to APC 5674 for CY 2025.

In summary, after consideration of the public comments that we received, we are finalizing our proposal with modification to assign CPT code 88309 to APC 5674. However, we will continue to monitor the claims data as they are updated and available.

We refer readers to Addendum B to this final rule with comment period for the final CY 2025 OPPS payment rate for this code. Addendum B is available via the internet on the CMS website.

56. Therapeutic Ultrafiltration, CPT 0692T (APC 5242)

In the CY 2025 OPPS/ASC proposed rule, we proposed to continue to assign CPT code 0692T (Therapeutic ultrafiltration), which became effective January 1, 2022, to APC 5241 (Level 1 Blood Product Exchange and Related Services) with a proposed payment rate of $431.37.

Therapeutic ultrafiltration reported with CPT code 0692T, is an apheresis procedure for fluid-overloaded heart failure patients through which plasma water and sodium are removed from the blood using the Aquadex SmartFlow System.

We received several comments requesting CMS reassign CPT code 0692T from APC 5241 (Level 1 Blood Product Exchange and Related Services) to APC 5242 (Level 2 Blood Product Exchange and Related Services).

Comment: Several commenters claimed that the payment rate for APC 5241 is inadequate for CPT code 0692T and that APC 5242 better aligns with the resource costs and clinical aspects of the service. According to the commenters, the resources required, and risks associated with ultrafiltration are the same as plasmapheresis, which is assigned to APC 5242. Ultrafiltration (*e.g.,* apheresis) is the extracorporeal removal of isotonic plasma water (water and salt/electrolytes) and is very similar to plasmapheresis according to the commenters, which involves the extracorporeal removal, return, or exchange of blood plasma or components and is assigned to APC 5242. Commenters suggested that reassigning the ultrafiltration therapy code 0692T to APC 5242 would align OPPS payment with the cost of providing the service.

Response: We thank commenters for their input. We have limited claims data (9 total claims) for CPT code 0692T available for CY 2025 ratesetting. However, based on the code's clinical similarity and expected resource cost similarity to CPT code 36514 (Therapeutic apheresis; for plasma pheresis), which we have assigned to APC 5242 (Level 2 Blood Product Exchange and Related Services) for CY 2025, we believe that we should reassign CPT code 0692T to APC 5242.

In summary, after consideration of the public comments that we received, we are finalizing our proposal with modification, and assigning CPT code 0692T to APC 5242 for CY 2025. The CY 2025 final payment rate for this code can be found in Addendum B of this final rule with comment period.

57. Thyroid Ablation, CPT Codes 60660 and 60661 (APC 5072)

The AMA established CPT codes 60660 (Ablation of 1 or more thyroid nodule(s), one lobe or the isthmus, percutaneous, including imaging guidance, radiofrequency) and 60661 (Ablation of 1 or more thyroid nodule(s), additional lobe, percutaneous, with imaging guidance, radiofrequency (List separately in addition to code for primary service), effective January 1, 2025. These codes were previously described by the placeholder codes 6XX01 and 6XX02. In the CY 2025 OPPS/ASC proposed rule, CMS crosswalked CPT code 60660 to CPT code 0673T (Ablation, benign thyroid nodule(s), percutaneous, laser, including imaging guidance) and proposed to assign it to APC 5072 (Level 2 Excision/Biopsy/Incision and Drainage) for CY 2025. CMS also proposed to assign CPT code 60661 to status indicator ''N'' (packaged), as it is an add-on code.

Comment: We received two comments requesting reassignment for CPT codes 60660 and 60661. One comment requested we reassign CPT code 60660 to APC 5073 (Level 3 Excision/Biopsy/Incision and Drainage), due to its clinical similarity and resource homogeneity with the other procedures in APC 5073. A second comment requested we reassign both 60660 and 60661 to APC 5164 (Level 4 ENT Procedures), due to their similarity to CPT code 30140 (Submucous resection inferior turbinate, partial or complete, any method).

Response: We thank the commenters for their suggestions. After further clinical review, we continue to believe that CPT code 0673T is the appropriate crosswalk for CPT code 60660 and that CPT code 30140 would not be the correct clinically comparable code. CPT code 0673T has a geometric mean cost of around $1,578 and is assigned to APC 5072, which has a payment rate of around $1,620. We believe that 0673T is appropriately placed in APC 5072, and therefore, CPT code 60660 is appropriately assigned to APC 5072 and should not be reassigned to APC 5073 at this time. Additionally, because CPT code 60661 is an add-on code, we believe that the current status indicator assignment of ''N'' is correct.

After consideration of the public comments we received, we are finalizing our proposal without modification to assign CPT code 60660 to APC 5072 (Level 2 Excision/Biopsy/Incision and Drainage) and 60661 to status indicator ''N'' for CY 2025. Table 103 shows the finalized status indicator and APC assignment for the procedure code. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 103: FINAL CY 2025 OPPS APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODES 60660 AND 60661

CPT Code	Long Descriptor	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
60660	Ablation of 1 or more thyroid nodule(s), one lobe or the isthmus, percutaneous, including imaging guidance, radiofrequency	J1	5072
60661	Ablation of 1 or more thyroid nodule(s), additional lobe, percutaneous, with imaging guidance, radiofrequency (List separately in addition to code for primary service	N	N/A

58. Thyroid Removal, CPT Code 60240 (APC 5361)

In the CY 2025 OPPS/ASC proposed rule, CPT code 60240 (Thyroidectomy, total or complete), which describes thyroid removal, was proposed to be assigned to APC 5361 (Level 1 Laparoscopy and Related Services) with a proposed geometric mean cost of $7,150.89 and proposed APC payment rate of $5,798.13.

Comment: We received one comment requesting that we reassign CPT code 60240 to APC 5362 (Level 2 Laparoscopy and Related Services), which had a proposed payment rate of $10,378.45. The commenter argued that keeping CPT code 60240 in APC 5361 would be a 2 times rule violation because CPT code 60240 has a geometric mean cost that is greater than 2 times the geometric mean value of CPT code 60281(Excision of thyroglossal duct cyst or sinus; recurrent), which had a proposed geometric mean cost of around $3,462 and is also in APC 5361.

Response: We thank the commenter for their input. Our review found that APC 5361 was not in violation of the 2 times rule. Because CPT code 60821 has only 2 claims for CY 2025, it does not meet the significance threshold for the 2 times rule evaluation. Additionally, the updated geometric mean cost for CPT code 60240 of $7,022.82 is closer to the payment rate of APC 5361 ($5,834.36) compared to APC 5362 ($10,411.39).

After consideration of the public comment we received, we are finalizing our proposal without modification to assign CPT code 60240 to 5361 (Level 1 Laparoscopy and Related Services) for CY 2025. Table 104 shows the finalized status indicator and APC assignment for the procedure code. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 104: FINAL CY 2025 OPPS APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODE 60240

CPT Code	Long Descriptor	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
60240	Thyroidectomy, total or complete	J1	5361

59. Trabecular Bypass Procedures, CPT Codes 66989, 66991, 0660T, 0661T, and 0671T (APCs 5492 and 5493)

Trabecular bypass procedures are used for the treatment of glaucoma and may be performed along with cataract surgery or as a stand-alone procedure. Another glaucoma treatment involves the implantation of a device that releases a drug into the eye. For the CY 2025 OPPS final rule, we proposed to assign CPT code 66989 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (*e.g.,* irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (*e.g.,* iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with insertion of intraocular (*e.g.,* trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more) with a geometric mean cost around $5,440; CPT code 66991 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (*e.g.,* irrigation and aspiration or phacoemulsification); with insertion of intraocular (*e.g.,* trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more) with a geometric mean cost around $4,990; and CPT code 0671T (Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external

reservoir, and without concomitant cataract removal, one or more) with a geometric mean cost around $5,527 to APC 5493 (Level 3 Intraocular Procedures) with a payment rate around $5,160.

Also, for the CY 2025 OPPS final rule, we proposed to assign CPT code 0660T (Implantation of anterior segment intraocular nonbiodegradable drug-eluting system, internal approach) with no claims data for CY 2025, and CPT code 0661T (Removal and reimplantation of anterior segment intraocular nonbiodegradable drug-eluting implant) with no claims data for CY 2025 to APC 5492 (Level 2 Intraocular Procedures) with a payment rate of around $4,023.

Comment: Multiple commenters supported our proposal to assign CPT codes 66989, 66991, and 0671T to APC 5493 (Level 3 Intraocular Procedures) with a payment rate around $5,160. The commenters also supported our proposal to assign CPT codes 0660T and 0661T to APC 5492 (Level 2 Intraocular Procedures) with a payment rate of around $4,023.

Response: We appreciate the commenters' support for our proposals.

After consideration of the public comments we received, we are finalizing our proposal without modification for CPT codes 66989, 66991, 0660T, 0661T, 0671T to assign these procedures to APC 5493 (Level 3 Intraocular Procedures). We also are implementing our proposal without modification for CPT codes 0660T and 0661T to assign these procedures to APC 5492 (Level 2 Intraocular Procedures). Table 105 shows the finalized status indicator and APC assignment for all of the procedure codes. We refer readers to Addendum B of this final rule for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 105: FINAL CY 2025 OPPS APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODES 66989, 66991, 0660T, 0661T, 0671T

CPT Code	Long Descriptor	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
66989	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (e.g., iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with insertion of intraocular (e.g., trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more	J1	5493
66991	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification); with insertion of intraocular (e.g., trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more	J1	5493
0671T	Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more	J1	5493
0660T	Implantation of anterior segment intraocular nonbiodegradable drug-eluting system, internal approach	J1	5492
0661T	Removal and reimplantation of anterior segment intraocular nonbiodegradable drug-eluting implant	J1	5492

60. Transcutaneous Magnetic Peripheral Nerve Stimulation CPT Codes 0766T and 0767T (APC 5722)

Transcutaneous Magnetic Peripheral Nerve Stimulation is intended to stimulate peripheral nerves for relief of chronic intractable pain, post-traumatic pain, post-surgical pain and/or for relief of chronic painful diabetic peripheral neuropathy in the lower extremities for patients 18 and older. CPT code 0766T (Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, with identification and marking of the treatment location, including noninvasive electroneurographic localization (nerve conduction localization), when performed; first nerve) became effective January 1, 2023. For CY 2024, CPT code 0766T has been assigned to APC 5721 (Level 1 Diagnostic Tests and Related Services) with the status indicator ''Q1'' (STV-Packaged Codes). There are no claims available for CPT codes 0766T in CY 2023. For CY 2025, we proposed to continue assigning CPT codes 0766T to APC 5721.

CPT code 0767T (Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, with identification and marking of the treatment location, including noninvasive electroneurographic localization (nerve conduction localization), when performed; each additional nerve (list separately in addition to code for primary procedure)) became effective January 1, 2023. CPT code 0767T is an add-on code and we proposed to assign status indicator ''N'' (packaged) for this code.

Comment: Commenters disagreed with the proposed assignment of APC 5721 (Level 1 Diagnostic Tests and Related Services) and the status indicator ''Q1'' for CPT code 0766T, claiming that CPT code 0766T is not clinically similar nor uses comparable resources to other services in APC 5721. The commenters stated that the HOP Panel recommended that 0766T be reassigned to APC 5431 (Level 1 Nerve Procedures) with a status indicator ''S'' (Significant Procedures, Not Discounted when Multiple. Paid under OPPS; separate APC payment). Additionally, commenters disagreed with the status indicator of ''N'' for CPT code 0767T and requested the 0767T be reassigned status indicator ''S'' and assigned to APC 5431 (Level 1 Nerve Procedures).

Response: We thank commenters for their input. We disagree that CPT code 0766T is comparable clinically and in resource costs to the services assigned to APC 5431. However, after further evaluation, we believe CPT code 0766T is more comparable clinically and from a resource cost perspective to CPT code 90867 (Therapeutic repetitive transcranial magnetic stimulation (tms) treatment; initial, including cortical mapping, motor threshold determination, delivery and management), which is assigned to APC 5722 (Level 2 Diagnostic Tests and Related Services), because these services share similar magnetic stimulation and nerve localization processes. Additionally, we believe that patients may receive this service as a primary standalone service. Therefore, for CY 2025, we are finalizing the reassignment of CPT code 0766T to APC 5722 (Level 2 Diagnostic Tests and Related Services) and its status indicator to ''S'' (Significant Procedures, Not Discounted when Multiple. Paid under OPPS; separate APC payment).

We note that CPT code 0767T is an add-on code. Add-on codes are always performed in addition to the primary service or procedure and must never be reported as a stand-alone code. As specified under regulation 42 CFR 419.2(b)(18), add-on codes are generally packaged under the OPPS, and payment for the codes are bundled with the primary codes. Consequently, CPT code 0767T is not paid separately under the OPPS, but instead, its payment is packaged into payment for the primary code.

After consideration of the public comments we received, we are finalizing reassigned status indicator and APC assignments for CPT codes 0766T and finalizing as proposed the status indicator assignment for 0767T. Please refer to Table 106 below for the final OPPS APC and status indicator assignment for CPT codes 0766T and 0767T for CY 2025. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 106: FINAL CY 2025 OPPS APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODES 0766T and 0767T

CPT Code	Long Descriptor	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
0766T	Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, with identification and marking of the treatment location, including noninvasive electroneurographic localization (nerve conduction localization), when performed; first nerve	S	5722
0767T	Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, with identification and marking of the treatment location, including noninvasive electroneurographic localization (nerve conduction localization), when performed; *each additional nerve* (List separately in addition to code for primary procedure)	N	NA

61. Transurethral Ultrasound Ablation (TULSA) Procedure, HCPCS Code C9734 and CPT Code 55882 (APC 5377)

The TULSA procedure is a minimally invasive procedure that, under MRI guidance, delivers precise doses of therapeutic ultrasound to treat prostate cancer. HCPCS code C9734 (Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (mr) guidance) became effective April 1, 2013.

For CY 2025, the OPPS payment rates are proposed based on available CY 2023 claims data. For CY 2025, based on our analysis of claims data, we found a total of 89 single frequency claims and an estimated geometric mean cost of $10,056 for HCPCS code C9734. For CY 2025, we proposed to continue to assign HCPCS code C9734 to APC 5115 (Level 5 Musculoskeletal Procedures) with a proposed payment rate of approximately $12,756.

Comment: Commenters pointed out that the AMA CPT created a new code, CPT code 5X008, to describe the TULSA procedure represented by HCPCS code C9734. CPT code 5X008 (Ablation of prostate tissue, transurethral, using thermal ultrasound, including magnetic resonance imaging guidance for, and monitoring of, tissue ablation; with insertion of transurethral ultrasound transducer for delivery of thermal ultrasound, including suprapubic tube placement and placement of an endorectal cooling device, when performed) becomes effective January 1, 2025.

Commenters also recommended that the TULSA procedure be reassigned to the Urology and Related Services APC series, which is more clinically consistent with other urology related procedures. Furthermore, commenters stated TULSA is more similar clinically and in terms of resources to the procedures in APC 5377 (Level 7 Urology and Related Services) than procedures in APC 5376 (Level 6 Urology and Related Services). Commenters referenced the use of a MRI technology, specialized staffing, and the longer procedural time that increases the resources needed to perform the TULSA procedure relative to other prostate ablation procedures in Level 6 Urology and Related Services (APC 5376). Commenters stated that HCPCS code C9734's geometric mean cost aligns more appropriately with APC 5377 (Level 7 Urology and Related Services) with a proposed APC geometric mean cost of $13,217.

Response: We thank the commenters for pointing out that CPT code 5X008 (55882) will become effective January 1, 2025. We note that we will replace HCPCS code C9734 with CPT code 5X008 (55882) effective January 1, 2025, as well as assign the underlying claims associated with C9734 to CPT code 5X008 (55882).

We agree with the commenters that the TULSA procedure, described by HCPCS code C9734 (CPT code 55882) should be reassigned to the Urology and Related Services APC series to be consistent with other urological related procedures. We also believe that the TULSA procedure is clinically similar to CPT code 55880 (Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (hifu), including ultrasound guidance) or CPT code 55873 (Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring)) which are assigned to APC 5376. However, we acknowledge that the TULSA procedure requires greater resources from MRI equipment and MRI technologists, and requires a longer procedure time than CPT codes 55880 and 55873. Therefore, for CY 2025, we are reassigning CPT code 5X008 (55882) to APC 5377 (Level 7 Urology and Related Services). We note that we will continue to evaluate and monitor the cost of CPT code 5X008 (55882) for future rulemaking.

After consideration of the public comments we received, we are finalizing our policy to assign CPT code 5X008 (55882) to APC 5377 (Level 7 Urology and Related Services). Please refer to Table 107 below for the final OPPS APC and status indicator assignment for CPT code 5X008 (55882) for CY 2025. The final CY 2025 payment rates can be found in Addendum B to this final rule with comment period via the internet on the CMS website.

TABLE 107: FINAL CY 2025 OPPS APC ASSIGNMENT AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODE 5X008 (55882)

CPT Code	Long Descriptor	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
5X008 (55882)	Ablation of prostate tissue, transurethral, using thermal ultrasound, including magnetic resonance imaging guidance for, and monitoring of, tissue ablation; with insertion of transurethral ultrasound transducer for delivery of thermal ultrasound, including suprapubic tube placement and placement of an endorectal cooling device, when performed	J1	5377

62. Unfold AI Service, CPT Code 0898T (APC 5724)

Unfold AI is an algorithm-based test that analyzes multiple clinical data inputs and multi-modal images to create a newly computed 3D visualization of the precise location and dimensions of clinically significant prostate cancer. The generated output assists physicians in identifying the cancer margins for treatment. The Unfold AI service is represented by CPT code 0898T (Noninvasive prostate cancer estimation map, derived from augmentative analysis of image-guided fusion biopsy and pathology, including visualization of margin volume and location, with margin determination and physician interpretation and report) which became effective July 1, 2024. As this is a new code in 2024, we have no claims data for CPT code 0898T. For CY 2025, we proposed to assign CPT Code 0898T to APC 5724 (Level 4 Diagnostic Tests and Related Services).

Comment: Commenters supported our proposal to assign CPT code 0898T to Level 4 Diagnostic Tests and Related Services (APC 5724).

Response: We thank the commenters for their support on our proposal to assign CPT code 0898T to Level 4 Diagnostic Tests and Related Services (APC 5724).

After consideration of the public comments we received, we are finalizing our proposal without modification for CPT code 0898T. Please refer to Table 108 below for the final OPPS APC and status indicator assignment for HCPCS code 0898T for CY 2025. The final CY 2025 payment rates can be found in Addendum B to this final rule with comment period via the internet on the CMS website.

TABLE 108: FINAL CY 2025 OPPS APC ASSIGNMENT AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODE 0898T

CPT Code	Long Descriptor	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
0898T	Noninvasive prostate cancer estimation map, derived from augmentative analysis of image-guided fusion biopsy and pathology, including visualization of margin volume and location, with margin determination and physician interpretation and report	S	5724

63. Ureteroscopy, HCPCS Code C9761 (APC 5376)

The ureteroscopy procedure addresses kidney stones and may apply catheterization to vacuum aspirate the fragmented kidney stones. HCPCS code C9761 (Cystourethroscopy, with ureteroscopy and/or, with lithotripsy, and ureteral catheterization for steerable vacuum aspiration of the kidney, collecting system, ureter, bladder, and urethra if applicable (must use a steerable ureteral catheter) became effective October 1, 2020.

For CY 2025, the OPPS payment rates are proposed based on available CY

2023 claims data. For the CY 2025 OPPS/ASC proposed rule, we found a total of 95 single frequency claims and a geometric mean cost of approximately $9,718 for HCPCS code C9761. For CY 2025, we proposed to continue to assign HCPCS code C9761 to APC 5376 (Level 6 Urology and Related Services) with a proposed payment rate of approximately $9,208.

Comment: One commenter requested CMS provide coding guidance if HCPCS code C9761 should be reported when the ureteroscopy procedure utilizes the flexible ureteroscopy (fURS) with the flexible and navigable suction (FANS) sheath.

Response: This comment is out of scope of this OPPS/ASC final rule with comment period. We note that if hospitals have questions about appropriate coding that they cannot resolve on their own, the appropriate first step would be to review the HCPCS codes or consult a Medicare Administrative Contractor (MAC).

64. V–LAP System Left Atrial Pressure Monitoring Procedure, CPT Code 0933T (APC 5191)

On January 1, 2025, CPT code 0933T (Transcatheter implantation of wireless left atrial pressure sensor for long-term left atrial pressure monitoring, including sensor calibration and deployment, right heart catheterization, transseptal puncture, imaging guidance, and radiological supervision and interpretation) will become effective to report the implantation and remote monitoring of the V–LAP System. The system is used to measure and monitor left atrial pressure in patients with advanced congestive heart failure (CHF).

The V–LAP system was designated as a Category A IDE clinical study (NCT06147336) on January 30, 2024. Since devices in Category A IDE studies are not covered by Medicare during the study, the payment for CPT code 0933T while in the Category A IDE study will reflect only the cost of the service that is performed each time it is reported on a claim. For CY 2025, we proposed to assign CPT code 0933T to APC 5191 (Level 1 Endovascular Procedures) and status indicator of ''J1'' (Hospital Part B Services Paid Through a Comprehensive APC) with a proposed payment of around $3,210.

Comment: We received one comment from the manufacturer requesting that we reassign CPT code 0933T from APC 5191 (Level 1 Endovascular Procedures) to APC 1532 (New Technology—Level 32 ($7001–$7500)), as it more accurately reflects the costs of this procedure.

Response: We appreciate the commenter's input. The commenter asserts that the current APC assignment of 5191 (Level 1 Endovascular Procedures) does not adequately reflect the complex nature and resource demands of the V–LAP procedure even though the procedure is described as a standard minimally invasive catheterization. We are unclear what procedural steps makes this procedure more complex than the other procedures assigned to APC 5191. Based on our understanding of the service and input from our medical advisors, we do not agree and believe that CPT code 93451 (Right heart catheterization including measurement(s) of oxygen saturation and cardiac output, when performed) is an appropriate crosswalk code while the V–LAP™ procedure is in a Category A IDE trial. Once the service receives appropriate FDA approval outside of the Category A IDE study (*e.g.,* PMA approval or 510(k)), we will work to assign CPT code 0933T to an APC that is more reflective of the cost of the service, beyond routine care items and services.

We remind the readers that for Category A IDE studies, Medicare only provides payment for routine care items and services furnished in the FDA-approved Category A study. We refer readers to the Medicare Benefit Policy Manual, See 20.1—Medicare Requirements for Coverage of Items and Services in FDA-approved Category A and B IDE Studies.

After consideration of the public comment we received, we are finalizing our proposal without modification to assign CPT code 0933T to APC 5191. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

65. Vagal Nerve Neurostimulator System, CPT Codes 0908T Through 0912T

The CPT Editorial Panel created 5 new Category III CPT codes, effective January 1, 2025, which describe the implantation, replacement, removal, interrogation, and programming of the integrated vagus nerve stimulation device used for the treatment of patients who have rheumatoid arthritis (RA) and are not responsive to pharmacological therapy. The patient is placed under general anesthesia (for about 60–90 minutes) while the neurosurgeon dissects the tissue on the left side of the neck to access the cervical vagus nerve within the carotid sheath. The rechargeable integrated neurostimulator is then placed directly on the cervical vagus nerve. The implant is charged weekly with an external charger. A rheumatologist is responsible for prescribing and making changes to the stimulation therapy via an app. See Table 109 for the CPT codes, their long descriptors, and the proposed payment assignments.

TABLE 109: PROPOSED CY OPPS SI AND APC ASSIGNMENTS FOR THE VAGAL NERVE NEUROSTIMULATOR SYSTEM

CPT Code (Placeholder Code and Final Code)	Long Descriptor	CY 2025 Proposed SI	CY 2025 Proposed APC
XX32T / 0908T	Open implantation of integrated neurostimulation system, vagus nerve, including analysis and programming, when performed	J1	5462
XX33T / 0909T	Replacement of integrated neurostimulation system, vagus nerve, including analysis and programming, when performed	J1	5462
XX34T / 0910T	Removal of integrated neurostimulation system, vagus nerve	J1	5461
XX35T / 0911T	Electronic analysis of implanted integrated neurostimulation system, vagus nerve; without programming by physician or other qualified healthcare professional	Q1	5733
XX36T / 0912T	Electronic analysis of implanted integrated neurostimulation system, vagus nerve; with simple programming by physician or other qualified health care professional	S	5742

For CY 2025, we proposed to assign 0908T and 0909T to APC 5462 (Level 2 Neurostimulator and Related Procedures) and status indicator ''J1'' (Hospital Part B Services Paid Through a Comprehensive APC; Paid under OPPS.) based on their similarity to CPT code 0587T (Percutaneous implantation or replacement of integrated single device neurostimulation system for bladder dysfunction including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve) and because CPT 0587T also describes an integrated system.

We proposed to assign 0910T to APC 5461 (Level 1 Neurostimulator and Related Procedures) and status indicator ''J1'' based on its similarity to CPT code 0588T (Revision or removal of percutaneously placed integrated single device neurostimulation system for bladder dysfunction including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve) as both codes describe the removal of an integrated neurostimulation system.

We also proposed to assign CPT codes 0911T to APC 5733 (Level 3 Minor Procedures) and status indicator ''Q1'' (STV-Packaged Codes; Paid Under OPPS) using CPT code 95981(Electronic analysis of implanted neurostimulator pulse generator system (*e.g.,* rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; subsequent, without reprogramming) as a crosswalk code and 0912T to APC 5742 (Level 2 Electronic Analysis of Devices) and status indicator of ''S'' (Procedure or Service, Not Discounted When Multiple; Paid under OPPS; separate APC payment.) using CPT code 0589T (Electronic analysis with simple programming of implanted integrated neurostimulation system for bladder dysfunction (*e.g.,* electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, posterior tibial nerve, 1–3 parameters) as a crosswalk code.

Comment: We received several comments from stakeholders requesting that CPT codes XX32T (0908T) and XX33T (0909T) be reassigned from APC 5462 (Level 2 Neurostimulator and Related Procedures) to APC 5465 (Level 5 Neurostimulator and Related Procedures) because the proposed APC assignments do not reflect the costs of the device and procedure or consider the clinical intensity and risk of the procedure. Commenters provided CPT code 64568 (Open implantation of cranial nerve (*e.g.,* vagus nerve) neurostimulator electrode array and pulse generator) as an appropriate comparator code, noting that the integrated devices do not require the creation of an additional subcutaneous pocket. While there are some differences in the two surgical procedures described by CPT codes XX32T (0908T) and XX33T (0909T) compared to CPT code 64568, the commenter asserted that

inserting the integrated system is a complex procedure to perform and is similar in cost, resources, and required skill.

Another commenter requested that we reassign XX34T (0910T) from APC 5461 (Level 1 Neurostimulator and Related Procedures) to APC 5463 (Level 3 Neurostimulator and Related Procedures) stating that CPT code 61888 (Revision or removal of cranial neurostimulator pulse generator or receiver) is an appropriate comparator code.

Commenters noted that the vagal nerve neurostimulation system is a novel treatment for rheumatoid arthritis patients who have exhausted other pharmacological options to manage their disease. They stated that biological therapies are expensive and may cost over $50,000/per year, while this neurostimulation system is expected to have a shelf life of 10 years. They asserted that APC reassignments of XX32T (0908T), XX33T (0909T), and XX34T (0910T) would support CMS' commitment to promoting new innovative treatment options and expanding access for beneficiaries with chronic conditions.

In addition to the comments requesting APC reassignments, the manufacturer stated they were expecting FDA approval, specifically Premarket Approval (PMA), in the 2nd quarter of 2025 with an expected statement ''for the treatment of adult patients with moderately to severely active RA who have had an inadequate response, loss of response or intolerance to one (1) or more biological or targeted synthetic DMARDs (disease-modifying antirheumatic drugs)''. They acknowledged that, in the past, CMS has assigned non-FDA approved technologies a status indicator of ''E1'' and addressed the APC assignments once FDA approval is received. The manufacturer asserted the lack of payment assignments (APCs and status indicators) would significantly hinder commercialization of their neurostimulation system.

Response: We thank the commenters for all their valuable input. Because this vagal nerve neurostimulation system has not yet received FDA approval, we believe that we should reassign CPT codes 0908T, 0909T, 0910T, 0911T, and 0912T to status indicator ''E1'' to indicate that the code is not payable by Medicare when submitted on outpatient claims (any outpatient bill type). When we are notified by stakeholders that the FDA has approved this neurostimulation system, we will reassess the status indicator and APC assignments for these codes based on the comments we have received, in a future quarterly update and/or rulemaking cycle.

In summary, after consideration of the public comments received, we are finalizing our proposal, with modification, to assign status indicator ''E1'' to CPT codes 0909T through 0912T. The final status indicator assignment for the codes is listed in Table 110. We refer readers to Addendum D1 of this final rule with comment period for the complete list of the OPPS payment status indicators and their definitions for CY 2025. Addendum D1 is available via the internet on the CMS website.

TABLE 110: FINAL CY 2025 OPPS STATUS INDICATOR ASSIGNMENTS FOR CPT CODES 0908T – 0912T

CPT Code	Long Descriptor	CY 2025 Final SI
0908T	Open implantation of integrated neurostimulation system, vagus nerve, including analysis and programming, when performed	E1
0909T	Replacement of integrated neurostimulation system, vagus nerve, including analysis and programming, when performed	E1
0910T	Removal of integrated neurostimulation system, vagus nerve	E1
0911T	Electronic analysis of implanted integrated neurostimulation system, vagus nerve; without programming by physician or other qualified healthcare professional	E1
0912T	Electronic analysis of implanted integrated neurostimulation system, vagus nerve; with simple programming by physician or other qualified health care professional	E1

66. VisONE® Synchronized Diaphragmatic Stimulation™ (SDS®) System CPT Codes 0674T Through 0685T

The VisONE® Synchronized Diaphragmatic Stimulation™ (SDS®) System is a technology being studied to treat select patients with chronic heart failure by delivering electrical stimulation to the diaphragm to modulate intrathoracic pressure pulses on the cardiovascular system. The SDS® System is comprised of an implantable pulse generator (IPG), sensing and therapy lead electrodes, a laparoscopic implant tool to place the leads, and an external programmer and telemetry wand.

There are 12 Category III CPT codes that may describe the various procedures related to the procedures involving the SDS® System: CPT codes 0674T–0685T. For CY 2025, as the SDS® System did not have FDA approval at the time of the proposed rule, we proposed to assign CPT codes 0674T–0685T to status indicator ''E1'' to indicate that the services are not paid by Medicare when submitted on outpatient claims (any outpatient bill type). Please refer to Table 111 for the full list of CPT codes and the proposed status indicators for CY 2025.

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TABLE 111: PROPOSED CY 2025 STATUS INDICATORS FOR CPT CODES FOR PROCEDURES INVOLVING SDS® SYSTEM

CPT Code	Long Descriptor	Proposed CY 2025 Status Indicator
0674T	Laparoscopic insertion of new or replacement of permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, including an implantable pulse generator and diaphragmatic lead(s)	E1
0675T	Laparoscopic insertion of new or replacement of diaphragmatic lead(s), permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, including connection to an existing pulse generator; first lead	E1
0676T	Laparoscopic insertion of new or replacement of diaphragmatic lead(s), permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, including connection to an existing pulse generator; each additional lead (list separately in addition to code for primary procedure)	E1
0677T	Laparoscopic repositioning of diaphragmatic lead(s), permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, including connection to an existing pulse generator; first repositioned lead	E1
0678T	Laparoscopic repositioning of diaphragmatic lead(s), permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, including connection to an existing pulse generator; each additional repositioned lead (list separately in addition to code for primary procedure)	E1
0679T	Laparoscopic removal of diaphragmatic lead(s), permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function	E1
0680T	Insertion or replacement of pulse generator only, permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, with connection to existing lead(s)	E1
0681T	Relocation of pulse generator only, permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, with connection to existing dual leads	E1
0682T	Removal of pulse generator only, permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function	E1
0683T	Programming device evaluation (in-person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional, permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function	E1
0684T	Peri-procedural device evaluation (in-person) and programming of device system parameters before or after a surgery, procedure, or test with analysis, review, and report by a physician or other qualified health care professional, permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function	E1
0685T	Interrogation device evaluation (in-person) with analysis, review and report by a physician or other qualified health care professional, including connection, recording and disconnection per patient encounter, permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function	E1

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Comment: One commenter, specifically, the manufacturer of the SDS® System, requested clinical APC assignments for 9 of the 12 CPT codes

describing the various procedures involving the SDS® System. The commenter requested assignments to packaged status indicator ''N'' for the remaining three add-on CPT codes for which they did not request a clinical APC assignment.

Specifically, the commenter requested that, for CY 2025, CMS assign:

- CPT code 0674T to APC 5465 (Level 5 Neurostimulator and Related Procedures) with SI ''J1'' based on a crosswalk to CPT code 63685.
- CPT code 0675T to APC 5463 (Level 3 Neurostimulator and Related Procedures) with SI ''J1'' based on a crosswalk to CPT code 43647.
- CPT codes 0677T and 0679T to APC 5362 (Level 2 Laparoscopy and Related Services) with SI ''J1'' based on a crosswalk to CPT code 43648.
- CPT code 0680T to APC 5464 (Level 4 Neurostimulator and Related Procedures) with SI ''J1'' based on a crosswalk to CPT code 64590.
- CPT code 0681T and 0682T to APC 5461 (Level 1 Neurostimulator and Related Procedures) with SI ''J1'' based on a crosswalk to CPT code 64595.
- CPT code 0683T and 0685T to APC 5741 (Level 1 Electronic Analysis of Devices) with SI ''Q1'' based on crosswalks to CPT codes 93281 and 93288, respectively.
- SI ''N'' to CPT codes 0676T, 0678T, and 0684T.

The commenter also provided additional information regarding the FDA approval status of the SDS® System. Per the commenter, on July 26, 2024, the SDS® System received FDA approval for the Investigational Device Exemption (IDE) regarding the RECOVER–HF trial, which was anticipated to begin in late 2024. The request for Medicare coverage of the RECOVER–HF trial was pending when the comment was submitted. The commenter requested that CMS make the 12 codes payable effective January 1, 2025, in anticipation of Medicare's approval of their Category B IDE trial application.

Response: We thank the commenter for their input and agree with the suggested CPT crosswalk codes provided by the commenter.

We note that the RECOVER–HF trial was approved for Medicare coverage on September 23, 2024. Because the Category B IDE trial meets the CMS standards for coverage, and appears on the CMS approved IDE list on the CMS website, we are not finalizing our proposal to assign the 12 codes that describe the various procedures associated with the SDS® System to status indicator ''E1.'' In light of the recent Category B IDE study approval for the RECOVER–HF clinical trial, and based on our review of the comment received, more specifically the crosswalk codes recommended by the commenter, we are finalizing the following clinical APC and status indicator assignments:

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TABLE G81: PROPOSED AND FINAL CY 2025 STATUS INDICATORS AND CLINICAL APC ASSIGNMENTS FOR CPT CODES FOR PROCEDURES INVOLVING SDS® SYSTEM

CPT Code	Long Descriptor	Proposed CY 2025 Status Indicator	Final CY 2025 APC	Final CY 2025 Status Indicator
0674T	Laparoscopic insertion of new or replacement of permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, including an implantable pulse generator and diaphragmatic lead(s)	E1	5465	J1
0675T	Laparoscopic insertion of new or replacement of diaphragmatic lead(s), permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, including connection to an existing pulse generator; first lead	E1	5463	J1
0676T	Laparoscopic insertion of new or replacement of diaphragmatic lead(s), permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, including connection to an existing pulse generator; each additional lead (list separately in addition to code for primary procedure)	E1	N/A	N
0677T	Laparoscopic repositioning of diaphragmatic lead(s), permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, including connection to an existing pulse generator; first repositioned lead	E1	5362	J1
0678T	Laparoscopic repositioning of diaphragmatic lead(s), permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, including connection to an existing pulse generator; each additional repositioned lead (list separately in addition to code for primary procedure)	E1	N/A	N
0679T	Laparoscopic removal of diaphragmatic lead(s), permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function	E1	5362	J1
0680T	Insertion or replacement of pulse generator only, permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, with connection to existing lead(s)	E1	5464	J1
0681T	Relocation of pulse generator only, permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, with connection to existing dual leads	E1	5461	J1
0682T	Removal of pulse generator only, permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function	E1	5461	J1
0683T	Programming device evaluation (in-person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional, permanent implantable synchronized	E1	5741	Q1

CPT Code	Long Descriptor	Proposed CY 2025 Status Indicator	Final CY 2025 APC	Final CY 2025 Status Indicator
	diaphragmatic stimulation system for augmentation of cardiac function			
0684T	Peri-procedural device evaluation (in-person) and programming of device system parameters before or after a surgery, procedure, or test with analysis, review, and report by a physician or other qualified health care professional, permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function	E1	N/A	N
0685T	Interrogation device evaluation (in-person) with analysis, review and report by a physician or other qualified health care professional, including connection, recording and disconnection per patient encounter, permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function	E1	5741	Q1

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The final CY 2025 payment rate for the codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 to this final rule with comment period for the complete list of the OPPS payment status indicators and their definitions for CY 2025. Addendum D1 is available via the internet on the CMS website.

67. Xenograft Implantation Into the Articular Surface, CPT Code 0737T (APC 5115)

For the July 1, 2022, update, the AMA CPT Editorial Panel established CPT code 0737T (Xenograft implantation into the articular surface) to describe xenograft implantation for use in cartilage and osteochondral defects in joints. Since July 1, 2022, CPT code 0737T has been assigned to status indicator ''E1'' (Not paid by Medicare when submitted on outpatient claims (any outpatient bill type)) to indicate that the code was not payable under the OPPS. In the OPPS Quarterly Change Request (Transmittal 12816, CR 13784) dated August 29, 2024, we noted that the device associated with this code (Agili-C™) had become available, and therefore we reassigned CPT code 0737T to status indicator ''J1'' (Hospital Part B Services Paid Through a Comprehensive APC; Paid under OPPS) and APC 5115 (Level 5 Musculoskeletal Procedures) effective July 1, 2024. For CY 2025, we proposed to continue to assign CPT code 0737T to APC 5115 with a proposed payment assignment of around $12,755.

Comment: We received a couple of comments expressing support for assigning CPT code 0737T to APC 5115 and status indicator ''J1''. Commenters noted that the reimbursement was consistent with the costs associated with the procedure and would ensure equitable patient access, even allowing some beneficiaries to possibly avoid more costly knee replacement procedures. They requested that we maintain the APC and status indicator assignments for several years to gather claims data as they anticipate the patient volume will be limited due to the patient selection criteria.

Response: We thank the commenters for their input. Under the OPPS, we review our claims data on an annual basis to determine payment rates and will continue to monitor the claims data and the appropriateness of the APC assignment for CPT code 0737T to APC 5115.

In summary, we are finalizing our proposal, without modification, to assign CPT code 0737T to APC 5115 for CY 2025. The final CY 2025 payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

68. OPPS Payment for Software as a Service

New clinical software, which includes clinical decision support software, clinical risk modeling, and computer aided detection (CAD), is becoming increasingly available to providers. These technologies often perform data analysis of diagnostic images from patients. While many of these technologies are new, we note that clinical software, particularly CAD, has been used to aid or augment clinical decision making for decades. These technologies rely on complex algorithms or statistical predictive modeling to aid in the diagnosis or treatment of a patient's condition. We refer to these algorithm-driven services that assist practitioners in making clinical assessments, and that providers pay for either on a subscription or per-use basis, as Software as a Service (SaaS).

We note the proliferation of SaaS procedures approved by the FDA and their subsequent assignment of CPT codes by the AMA has led the agency to seek a workable SaaS payment strategy. We are seeking a strategy that would provide equitable payment for these new technologies while also preserving the integrity of the OPPS payment bundles, an essential component of a prospective payment system. We are seeking a payment strategy that aligns with our agency's mission to improve quality, health, reduce cost, and strengthen the health care system. We note that the manufacturer-supplied cost data of

these SaaS services is often high and the true return in investment for these services is still unknown. Moreover, many SaaS services often do not share clinical and resource similarity to existing medical services. Thus, it generally has been challenging to compare a new SaaS service to existing medical services for the purpose of determining a fair payment rate for these new services.

Although some have recently received separate payment for these SaaS procedures under the OPPS, we recognize that certain clinical decision support software, including machine learning or ''AI,'' has been available for many years. In the past ten years, clinical decision support software has been commonly used alongside electronic medical records by medical practitioners. Nonetheless, the number of FDA approved or cleared ''machine learning'' or ''AI'' clinical software programs has rapidly increased in the past few years. We note that the FDA has approved many SaaS procedures for similar functions: there are at least six software products that purport to detect findings in Computed Tomography (CT) studies of the chest.[29] Additionally, we note some clinical software developers are now using alternative licensing that charges per use rather than using the traditional annual subscription or bulk use subscription. As a result of these variables and potentially others, there is significant price variation within the SaaS procedure space.

We recognize that, as described in the CY 2023 OPPS/ASC final rule with comment period (87 FR 72027), SaaS procedures are a heterogenous group of services, which presents challenges when it comes to adopting payment policy for SaaS procedures as a whole. In the CY 2023 OPPS/ASC final rule, we solicited public comment on a payment approach that would broadly apply to SaaS procedures and have received some valuable feedback. Some of the feedback includes incorporating AI taxonomy across agencies and interested parties, or not to establish a single policy that would apply to all SaaS-type technology but instead separately evaluate each new technology to determine the appropriate HCPCS coding, including whether or not a potential CPT code can be used to support payment for the separate and distinct service under the OPPS.

For CY 2025, we are continuing to work to formulate a workable SaaS payment policy that would enhance our ability to provide equitable payment for SaaS procedures while responsibly managing cost and protecting the Medicare trust fund. Specifically, we are working to address the following:

- Identifying a payment strategy that is applicable across the settings of care (physician offices, for example);
- Identifying the fair costs associated for SaaS services;
- Distinguishing services that should be paid separately versus services that should be packaged under a prospective payment system; and
- Identifying a payment strategy for SaaS services that are part of other medical devices versus those that are distinct services.

We did not make any proposals on OPPS payment for SaaS for CY 2025 but received a number of comments on the topic.

Comment: Commenters suggested CMS formulate a SaaS payment policy that would incentivize adoption of new AI and ensure access and provide stability for its adoption of SaaS technologies. Commenters stated that CMS payment decisions have not uniformly and consistently ensured appropriate levels of payment. Some commenters recommended that we adopt the term ''Algorithm-based healthcare services'' (ABHS), which include SaaS procedures. ABHS includes these services regardless of whether they are delivered by a third party, or a health care professional using the AI software through the cloud, the web, a workstation, or embedded in imaging acquisition hardware. Commenters also recommended that ABHS codes be initially assigned to New Technology APCs for at least 5 years based on manufacture-supply cost data, until sufficient claims data are available. Some commenters also recommend that we codify the 2023 packaging exemption for SaaS add-on codes policy.

Response: We appreciate the commenters' valuable input on a SaaS payment policy approach, and we will consider their input for any future SaaS payment policy. We note that the suggestion for any new SaaS services to remain in the initial New Technology APC assignment for at least 5 years is in contrast to our current Transitional Pass-Through policy of three years for device or drugs. Moreover, we would need to examine the feasibility of payment determination based on manufacture-supplied cost data, which has historically not been comparable when the claims data become available.

Comment: One commenter requested CMS clarify that SaaS codes created by the AMA CPT are to be vendor neutral, and that these codes do not represent any single vendor's services. The commenter stated the focus on a single commercial platform for a code is not accurate, confuses the applicability, and limits adoption of other tools for which the code was intended. The commenter recommended removing the current language that these codes are ''associated with'' a specific service, which may result in an increase in claims, therefore allowing for a more accurate understanding of actual costs associated with these services.

Response: We thank the commenter for the valuable input. We recognize that the proliferation of SaaS procedures has created a need for the agency to continue to update our payment approach. We are continuing to work to improve SaaS payment policy in future rulemakings to enhance our ability to provide equitable payment for SaaS procedures while responsibly managing cost and protecting the Medicare trust fund.

69. APC and Status Indicator Review Process

Each year, CMS receives a high volume of requests from stakeholders and other interested parties to make certain OPPS payment policy changes, including many requesting changes to the APC and status indicator assignments of new or revised codes. Current APC groupings, APC assignments, and status indicators are reflected in the various addenda to the proposed and final OPPS payment rules. In addition, comments within the scope of the proposed rule, are summarized and responded to in the annual OPPS final rule with comment period.

Comment: We received one comment requesting that CMS outline a process that describes the criteria used to determine which stakeholder requests regarding APC assignments are included in the OPPS proposed rule. The commenter suggested that all APC assignment requests, including APC structure requests, be included in the OPPS proposed rule and that we should follow a process similar to the IPPS, which includes an annual deadline, and requests discussed in the following year's proposed rule.

Response: We appreciate the feedback and will consider this comment for future rulemaking. As a reminder, codes are updated and changed throughout the year. CPT and Level II HCPCS code changes that affect the OPPS are published through the annual rulemaking cycle and through the OPPS quarterly update Change Requests (CRs). Generally, these code changes are effective January 1, April 1, July 1, or

[29] *https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices*

October 1. CPT code changes are released by the AMA (via their website) while Level II HCPCS code changes are released to the public via the CMS HCPCS website. CMS recognizes the release of new CPT and Level II HCPCS codes outside of the formal rulemaking process via OPPS quarterly update CRs. Based on our review, we assign the new codes to interim status indicators (SIs) and APCs. These interim assignments are finalized in the OPPS/ASC final rules. This quarterly process offers hospitals access to codes that more accurately describe the items or services furnished and provides payment for these items or services in a timelier manner than if we waited for the annual rulemaking process. We solicit public comments on the new CPT and Level II HCPCS codes, status indicators, and APC assignments through our annual rulemaking process.

Comment: We received one comment requesting information about our process for assigning status indicator ''E1'' to CPT or HCPCS codes that are not FDA approved. The commenter asserts that the delay in timing (from FDA approval to APC and SI assignment) affects beneficiary access to new technologies and services and impacts how other payers will pay for the services.

Response: We appreciate the feedback. We believe for items and services that are not FDA approved, it is appropriate to assign the codes to status indicator ''E1'' to indicate that they are not payable by Medicare when submitted on outpatient claims (any outpatient bill type) because the services are either not covered by any Medicare outpatient benefit category, statutorily excluded by Medicare, or not reasonable and necessary. We rely on stakeholders to notify us upon FDA approval of their device and/or service and we work to ensure a timely transition and assign the applicable codes to APCs that reflect clinical and resource similarity to the new codes. We accept information regarding the device and/or service that the stakeholder can provide to us to assist us in our review. We remind readers that OPPS payment policies are updated quarterly through a sub-regulatory process.

IV. OPPS Payment for Devices

A. Pass-Through Payment for Devices

1. Beginning Eligibility Date for Device Pass-Through Status and Quarterly Expiration of Device Pass-Through Payments

a. Background

The intent of transitional device pass-through payment, as implemented at § 419.66, is to facilitate access for beneficiaries to the advantages of new and truly innovative devices by allowing for adequate payment for these new devices while the necessary cost data is collected to incorporate the costs for these devices into the procedure APC rate (66 FR 55861). Under section 1833(t)(6)(B)(iii) of the Act, the period for which a device category eligible for transitional pass-through payments under the OPPS can be in effect is at least 2 years but not more than 3 years. Prior to CY 2017, our regulation at § 419.66(g) provided that this pass-through payment eligibility period began on the date CMS established a particular transitional pass-through category of devices, and we based the pass-through status expiration date for a device category on the date on which pass-through payment was effective for the category. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79654), in accordance with section 1833(t)(6)(B)(iii)(II) of the Act, we amended § 419.66(g) to provide that the pass-through eligibility period for a device category begins on the first date on which pass-through payment is made under the OPPS for any medical device described by such category.

In addition, prior to CY 2017, our policy was to propose and finalize the dates for expiration of pass-through status for device categories as part of the OPPS annual update. This means that device pass-through status would expire at the end of a calendar year when at least 2 years of pass-through payments had been made, regardless of the quarter in which the device was approved. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79655), we changed our policy to allow for quarterly expiration of pass-through payment status for devices, beginning with pass-through devices approved in CY 2017 and subsequent calendar years, to afford a pass-through payment period that is as close to a full 3 years as possible for all pass-through payment devices. We also have an established policy to package the costs of the devices that are no longer eligible for pass-through payments into the costs of the procedures with which the devices are reported in the claims data used to set the payment rates (67 FR 66763).

We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79648 through 79661) for a full discussion of the current device pass-through payment policy.[30]

In the CY 2023 OPPS/ASC final rule with comment period, we finalized our policy to publicly post online OPPS device pass-through applications received on or after March 1, 2023, beginning with the issuance of the CY 2025 proposed rule and for each OPPS rulemaking thereafter. We refer readers to the CY 2023 OPPS/ASC final rule with comment period (87 FR 71934 through 71938) for a full discussion of the policy to publicly post OPPS device pass-through applications.

b. Expiration of Transitional Pass-Through Payments for Certain Devices

As stated earlier, section 1833(t)(6)(B)(iii) of the Act requires that, under the OPPS, a category of devices be eligible for transitional pass-through payments for at least 2 years, but not more than 3 years. Currently, there are 13 device categories eligible for pass-through payment. These devices are listed in Table 112 of this final rule where we detail the expiration dates of pass-through payment status for each of the 13 devices currently receiving device pass-through payment.

[30] To apply for OPPS transitional device pass-through status, applicants complete an application that is subject to the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*). This information collection (CMS–10052) is currently approved under OMB control number 0938–0857 and has an expiration date of November 30, 2025.

TABLE 112: DEVICES WITH PASS-THROUGH STATUS EXPIRING IN 2024, IN 2025, IN 2026, OR IN 2027

HCPCS Code	Long Descriptor	Effective Date	Pass-Through Expiration Date
C1832	Autograft suspension, including cell processing and application, and all system components	01/01/2022	12/31/2024
C1833	Monitor, cardiac, including intracardiac lead and all system components (implantable)	01/01/2022	12/31/2024
C1826	Generator, neurostimulator (implantable), includes closed feedback loop leads and all implantable components, with rechargeable battery and charging system	01/1/2023	12/31/2025
C1827	Generator, neurostimulator (implantable), non-rechargeable, with implantable stimulation lead and external paired stimulation controller	01/01/2023	12/31/2025
C1747	Endoscope, single-use (*i.e.* disposable), urinary tract, imaging/illumination device (insertable)	01/01/2023	12/31/2025
C1600	Catheter, transluminal intravascular lesion preparation device, bladed, sheathed (insertable)	01/01/2024	12/31/2026
C1601	Endoscope, single-use (*i.e.* disposable), pulmonary, imaging/illumination device (insertable)	01/01/2024	12/31/2026
C1602	Orthopedic/device/drug matrix/absorbable bone void filler, antimicrobial-eluting (implantable)	01/01/2024	12/31/2026
C1603	Retrieval device, insertable, laser (used to retrieve intravascular inferior vena cava filter)	01/01/2024	12/31/2026
C1604	Graft, transmural transvenous arterial bypass (implantable), with all delivery system components	01/01/2024	12/31/2026
C1605	Pacemaker, leadless, dual chamber (right atrial and right ventricular implantable components), rate-responsive, including all necessary components for implantation	07/01/2024	06/30/2027
C1606	Adapter, single-use (*i.e.* disposable), for attaching ultrasound system to upper gastrointestinal endoscope	07/01/2024	06/30/2027
C8000	Support device, extravascular, for arteriovenous fistula (implantable)	10/01/2024	9/30/2027

As discussed in section IV.A.2. New Device Pass-Through Applications for CY 2024 of the CY 2024 OPPS/ASC final rule with comment period, we approved HCPCS code C1601 (Endoscope, single-use (*i.e.* disposable), pulmonary, imaging/illumination device (insertable)), as a new device category for pass-through status under the OPPS, with an effective date of January 1, 2024. For the full discussion of the criteria used to evaluate device pass-through applications, refer to the CY 2024 OPPS/ASC final rule with comment period, which was published in the **Federal Register** on November 22, 2023 (88 FR 81729 through 81743). We note that HCPCS code C1601 was established for a bronchoscope that can only be used for a single procedure and cannot be reprocessed. As such, HCPCS code C1601 only describes devices that cannot be reprocessed.

In addition, as discussed in section IV.A.2 (New Device Pass-Through Applications for CY 2023) of the CY 2023 OPPS/ASC final rule with comment period, we approved HCPCS code C1747 (Endoscope, single-use (*i.e.* disposable), urinary tract, imaging/illumination device (insertable)), as a new device category for pass-through status under the OPPS, with an effective date of January 1, 2023. For the full discussion on the criteria used to evaluate device pass-through applications, refer to the CY 2023 OPPS/ASC final rule with comment period, which was published in the **Federal Register** on November 23, 2022 (87 FR 71929 through 71934). We note that HCPCS code C1747 was established for a ureteroscope that can only be used for a single procedure and cannot be reprocessed. As such, HCPCS code C1747 only describes devices that cannot be reprocessed.

2. New Device Pass-Through Applications for CY 2025

a. Background

Section 1833(t)(6) of the Act provides for pass-through payments for devices, and section 1833(t)(6)(B) of the Act requires CMS to use categories in determining the eligibility of devices for pass-through payments. As part of implementing the statute through regulations, we have continued to believe that it is important for hospitals to receive pass-through payments for devices that offer substantial clinical improvement in the treatment of Medicare beneficiaries to facilitate access by beneficiaries to the advantages of the new technology. Conversely, we have noted that the need for additional payments for devices that offer little or no clinical improvement over previously existing devices is less apparent. In such cases, these devices can still be used by hospitals, and hospitals will be paid for them through appropriate APC payment. Moreover, a goal is to target pass-through payments for those devices where cost considerations are most likely to interfere with patient access (66 FR 55852; 67 FR 66782; and 70 FR 68629).

As specified in regulations at § 419.66(b)(1) through (3), to be eligible for transitional pass-through payment under the OPPS, a device must meet the following criteria:

- If required by FDA, the device must have received FDA approval or clearance and FDA marketing authorization (except for a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by FDA), or meet another appropriate FDA exemption; and the pass-through payment application must be submitted within 3 years from the date of the initial FDA marketing authorization, if required, unless there is a documented, verifiable delay in U.S. market availability after FDA marketing authorization is granted, in which case CMS will consider the pass-through payment application if it is submitted within 3 years from the date of market availability;
- The device is determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part, as required by section 1862(a)(1)(A) of the Act; and
- The device is an integral part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted (either permanently or temporarily), or applied in or on a wound or other skin lesion.

In addition, according to § 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker).

Separately, we use the following criteria, as set forth under § 419.66(c), to determine whether a new category of pass-through payment devices should be established. The device to be included in the new category must—

- Not be appropriately described by an existing category or by any category previously in effect established for transitional pass-through payments, and was not being paid for as an outpatient service as of December 31, 1996;
- Have an average cost that is not ''insignificant'' relative to the payment amount for the procedure or service with which the device is associated as determined under § 419.66(d) by demonstrating: (1) the estimated average reasonable cost of devices in the category exceeds 25 percent of the applicable APC payment amount for the service related to the category of devices; (2) the estimated average reasonable cost of the devices in the category exceeds the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent; and (3) the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device exceeds 10 percent of the APC payment amount for the related service (with the exception of brachytherapy and temperature-monitored cryoablation, which are exempt from the cost requirements as specified at § 419.66(c)(3) and (e)); and
- Demonstrate a substantial clinical improvement, that is, substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment, or, for devices for which pass-through payment status will begin on or after January 1, 2020, as an alternative pathway to demonstrating substantial clinical improvement, a device is part of the FDA's Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation.

Beginning in CY 2016, we changed our device pass-through evaluation and determination process. Device pass-through applications are still submitted to CMS through the quarterly subregulatory process, but the applications are subject to notice and comment rulemaking in the next applicable OPPS annual rulemaking cycle. Under this process, all applications that are preliminarily approved upon quarterly review will automatically be included in the next applicable OPPS annual rulemaking cycle, while submitters of applications that are not approved upon quarterly review will have the option of being

included in the next applicable OPPS annual rulemaking cycle or withdrawing their application from consideration. Under this notice-and-comment process, applicants may submit new evidence, such as clinical trial results published in a peer-reviewed journal or other materials, for consideration during the public comment process for the proposed rule. This process allows those applications that we are able to determine meet all of the criteria for device pass-through payment under the quarterly review process to receive timely pass-through payment status, while still allowing for a transparent, public review process for all applications (80 FR 70417 through 70418).

In the CY 2020 annual rulemaking process, we finalized an alternative pathway for devices that are granted a Breakthrough Device designation (84 FR 61295) and receive FDA marketing authorization for the indication covered by the Breakthrough Device designation. Under this alternative pathway, devices that are granted an FDA Breakthrough Device designation are not evaluated in terms of the current substantial clinical improvement criterion at § 419.66(c)(2) for the purposes of determining device pass-through payment status, but do need to meet the other requirements for pass-through payment status in our regulation at § 419.66. Devices that are part of the Breakthrough Devices Program, have received FDA marketing authorization for the indication covered by the Breakthrough Devices designation, and meet the other criteria in the regulation can be approved through the quarterly process and announced through that process (81 FR 79655). Proposals regarding these devices and whether pass-through payment status should continue to apply are included in the next applicable OPPS rulemaking cycle. This process promotes timely pass-through payment status for innovative devices, while also recognizing that such devices may not have a sufficient evidence base to demonstrate substantial clinical improvement at the time of FDA marketing authorization.

More details on the requirements for device pass-through payment applications are included on the CMS website in the application form itself at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html*, in the ''Downloads'' section. In addition, CMS is amenable to meeting with applicants or potential applicants to facilitate information sharing to support the evaluation of an OPPS device pass-through payment application or discuss general application criteria, including the substantial clinical improvement criterion.

b. Applications Received for Device Pass-Through Status for CY 2025

We received 14 complete applications by the March 1, 2024, quarterly deadline, which was the last quarterly deadline for applications to be received in time to be included in this final rule. Of the complete applications, we received two applications in the second quarter of 2023, two application in the third quarter of 2023, three applications in the fourth quarter of 2023, and seven applications in the first quarter of 2024. Three of the applications were approved for device pass-through payment during the quarterly review process: The DETOUR™ System, which was preliminarily approved upon quarterly review under the alternative pathway effective January 1, 2024, and the AVEIR™ DR Dual Chamber Leadless Pacemaker System and the EndoSound Vision System™ (EVS™) which both were preliminarily approved upon quarterly review under the alternative pathway effective July 1, 2024. As previously stated, all applications that are preliminarily approved upon quarterly review will automatically be included in the next applicable OPPS annual rulemaking cycle. Therefore, the DETOUR™ System, the AVEIR™ DR Dual Chamber Leadless Pacemaker System, and the EndoSound Vision System™ (EVS™) are discussed in the following section IV.2.b.1.

We note that the quarterly application process and requirements have not changed because of the addition of rulemaking review. Detailed instructions on submission of a quarterly device pass-through payment application are included on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf*.

Discussions of the applications we received by the March 1, 2024, deadline are included below. We did not include the description and discussion of new device category for transitional pass-through payment status applications which were included in the proposed rule that were withdrawn for consideration for the upcoming calendar year. We also do not summarize or respond to public comments received regarding these withdrawn or ineligible applications.

(1) Alternative Pathway Device Pass-Through Applications

We received 10 device pass-through applications by the March 2024 quarterly application deadline for devices that have received Breakthrough Device designation from FDA and FDA marketing authorization for the indication for which they have a Breakthrough Device designation, and therefore were eligible to apply under the alternative pathway.

(a) AGENT™ Paclitaxel-Coated Balloon Catheter

Boston Scientific Corporation submitted an application for a new device category for transitional pass-through payment status for the AGENT™ Paclitaxel-Coated Balloon Catheter for CY 2025. Per the applicant, the AGENT™ Paclitaxel-Coated Balloon Catheter is a device/drug combination product consisting of a semi-compliant intracoronary balloon catheter with a paclitaxel/acetyl tributyl citrate drug coating on the balloon component. The applicant asserted that the AGENT™ Paclitaxel-Coated Balloon Catheter delivers paclitaxel, an antiproliferative drug, directly to the arterial tissue which inhibits the proliferation of neointimal smooth muscle cells without introducing an additional stent layer, thereby reducing the rate of restenosis. According to the applicant, the AGENT™ Paclitaxel-Coated Balloon Catheter is intended for use in adult patients, after appropriate vessel preparation, undergoing percutaneous coronary intervention (PCI) in coronary arteries 2.0 mm to 4.0 mm in diameter and lesions up to 26 mm in length for the purpose of improving myocardial perfusion when treating in-stent restenosis (ISR) and the management of atherosclerotic coronary artery disease.

Please refer to the online application posting for the AGENT™ Paclitaxel-Coated Balloon Catheter, available at *https://mearis.cms.gov/public/publications/device-ptp/DEP2402295H2TU*, for additional detail describing this device and the disease treated by the device.

Comment: Many commenters expressed their support for the approval of transitional pass-through payment for the AGENT™ Paclitaxel-Coated Balloon Catheter. The commenters, including the applicant, emphasized their positive views on the device's transformational nature as a treatment for ISR, the device's ability to demonstrate clinical improvement relative to other available treatments, and the device's safety profile. In addition, many commenters expressed their concerns that without

adequate reimbursement many medical facilities may not adopt widespread use of the AGENT™ Paclitaxel-Coated Balloon Catheter.

Response: We appreciate the commenters' input and support for the AGENT™ Paclitaxel-Coated Balloon Catheter application for transitional pass-through payment. We have taken these comments into consideration in our final determination for pass-through status for the AGENT™ Paclitaxel-Coated Balloon Catheter.

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), the AGENT™ Paclitaxel-Coated Balloon Catheter received FDA Breakthrough Device designation effective January 22, 2021, as a combination product indicated for percutaneous transluminal coronary angioplasty (PTCA) in coronary arteries 2.0 mm to 4.0 mm in diameter to treat ISR, up to 26 mm in length, for the purpose of improving myocardial perfusion. FDA approved the premarket approval application (PMA) for the AGENT™ Paclitaxel-Coated Balloon Catheter on February 29, 2024, as indicated for use after appropriate vessel preparation in adult patients undergoing PCI in coronary arteries 2.0 mm to 4.0 mm in diameter and lesions up to 26 mm in length for the purpose of improving myocardial perfusion when treating ISR. We noted that while the indication for the FDA Breakthrough Device designation and the indication for the FDA premarket approval vary slightly, we stated that we believe that FDA premarket approval indication is the indication covered by the Breakthrough Device designation. We received the application for a new device category for transitional pass-through payment status for the AGENT™ Paclitaxel-Coated Balloon Catheter on February 29, 2024, which is within 3 years of the date of the initial FDA marketing authorization.

We invited public comment on whether the AGENT™ Paclitaxel-Coated Balloon Catheter meets the newness criterion at § 419.66(b)(1).

Comment: With respect to the newness criterion at § 419.66(b)(1), the applicant reiterated that the AGENT™ Paclitaxel-Coated Balloon Catheter received FDA premarket approval on February 29, 2024, for use after appropriate vessel preparation in adult patients undergoing PCI in coronary arteries 2.0 mm to 4.0 mm in diameter and lesions up to 26 mm in length for the purpose of improving myocardial perfusion when treating ISR. In addition, a few other commenters expressed their belief that the AGENT™ Paclitaxel-Coated Balloon Catheter meets the newness criterion at § 419.66(b)(1).

Response: We appreciate the applicant's and commenters' input. The AGENT™ Paclitaxel-Coated Balloon Catheter received FDA Breakthrough Device designation effective January 22, 2021. We received the application for a new device category for transitional pass-through payment status for the AGENT™ Paclitaxel-Coated Balloon Catheter on February 29, 2024, which is within 3 years of February 29, 2024, the date of FDA premarket approval application. Based on our review of the application, we have determined that the AGENT™ Paclitaxel-Coated Balloon Catheter meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criterion at § 419.66(b)(3), the device must be an integral part of the service furnished, used for one patient only, come in contact with human tissue, and be surgically inserted or implanted, or applied in or on a wound or other skin lesion. The applicant did not explicitly indicate whether the AGENT™ Paclitaxel-Coated Balloon Catheter is integral to the service provided. The applicant stated that the AGENT™ Paclitaxel-Coated Balloon Catheter is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted as required by § 419.66(b)(3).

We invited public comment on whether the AGENT™ Paclitaxel-Coated Balloon Catheter meets the eligibility criterion at § 419.66(b)(3).

Comment: The applicant and another commenter asserted that the AGENT™ Paclitaxel-Coated Balloon Catheter meets all the requirements of § 419.66(b)(3). The applicant submitted a comment clarifying that the AGENT™ Paclitaxel-Coated Balloon Catheter is integral to the service provided and meets the eligibility criterion at § 419.66(b)(3) because the service cannot be furnished without the AGENT™ Paclitaxel-Coated Balloon Catheter. Specifically, the applicant commented that that the AGENT™ Paclitaxel-Coated Balloon Catheter is a device/drug combination product consisting of a semi-compliant intracoronary balloon catheter with a drug coating consisting of paclitaxel/acetyl tributyl citrate on the balloon component. In addition, the applicant provided that the AGENT™ Paclitaxel-Coated Balloon Catheter is inserted transiently in a coronary artery suffering from ISR and transfers a long-dwelling, therapeutic dose of paclitaxel to the vessel wall of the artery to prevent ISR reoccurrence. The applicant reiterated that the AGENT™ Paclitaxel-Coated Balloon Catheter is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted.

Response: We appreciate the applicant's and commenter's clarification, and we agree that the AGENT™ Paclitaxel-Coated Balloon Catheter is integral to the service furnished. We agree with the applicant and commenter that the AGENT™ Paclitaxel-Coated Balloon Catheter is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted, or applied in or on a wound or other skin lesion. After consideration of the public comments received and our review of the application, we have determined that the AGENT™ Paclitaxel-Coated Balloon Catheter meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker). The applicant did not indicate whether the AGENT™ Paclitaxel-Coated Balloon Catheter is equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered, or if the AGENT™ Paclitaxel-Coated Balloon Catheter is a supply or material furnished incident to a service.

We invited public comment on whether the AGENT™ Paclitaxel-Coated Balloon Catheter meets the exclusion criterion at § 419.66(b)(4).

Comment: The applicant and commenter submitted a comment clarifying that the AGENT™ Paclitaxel-Coated Balloon Catheter meets the eligibility criterion at § 419.66(b)(4) because it is not equipment, an instrument, apparatus, implement or any type of item for which depreciation and financing expenses are recovered, and because it is the primary therapeutic intervention and is not a supply or material furnished incident to a service.

Response: We appreciate the applicant's and commenter's clarification. We agree with the

applicant and commenter that the AGENT™ Paclitaxel-Coated Balloon Catheter is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets, or a material or supply furnished incident to a service. After consideration of the public comments received and our review of the application, we have determined that the AGENT™ Paclitaxel-Coated Balloon Catheter meets the eligibility criterion at § 419.66(b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), the criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. According to the applicant, no previous or existing device categories for pass-through payment appropriately describe the AGENT™ Paclitaxel-Coated Balloon Catheter. Per the applicant, while device category C2623 (Catheter, transluminal angioplasty, drug-coated, non-laser) describes related or similar products to the AGENT™ Paclitaxel-Coated Balloon Catheter, the AGENT™ Paclitaxel-Coated Balloon Catheter is not appropriately described by C2623 because the devices in this category differ from the AGENT™ Paclitaxel-Coated Balloon Catheter in both size and indicated use, and therefore, the device is not appropriately described by C2623. The applicant further claimed that the devices described by C2623 are approved for use in the femoral or popliteal arteries in vessels with a diameter of at least 4.0 mm, whereas the AGENT™ Paclitaxel-Coated Balloon Catheter is indicated for use in coronary arteries that are between 2.0 mm to 4.0 mm in diameter. In addition, the applicant also noted that the length of the lesions (up to 180 mm) treated with devices in this device category greatly exceeds the maximum lesion size of 26 mm for the AGENT™ Paclitaxel-Coated Balloon Catheter. Moreover, the applicant asserted that the devices described by C2623 are used to treat peripheral arterial disease and are contraindicated for use in coronary arteries. Per the applicant, the AGENT™ Paclitaxel-Coated Balloon Catheter is used in conjunction with transluminal PCIs which are described by different procedure codes than the percutaneous transluminal angioplasty services used for the devices in C2623. Lastly, the applicant stated that an analysis of claims found that the devices described by C2623 are typically reported with femoral or popliteal revascularization procedures (HCPCS codes from 37224 to 37227).

We noted that, based on the description the applicant provided, the AGENT™ Paclitaxel-Coated Balloon Catheter is a device/drug combination product consisting of a semi-compliant intracoronary balloon catheter with a paclitaxel/acetyl tributyl citrate drug coating on the balloon component and thus could be appropriately described by C2623. Specifically, we stated that we believe that C2623 may appropriately describe the AGENT™ Paclitaxel-Coated Balloon Catheter because it is a non-laser, drug-coated catheter used for transluminal angioplasty procedures. In this context, we noted that we believe the AGENT™ Paclitaxel-Coated Balloon Catheter may be similar to the devices described by C2623, and therefore, the AGENT™ Paclitaxel-Coated Balloon Catheter may also be appropriately described by C2623.

In addition, while we acknowledged that when C2623 was established as a device category code effective April 1, 2015, the procedure codes with which C2623 could be reported (HCPCS code 37224 and HCPCS code 37226) were limited to use in the femoral or popliteal arteries. However, based on the subsequent changes that were made to the procedure codes with which C2623 could be reported, we did not agree that C2623 is limited to use with femoral or popliteal revascularization procedures. First, we noted that effective August 25, 2017, while C2623 was in device pass-through payment status, CMS added two procedure codes with which C2623 could be reported that were for procedures other than femoral popliteal revascularization procedures. Specifically, based on the FDA approval of a new indication for an existing device (a drug-coated balloon catheter for use with dialysis circuit procedures for the treatment of patients with dysfunctional arteriovenous fistulae),[31] CMS added two procedure codes, HCPCS codes 36902 and 36903 (transluminal balloon angioplasty procedures in peripheral dialysis segments),[32] with which C2623 could be reported effective August 25, 2017. The devices used with these two added HCPCS codes, 36902 and 36903, which are also described by C2623, are drug-coated balloon catheters used for dialysis circuit procedures in the upper extremities. We stated that we believe the inclusion of these additional reportable procedure codes illustrates that devices that may be described by C2623 were neither intended to be restricted to the treatment of vascular lesions of a specified dimension nor anatomically limited to femoral or popliteal revascularization procedures and is inconsistent with the applicant's assertion that the AGENT™ Paclitaxel-Coated Balloon Catheter is not appropriately described by C2623 because the category is only applicable for devices used in femoral or popliteal arteries with a diameter of at least 4.0 mm, and not smaller coronary arteries.

Further, beginning January 1, 2018, upon the expiration of device pass-through payment status for C2623, CMS packaged the payment for the costs of each of the devices described by C2623 into the payment for the costs related to the procedure with which each device is reported in the hospital claims data (FR 82 59321 through 59323). We further noted that upon becoming packaged for payment, C2623 effectively became reportable with other transluminal angioplasty procedure codes, including procedure codes for percutaneous coronary transluminal angioplasty services. Finally, we noted that while, per the applicant, the devices described by C2623 are typically reported with femoral or popliteal revascularization procedures, other procedure codes, including procedure codes for other percutaneous transluminal angioplasty services and

[31] Centers for Medicare & Medicaid Services (2017). Pub 100–04 Medicare Claims Processing (Transmittal 3941) in CMS Manual System. Accessed at *https://www.cms.gov/regulations-and-guidance/guidance/transmittals/2017downloads/r3941cp.pdf.*

[32] HCPCS code 36902 (Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, radiological supervision and interpretation and image documentation and report; with transluminal balloon angioplasty, peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty) and HCPCS code 36903 (Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, radiological supervision and interpretation and image documentation and report; with transcatheter placement of intravascular stent(s) peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the stenting, and all angioplasty within the peripheral dialysis segment).

other related coronary procedure codes can and have been performed with devices described by C2623. As such, we stated that we believe the procedures with which the AGENT™ Paclitaxel-Coated Balloon Catheter is utilized could be reported with C2623.

In this context, based on the description the applicant provided, we stated that we believe the AGENT™ Paclitaxel-Coated Balloon Catheter may be similar to the devices described by C2623, and therefore, the AGENT™ Paclitaxel-Coated Balloon Catheter may also be appropriately described by C2623.

We invited public comment on whether the AGENT™ Paclitaxel-Coated Balloon Catheter meets the device category criterion at § 419.66(c)(1).

Comment: In response to our concerns that the AGENT™ Paclitaxel-Coated Balloon Catheter may be appropriately described by C2623, the applicant and many commenters asserted that the AGENT™ Paclitaxel-Coated Balloon Catheter is not described by C2623 because the device is not used to perform transluminal angioplasties. Specifically, these commenters explained that the AGENT™ Paclitaxel-Coated Balloon Catheter is used to effectively deliver its drug to a lesion after the vessel wall has been prepared, typically through an angioplasty. They also asserted that C2623 is used to describe drug-coated balloons indicated for use in the peripheral vasculature which are capable of both angioplasty and drug-delivery; however, according to the commenters, the AGENT™ Paclitaxel-Coated Balloon Catheter is used solely for drug-delivery and cannot be used for performing an angioplasty. In addition, the applicant commented that peripheral drug-coated balloon catheters, like those described by C2623, are primarily used for treating typically diffused atherosclerotic/restenotic lesions in the comparatively elastic femoral or popliteal arteries, whereas coronary drug-coated balloons are used for treatment of substantially smaller, stented (and therefore, relatively inelastic) coronary segments, with largely focal lesions. Similarly, many commenters underlined the differences between the AGENT™ Paclitaxel-Coated Balloon Catheter and peripheral drug-coated balloon catheters, including design, size, deployment location and time length, clinical indication, and procedural complexity.

The applicant and a few commenters noted that CMS has historically included specific anatomy in several device categories, including those differentiating coronary and non-coronary devices. The applicant offered the following as examples of device categories that are specific to a particular type of intervention: C1759 (Catheter, intracardiac echocardiography), C1761 (Catheter, transluminal intravascular lithotripsy, coronary), and C1888 (Catheter, ablation, non-cardiac, endovascular). A few commenters highlighted device categories that are more granular in description than C2623, such as C1714 (Catheter, transluminal atherectomy, directional), C1724 (Catheter, transluminal atherectomy, rotational), C1732 (Catheter, electrophysiology, diagnostic/ablation, 3D or vector mapping), and C1733 (Catheter, electrophysiology, diagnostic/ablation, other than 3D or vector mapping, other than cool-tip), and suggested that CMS similarly acknowledge the differences between the AGENT™ Paclitaxel-Coated Balloon Catheter and those devices in device category C2623.

Response: We appreciate the applicant's and commenters' input. We note that while the FDA Breakthrough Device designation for the AGENT™ Paclitaxel-Coated Balloon Catheter stated a proposed indication for PTCA in coronary arteries 2.0 mm to 4.0 mm in diameter to treat ISR, up to 26 mm in length, for the purpose of improving myocardial perfusion, the FDA PMA for the AGENT™ Paclitaxel-Coated Balloon Catheter on February 29, 2024, stated the combination drug/device is indicated for use after appropriate vessel preparation in adult patients undergoing PCI in coronary arteries 2.0 mm to 4.0 mm in diameter and lesions up to 26 mm in length for the purpose of improving myocardial perfusion when treating ISR, removing the PTCA indication. This appears to be consistent with the applicant's and commenters' assertions that the AGENT™ Paclitaxel-Coated Balloon Catheter is not utilized in the treatment of PTCA. After consideration of the public comments received, we agree that the AGENT™ Paclitaxel-Coated Balloon Catheter is not indicated for use in transluminal angioplasty; rather, it is intended for improving myocardial perfusion when treating in-stent restenosis after appropriate vessel preparation. Further, we agree that C2623 describes drug-coated balloons which are capable of angioplasty, while the AGENT™ Paclitaxel-Coated Balloon Catheter appears to be used solely for drug-delivery and cannot be used for performing an angioplasty, including PCTAs. As such, we do not believe that the AGENT™ Paclitaxel-Coated Balloon Catheter is described by C2623.

We acknowledge that CMS has included specific anatomic language in the descriptors of previous device category codes when such language was necessary based on the unique circumstances surrounding the establishment of a particular device category code. We note that CMS does not establish pass-through device categories for the purposes of describing specific devices, but rather, device categories which are intended to encompass all devices that can be appropriately described by a category. As such, all device categories, regardless of the language utilized in the descriptors, are established in such a way that no medical device is described by more than one category in accordance with section 1833(t)(6)(B)(ii)(II) of the Act.

After consideration of the public comments received and our review of the application, we agree there is no existing category or category previously in effect that appropriately describes the AGENT™ Paclitaxel-Coated Balloon Catheter. Based on this information, we have determined that the AGENT™ Paclitaxel-Coated Balloon Catheter meets the eligibility criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The AGENT™ Paclitaxel-Coated Balloon Catheter has a Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation (as explained in the discussion of the newness criterion), and therefore, is not evaluated for substantial clinical improvement.

We invited public comment on whether the AGENT™ Paclitaxel-Coated Balloon Catheter meets the device category criterion at § 419.66(c)(2)(ii).

Comment: The applicant and one commenter confirmed that the

AGENT™ Paclitaxel-Coated Balloon Catheter has received both Breakthrough Device designation and marketing authorization from FDA, meeting the device category criterion at § 419.66(c)(2).

Response: We appreciate the applicant's and commenter's input. The AGENT™ Paclitaxel-Coated Balloon Catheter has a Breakthrough Device designation effective January 22, 2021, and marketing authorization from FDA effective February 29, 2024, for the indication covered by the Breakthrough Device designation. Therefore, the AGENT™ Paclitaxel-Coated Balloon Catheter meets the criterion at 419.66(c)(2)(ii) and is not evaluated for substantial clinical improvement at § 419.66(c)(2)(i). Based on our review of the application, we have determined that the AGENT™ Paclitaxel-Coated Balloon Catheter meets the device category criterion at § 419.66(c)(2).

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the AGENT™ Paclitaxel-Coated Balloon Catheter would be reported with the HCPCS codes as shown in Table 113.

TABLE 113: HCPCS CODES REPORTED WITH THE AGENT™ PACLITAXEL-COATED BALLOON CATHETER

HCPCS Code	Long Descriptor	SI	APC
92920	Percutaneous transluminal coronary angioplasty; single major coronary artery or branch	J1	5192
92924	Percutaneous transluminal coronary atherectomy, with coronary angioplasty when performed; single major coronary artery or branch	J1	5193
92928	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch	J1	5193
92933	Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch	J1	5194
C9600	Percutaneous transcatheter placement of drug-eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch	J1	5193
C9602	Percutaneous transluminal coronary atherectomy, with drug-eluting intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch	J1	5194

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). We noted that the applicant utilized the CY 2024 payment rates for the three tests of the cost criterion. For our calculations, we used APC 5192, which had a CY 2024 payment rate of $5,445.84 at the time the application was received. HCPCS code 92920 in APC 5192 had a device offset amount of $1,662.61 at the time the application was received. According to the applicant, the cost of the AGENT™ Paclitaxel-Coated Balloon Catheter is $5,500.00.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The average reasonable cost of $5,500.00 for the AGENT™ Paclitaxel-Coated Balloon Catheter is 101.00 percent of the applicable APC payment amount for the service related to the category of devices of $5,445.84 (($5,500.00/$5,445.84) × 100 = 101.00 percent). Therefore, we stated that we believe the AGENT™ Paclitaxel-Coated Balloon Catheter meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $5,500.00 for the AGENT™ Paclitaxel-Coated Balloon Catheter is 330.81 percent of the cost of the device-related portion of the APC payment amount for the related service of $1,662.61 (($5,500.00/$1,662.61) × 100 = 330.81 percent). Therefore, we stated that we believe the AGENT™ Paclitaxel-Coated Balloon Catheter meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $5,500.00 for the AGENT™ Paclitaxel-Coated Balloon Catheter and the portion of the APC payment amount for the device of $1,662.61 is 70.46 percent of the APC payment amount for the related service of $5,445.84 (((($5,500.00 −

$1,662.61)/$ 5,445.84) × 100 = 70.46 percent). Therefore, we stated that we believe the AGENT™ Paclitaxel-Coated Balloon Catheter meets the third cost significance requirement.

We invited public comment on whether the AGENT™ Paclitaxel-Coated Balloon Catheter meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

Comment: With respect to cost significance criteria, the applicant and a commenter reiterated that the AGENT™ Paclitaxel-Coated Balloon Catheter meets all three of the cost significance criteria.

Response: We appreciate the applicant's and commenter's input. After consideration of the public comments received and our findings from the first, second, and third cost significance tests, we agree that the AGENT™ Paclitaxel-Coated Balloon Catheter meets the cost significance criteria specified at § 419.66(d).

After consideration of the public comments received and our review of the device pass-through application, we have determined that the AGENT™ Paclitaxel-Coated Balloon Catheter meets the requirements for device pass-through status described at § 419.66. We are finalizing approval for device pass-through payment status for the AGENT™ Paclitaxel-Coated Balloon Catheter effective January 1, 2025 under the alternative pathway for devices that have an FDA Breakthrough Device designation and have received FDA marketing authorization for the indication covered by the Breakthrough Device designation.

(b) Aveir™ DR Dual Chamber Leadless Pacemaker System

Abbott Laboratories submitted an application for a new device category for transitional pass-through payment status for the Aveir™ DR Dual Chamber Leadless Pacemaker System (Aveir™ DR System) for CY 2025. Per the applicant, the Aveir™ DR System is comprised of two leadless pacemakers, one atrial and one ventricular with each containing a generator and electrodes, that provide dual-chamber pacing therapy after being placed within the heart's myocardium through a minimally invasive catheter-based procedure. According to the applicant, the Aveir™ DR System is without the need for traditional wire electrodes and can provide beat-to-beat communication and synchrony between the two pacemakers for the treatment of arrhythmia/bradycardia. Per the applicant, patients with indication for dual-chamber pacing would benefit from a dual-chamber leadless pacemaker system that provides atrial and ventricular bradycardia therapy, while eliminating the complications associated with conventional pacing systems.

Please refer to the online application posting for the Aveir™ DR System, available at *https://mearis.cmsgov/public/publications/device-ptp/DEP230831B8DX0*, for additional detail describing the device and the disease treated by the device.

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), the Aveir™ DR System received FDA Breakthrough Device designation effective March 27, 2020, as a pacemaker implantation indicated in one or more of the following permanent conditions: syncope, presyncope, fatigue, disorientation due to arrhythmia/bradycardia, or any combination of these symptoms. FDA approved the premarket approval application (PMA) for the Aveir™ DR System on June 29, 2023, for the indication covered by the Breakthrough Device designation. We received the application for a new device category for transitional pass-through payment status for the Aveir™ DR System on March 23, 2023, which is within 3 years of the date of the initial FDA marketing authorization.

We invited public comment on whether the Aveir™ DR System meets the newness criterion at § 419.66(b)(1).

We did not receive public comments regarding whether the Aveir™ DR System meets the newness criterion at § 419.66(b)(1). The Aveir™ DR System received FDA Breakthrough Device designation effective March 27, 2020. We received the application for a new device category for transitional pass-through payment status for the Aveir™ DR System on March 23, 2023, which is within 3 years of June 29, 2023, the date of FDA PMA. Based on our review of the application, we have determined that the Aveir™ DR System meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criteria at § 419.66(b)(3), the device must be an integral part of the service furnished, used for one patient only, come in contact with human tissue and be surgically inserted or implanted, or applied in or on a wound or other skin lesion. As noted in the proposed rule, the applicant did not indicate whether the Aveir™ DR System is integral to the service furnished. The applicant also did not explicitly state that the Aveir™ DR System is single-use; however, the applicant did state that one Aveir™ DR System is required per patient per procedure. While the applicant did not explicitly state whether the Aveir™ DR System comes in contact with human tissue or is surgically inserted or implanted, the applicant noted that the two Aveir™ Delivery Catheters are inserted into the peripheral vasculature and the cardiovascular system to deliver and implant the Aveir™ AR Atrial Leadless Pacemaker and the Aveir™ VR Ventricular Leadless Pacemaker into the right atrium and right ventricle of the heart, respectively.

We invited public comment on whether the Aveir™ DR System meets the eligibility criterion at § 419.66(b)(3).

Comment: The applicant submitted a comment confirming that the Aveir™ DR System is an integral part of the service provided, is used for one patient only, comes in contact with human tissue, and is surgically inserted or implanted using two delivery catheters that are inserted into the peripheral vasculature and cardiovascular system to deliver and implant the Aveir™ AR Atrial Leadless Pacemaker and the Aveir™ VR Ventricular Leadless Pacemaker into the right atrium and right ventricle of the heart, respectively. The applicant also stated that therefore, it believes the Aveir™ DR System meets the eligibility criterion at § 419.66(b)(3).

Response: We appreciate the applicant's input. We agree with the applicant that the Aveir™ DR System is an integral part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted, or applied in or on a wound or other skin lesion. After consideration of the public comment received and our review of the application, we have determined that the Aveir™ DR System meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker). The applicant did not indicate whether the Aveir™ DR System is equipment, an instrument, apparatus, implement, or item of this type for which depreciating and financing expenses are recovered,

or if the Aveir™ DR System is a supply or material furnished incident to a service.

We invited public comment on whether the Aveir™ DR System meets the exclusion criterion at § 419.66(b)(4).

Comment: The applicant confirmed that the Aveir™ DR System is not an instrument, apparatus, implement, or similar item for which depreciation and financing expenses are recovered. The applicant also stated that the Aveir™ DR System is not a supply or material furnished incident to a service, and therefore, meets the eligibility criterion at § 419.66(b)(4).

Response: We appreciate the applicant's input. With respect to the eligibility criterion at § 419.66(b)(4), we agree with the applicant that the Aveir™ DR System is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets, or a material or supply furnished incident to a service. After consideration of the public comment received and our review of the application, we have determined that the Aveir™ DR System meets the eligibility criterion at § 419.66(b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), the criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. The applicant asserted that the Aveir™ DR System is the only dual-chamber leadless pacemaker authorized by FDA and indicated for implantation in patients with one or more of the following permanent conditions: syncope, presyncope, fatigue, disorientation due to arrhythmia/bradycardia, or any combination of those conditions. Per the applicant, the Aveir™ DR System is a modular dual-chamber leadless pacemaker system with bidirectional implant-to-implant communication that can accommodate all pacing indications. According to the applicant, no previous or existing device categories for pass-through payment appropriately describe the Aveir™ DR System. The applicant stated that device categories C1785 (Pacemaker, dual-chamber, rate-responsive (implantable)) and C1889 (Insertable/implantable device, not otherwise classified) do not appropriately describe the Aveir™ DR System because the Aveir™ DR System received Breakthrough Device designation from FDA and has specific functionality and capabilities that are new to the market. The applicant also asserted that the Aveir™ DR system is modular, such that a single device can be implanted in a heart chamber initially, and the second pacemaker added to the other heart chamber in the future should the clinical need arise; and therefore, it is not appropriately described by either C1785 or C1889.

We did not identify an existing pass-through payment category that describes the Aveir™ DR System. We invited public comment on whether the Aveir™ DR System meets the device category criterion at § 419.66(c)(1).

Comment: The applicant agreed with CMS's assessment that there are no existing pass-through payment categories that describe the Aveir™ DR System.

Response: We appreciate the applicant's input. After consideration of the public comment received and our review of the application, we continue to believe that there is no existing category or category previously in effect that appropriately describes the Aveir™ DR System. Therefore, we have determined that the Aveir™ DR System meets the device category eligibility criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The Aveir™ DR System has a Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation (as explained in more detail in the discussion of the newness criterion), and therefore, is not evaluated for substantial clinical improvement.

We invited public comment on whether the Aveir™ DR System meets the device category criterion at § 419.66(c)(2)(ii).

We did not receive public comment regarding whether the Aveir™ DR System meets the device category criterion at § 419.66(c)(2)(ii). However, the Aveir™ DR System has a Breakthrough Device designation effective March 27, 2020, and a marketing authorization from FDA effective June 29, 2023, for the indication covered by the Breakthrough Device designation. Therefore, the Aveir™ DR System meets the criterion at § 419.66(c)(2)(ii) and is not evaluated for substantial clinical improvement at § 419.66(c)(2)(i). Based on our review of the application, we have determined that the Aveir™ DR System meets the device category criterion at § 419.66(c)(2).

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the Aveir™ DR System would be reported with HCPCS codes as shown in Table 114.

TABLE 114: HCPCS CODES REPORTED WITH THE AVEIR™ DR SYSTEM

HCPCS Code	Long Descriptor	SI	APC
0801T**	Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (*e.g.*, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (*e.g.*, interrogation or programming), when performed; dual-chamber system (*i.e.*, right atrial and right ventricular pacemaker components)	J1	5224
0795T**	Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (*e.g.*, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (*e.g.,* interrogation or programming), when performed; complete system (*i.e.*, right atrial and right ventricular pacemaker components)	J1	5224

**Denotes a HCPCS code that was not included in Addendum P to the CY 2023 OPPS/ASC final rule with comment period, with no CY 2023 HCPCS/CPT code level device offset amount available. We noted the applicant used the CY 2023 payment rates for the three tests of the cost criterion. Since neither of the HCPCS/CPT codes provided by the applicant had a CY 2023 HCPCS/CPT code level device offset amount available at the time the application was received, we used the CY 2023 APC level device offset amount to assess whether the device meets the cost significance criterion.

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). We noted that the applicant used the CY 2023 payment rates for the three tests of the cost criterion. For our calculations, we used APC 5224, which had a CY 2023 payment rate of $18,672.01 at the time the application was received. We used the CY 2023 APC level device offset amount of $11,739.09 for APC 5224, as HCPCS codes 0795T and 0801T provided by the applicant were not included in Addendum P to the CY 2023 OPPS/ASC final rule with comment period and no CY 2023 HCPCS/CPT code level device offset amount was available at the time the application was received.[33] According to the applicant, the cost of the Aveir™ DR System is $24,000.00.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The average reasonable cost of $24,000.00 for the Aveir™ DR System is 128.54 percent of the applicable APC payment amount for the service related to the category of devices of $18,672.01 (($24,000.00/$18,672.01) × 100 = 128.54 percent). Therefore, we stated that we believe the Aveir™ DR System meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $24,000.00 for the Aveir™ DR System is 204.45 percent of the cost of the device-related portion of the APC payment amount for the related service of $11,739.09 (($24,000.00/$11,739.09) × 100 = 204.45 percent). Therefore, we stated that we believe the Aveir™ DR System meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $24,000.00 for the Aveir™ DR System and the portion of the APC payment amount for the device of $11,739.09 is 65.66 percent of the APC payment amount for the related service of $18,672.01 ((($24,000.00 − $11,739.09)/$18,672.01) × 100 = 65.66 percent). Therefore, we stated that we believe the Aveir™ DR System meets the third cost significance requirement.

We invited public comment on whether the Aveir™ DR System meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

Comment: With respect to cost significance criteria, the applicant reiterated that the Aveir™ DR System meets all three of the cost significance criteria.

Response: We appreciate the applicant's input. After consideration of the public comment we received and our findings from the first, second, and third cost significance tests, we agree that the Aveir™ DR System meets the cost significance criteria specified at § 419.66(d).

[33] We noted that the applicant originally utilized APC 5231 (Level 1 ICD and Similar Procedures) for the three tests of the cost criteria in the application. However, the applicant provided supplemental information indicating that, HCPCS codes 0795T and 0801T were assigned to APC 5224 (Level 4 Pacemaker and Similar Procedures) in the corrected Addendum B to the CY 2024 OPPS/ASC final rule with comment period and they believed that APC 5224 is currently the appropriate APC for the purposes of performing the cost significance calculations. We agreed with the applicant and selected APC 5224 for our calculation, which we believe is a more appropriate APC to use based on the assignment of HCPCS codes 0795T and 0801T to APC 5224 and the clinical similarity to other pacemaker insertion codes in APC 5224.

Comment: The applicant submitted a comment requesting that CMS revise the proposed device offset for HCPCS code 0795T (Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (*e.g.,* fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (*e.g.,* interrogation or programming), when performed; complete system (*i.e.,* right atrial and right ventricular pacemaker components)) used to report dual-chamber leadless pacemaker procedures.

Response: We appreciate the applicant's input regarding the device offset amount associated with HCPCS code 0795T. We note that we have addressed this comment in Section IV.B of this final rule with comment period.

As discussed, the Aveir™ DR System pass-through application was preliminarily approved for transitional pass-through payment under the alternative pathway effective July 1, 2024. After consideration of the public comment we received and our review of the device pass-through application, we have determined that the Aveir™ DR System meets the requirements for device pass-through status described at § 419.66 and we are finalizing approval for device pass-through payment status for the Aveir™ DR System under the alternative pathway for devices that have an FDA Breakthrough Device designation and have received FDA marketing authorization for the indication covered by the Breakthrough Device designation.

(c) The DETOUR™ System

Endologix, LLC submitted an application for a new device category for transitional pass-through payment status for the DETOUR™ System for CY 2025. According to the applicant, the DETOUR™ System is an implantable component, used to create a femoropopliteal bypass routed through the femoral vein. The DETOUR™ System is comprised of two main components: (1) the TORUS™ Stent Graft System, which is comprised of the TORUS™ Stent Graft and the TORUS™ Stent Graft Delivery System, and (2) the ENDOCROSS™ Device. Per the applicant, the DETOUR™ System is used to treat patients with advanced peripheral vascular disease, specifically those with long complex femoropopliteal artery stenoses and occlusions resulting in lifestyle limiting claudication or severe lower limb threatening ischemia. According to the applicant, the DETOUR™ System can restore arterial blood flow to the lower limb around the blocked femoral artery and allows for venous blood flow around the conduit for normal venous return, to reduce signs and symptoms of lower limb ischemia and prevent amputation.

Please refer to the online application posting for the DETOUR™ System, available at *https://mearis.cms.gov/public/publications/device-ptp/DEP23090164QL2*, for additional detail describing the device and the disease treated by the device.

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), the DETOUR™ System received FDA Breakthrough Device designation effective September 2, 2020, under the name the PQ Bypass System, as a device intended for percutaneous revascularization of symptomatic femoropopliteal lesions 200mm to 460mm with a chronic total occlusion 100mm to 425mm, and/or moderate-to-severe calcification, and/or in-stent-restenosis in patients with severe peripheral arterial disease. FDA approved the premarket approval application (PMA) for the DETOUR™ System on June 7, 2023, indicated for use for percutaneous revascularization in patients with symptomatic femoropopliteal lesions from 200 mm to 460 mm in length with chronic total occlusions (100 mm to 425 mm) or diffuse stenosis >70 percent who may be considered suboptimal candidates for surgical or alternative endovascular treatments. The DETOUR™ System, or any of its components, is not for use in the coronary and cerebral vasculature. We noted that while the indication for the FDA Breakthrough Device designation and the indication for the FDA premarket approval vary slightly, we stated we believe that FDA premarket approval indication is the indication covered by the Breakthrough Device designation. We received the application for a new device category for transitional pass-through payment status for the DETOUR™ System on September 1, 2023, which is within 3 years of the date of the initial FDA marketing authorization.

We invited public comment on whether the DETOUR™ System meets the newness criterion at § 419.66(b)(1).

We did not receive public comments regarding whether the DETOUR™ System meets the newness criterion at § 419.66(b)(1). The DETOUR™ System received FDA Breakthrough Device designation effective September 2, 2020. We received the application for a new device category for transitional pass-through payment status for the DETOURÔ System on September 1, 2023, which is within 3 years of June 7, 2023, the date of FDA PMA. Based on our review of the application, we have determined that the DETOUR™ System meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criteria at § 419.66(b)(3), the device must be an integral part of the service furnished, used for one patient only, come in contact with human tissue, and be surgically inserted or implanted, or applied in or on a wound or other skin lesion. Per the applicant, the DETOUR™ System is integral to the service provided and is used for one patient only. While the applicant did not indicate whether the DETOUR™ System comes in contact with human tissue, the applicant did specify that both components of the DETOUR™ System, the TORUS™ Stent Graft System and the ENDOCROSS™ Device, are inserted or implanted during the percutaneous transmural femoropopliteal bypass procedure, as required by § 419.66(b)(3).

We invited public comments on whether the DETOUR™ System meets the eligibility criterion at § 419.66(b)(3).

We did not receive public comments regarding whether the DETOUR™ System meets the eligibility requirements of § 419.66(b)(3). As noted in the proposed rule, the applicant did not indicate that the DETOUR™ System comes in contact with human tissue. However, because both components of the DETOUR™ System, the TORUS™ Stent Graft System and the ENDOCROSS™ Device, are inserted or implanted during the percutaneous transmural femoralpopliteal bypass procedure, we believe that the DETOUR™ System comes into contact with human tissue. After consideration of the information in the application, we have determined that the DETOUR™ System meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker). The applicant asserted that the DETOUR™ System meets the device eligibility

requirements because it is not an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service.

We invited public comment on whether the DETOUR™ System meets the exclusion criterion at § 419.66(b)(4).

We did not receive public comments regarding whether the DETOUR™ System meets the eligibility requirements of § 419.66(b)(4). Based on our review of the application, we agree with the applicant that the DETOUR™ System is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets, or a material or supply furnished incident to a service. Therefore, we have determined that the DETOUR™ System meets the eligibility criterion at § 419.66(b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), the criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. The applicant described that the DETOUR™ System is a minimally invasive, single-use device with an implantable component, used to create a femoropopliteal bypass routed through the femoral vein. The applicant provided a list of existing and previous device categories for pass-through payment for other stents and explained why they do not believe any of the categories describe the DETOUR™ System. In summary, the applicant asserted that the referenced device categories do not adequately describe the DETOUR™ System because, in contrast to the DETOUR™ System, the referenced device categories do not have: (1) a crossing device with long needle for transmural access, (2) a crossing device with high pressure needle delivery for heavily calcified and atherosclerotic arteries, (3) a high radial strength transmural stent graft capable of self-support and sustaining blood flow through conduit bridging artery to vein and back to artery, (4) a percutaneous stent graft delivery catheter, (5) a covered stent graft to allow for arterial blood flow within the conduit as venous blood flows around it in the vein, or (6) a permanent implant to maintain arterial and venous blood flow. The reasons the applicant asserted for why the DETOUR™ System is not adequately described by each of the device categories are shown in Table 115.

TABLE 115: POTENTIAL EXISTING/PREVIOUS DEVICE CATEGORIES

HCPCS Code	Device Category Description	Applicant Assertion: The DETOUR™ System Is Not Appropriately Described by Existing/Previous Device Category
C1874	Stent, coated/covered, with delivery system	(1) No crossing device with long needle for transmural access; (2) No crossing device with high pressure needle delivery for heavily calcific and atherosclerotic arteries; (3) No high radial strength transmural stent graft capable of self-support and sustaining blood flow through conduit bridging artery to vein and back to artery
C1875	Stent, coated/covered, without delivery system	Reasons (1); (2); (3); and (4) No percutaneous stent graft delivery catheter
C1876	Stent, non-coated/non-covered, with delivery system	Reasons (1); (2); (3); and (5) No covered stent graft to allow for arterial blood flow within the conduit as venous blood flows around it in the vein
C1877	Stent, non-coated/non-covered, without delivery system	Reasons (1); (2); (3); (4); and (5)
C2625	Stent, non-coronary, temporary, with delivery system	Reasons (1); (2); (3); (5); and (6) No permanent implant to maintain arterial and venous blood flow
C2617	Stent, non-coronary, temporary, without delivery system	Reasons (1); (2); (3); (4); (5); and (6)
C1768	Graft, vascular	Reasons (1); (2); (3); and (5)
C1894	Introducer/sheath, other than guiding, other than intracardiac electrophysiological, non-laser	Reasons (1); (2); (3); and (5)
C2629	Introducer/sheath, other than guiding, other than intracardiac electrophysiological, laser	Reasons (1); (2); (3); and (5)

We did not identify an existing pass-through payment category that describes the DETOUR™ System.

We invited public comment on whether the DETOUR™ System meets the device category criterion at § 419.66(c)(1).

We did not receive any comments regarding whether the DETOUR™ System meets the eligibility requirements at § 419.66(c)(1). Based on our review of the application, we continue to believe there is no existing category or category previously in effect that appropriately describes the DETOUR™ System. Therefore, we have determined that the DETOUR™ System meets the device category eligibility criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The DETOUR™ System has a Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation (as explained in more detail in the discussion of the newness criterion), and therefore, is not evaluated for substantial clinical improvement.

We invited public comment on whether the DETOUR™ System meets the device category criterion at § 419.66(c)(2).

We did not receive public comment regarding whether the DETOUR™ System meets the device category criterion at § 419.66(c)(2). However, the DETOUR™ System has a Breakthrough Device designation effective September 2, 2020, and marketing authorization from FDA effective June 7, 2023, for the indication covered by the Breakthrough Device. Therefore, the DETOUR™ System meets the criterion at § 419.66(c)(2)(ii) and is not evaluated for substantial clinical improvement at § 419.66(c)(2)(i). Based on our review of the application, we have determined that the DETOUR™ System meets the device category criterion at § 419.66(c)(2).

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the DETOUR™ System would be reported with the HCPCS code as shown in Table 116.

TABLE 116: HCPCS CODE REPORTED WITH THE DETOUR™ SYSTEM

HCPCS Code	Long Descriptor	SI	APC
0505T	Endovenous femoral-popliteal arterial revascularization, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed, with crossing of the occlusive lesion in an extraluminal fashion.	J1	5193

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). We noted that the applicant used the CY 2023 payment rates for the three tests of the cost criterion. For our calculations, like the applicant, we used APC 5193, which had a CY 2023 payment rate of $10,615.31 at the time the application was received. HCPCS code 0505T in APC 5193 had a CY 2023 device offset amount of $5,229.10 at the time the application was received. According to the applicant, the cost of the DETOUR™ System is $25,000.00.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The average reasonable cost of $25,000.00 for the DETOUR™ System is 235.51 percent of the applicable APC payment amount for the service related to the category of devices of $10,615.31 (($25,000.00/$10,615.31) × 100 = 235.51 percent). Therefore, we stated that we believe the DETOUR™ System meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $25,000.00 for the DETOUR™ System is 478.09 percent of the cost of the device-related portion of the APC payment amount for the related service of $5,229.10 (($25,000.00/$5,229.10) × 100 = 478.09 percent). Therefore, we stated that we believe the DETOUR™ System meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related

service. The difference between the estimated average reasonable cost of $25,000.00 for the DETOUR™ System and the portion of the APC payment amount for the device of $5,229.10 is 186.25 percent of the APC payment amount for the related service of $10,615.31 ((($25,000.00 − $5,229.10)/$10,615.31) × 100 = 186.25 percent). Therefore, we stated that we believe the DETOUR™ System meets the third cost significance requirement.

We invited public comment on whether the DETOUR™ System meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

We did not receive any comments regarding whether the DETOURÔ System meets the cost significance criteria as described at § 419.66(d). Based on our findings from the first, second, and third cost significance tests, we have determined that the DETOURÔ System meets the cost significance criteria specified at § 419,66(d).

Comment: The applicant commented that the device offset amount assigned to HCPCS code 0505T should remain at $0.00 to align with the precedent set for similarly situated devices and ensure that hospitals continue to receive full and fair reimbursement for C1604.

Response: We appreciate the applicant's input regarding the device offset amount associated with HCPCS code 0505T. We note that we have addressed this comment in section IV.B of this final rule with comment period.

As discussed, the DETOUR™ System pass-through application was preliminarily approved for transitional pass-through payment under the alternative pathway effective January 1, 2024. After our review of the device pass-through application, we have determined that the DETOURÔ System meets the requirements for device pass-through status described at § 419.66 and we are finalizing approval for device pass-through payment status for the DETOURÔ System under the alternative pathway for devices that have an FDA Breakthrough Device designation and have received FDA marketing authorization for the indication covered by the Breakthrough Device designation.

(d) EndoSound Vision System™ (EVS™)

EndoSound, Inc. submitted an application for a new device category for transitional pass-through payment status for the EVS™ for CY 2025. The applicant is only seeking a new device category for transitional pass-through payment status for the Ultrasound Disposable Kit—Diagnostic/Therapeutic (UDK–T) component (hereinafter referred to as ''UDK–T'') of the EVS™. According to the applicant, the EVS™ is an ultrasound system designed to externally attach to an upper gastrointestinal (GI) endoscope (gastroscope/upper (EGD) endoscope). Per the applicant, the EVS™ is a device that, once attached to an EGD endoscope, temporarily converts the EGD endoscope to a fully capable endoscopic ultrasound (EUS) endoscope. The applicant asserted that the EVS™ can be coupled with an upper GI endoscope device to enable real-time ultrasound imaging, ultrasound guided needle aspiration, and other EUS guided procedures within the upper GI tract and surrounding organs. According to the applicant, the EVS™ consists of: (1) the EVS Scanner, a beamformer/scanner that performs ultrasound signal processing; (2) the Ultrasound Transducer Module (UTM), a reusable transducer assembly that converts the electrical signals from the scanner into ultrasound energy; (3) the Transducer Extension Cable (TEC), a cable/connector to interface the UTM to the EVS Scanner; and (4) the UDK–T, a disposable mounting kit with an operator control mechanism used to externally affix the EVS™ to a standard EGD endoscope and to provide needle and transducer angulation while maintaining the native gastroscope controls.

Please refer to the online application posting for the EVS™, available at *https://mearis.cms.gov/public/publications/device-ptp/DEP240228GJT0X*, for additional detail describing this device and the disease treated by the device.

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), the EVS™, which includes the UDK–T, received FDA Breakthrough Device designation effective July 29, 2021, as a device intended to provide optical visualization of, ultrasonic visualization of, and therapeutic access to, the upper GI tract including but not restricted to the organs, tissues, and subsystems: esophagus, stomach, duodenum, and underlying areas. FDA granted the applicant 510(k) clearance for the EVS™ on December 27, 2023, indicated for use such that when affixed to an endoscope, is intended to provide ultrasonic visualization of, and ultrasound guided therapeutic access to the upper GI tract including but not restricted to the organs, tissues, and subsystems: esophagus, stomach, duodenum, and underlying areas. The EVS™, mounted on an endoscope, is introduced orally when indications consistent with the requirement for a GI procedure are met. The EVS™ is a prescription-only device to be used by a qualified physician. The clinical environments where the system can be used include clinics, hospitals, and ambulatory surgery centers. We noted that while the indication for the FDA Breakthrough Device designation and the indication for the FDA 510(k) clearance vary slightly, we stated we believe that the FDA 510(k) clearance indication is the one covered by the Breakthrough Device designation. We received the application for a new device category for transitional pass-through payment status for the EVS™ on February 28, 2024, which is within 3 years of the date of the initial FDA marketing authorization.

We invited public comment on whether the EVS™, inclusive of the UDK–T component, meets the newness criterion at § 419.66(b)(1).

Comment: With respect to the newness criterion at § 419.66(b)(1), the applicant clarified that the EVS™ received FDA market authorization for 510(k) clearance. The applicant asserted that, according to FDA guidance,[34] 510(k) clearance is permissible for pre-determined Breakthrough Device designation and stated there were no changes specific to device components, mechanism of use, or indications of use for either the Breakthrough Device designation or the 510(k) clearance. The applicant stated the 510(k) clearance occurred within 3 years of the submission of the pass-through application such that the EVS™ meets the newness criterion at 42 CFR 419.66(b)(1).

Response: We appreciate the commenter's input. The EVS™ received Breakthrough Device designation effective July 29, 2021. We received the application for a new device category for transitional pass-through payment status for the EVS™ on February 28, 2024, which is within 3 years of December 27, 2023, the date of FDA 510(k) clearance. Based on our review of the application, we have determined that the EVS™ meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criterion at § 419.66(b)(3), the device must be an integral part of the service furnished, used for one patient only, come in

[34] See Breakthrough Devices Program, Guidance for Industry and Food and Drug Administration Staff Document issued on September 15, 2023. *https://www.fda.gov/media/162413/download.*

contact with human tissue, and be surgically inserted or implanted, or applied in or on a wound or other skin lesion. The applicant did not indicate whether the UDK–T component of the EVS™ is integral to the service furnished; however, the applicant did indicate that the UDK–T is single-use, comes in contact with human tissue, and is inserted as part of an endoscopy procedure. We preliminarily approved the EVS™ HCPCS code C1606 (Adapter, single-use (*i.e.,* disposable), for attaching ultrasound system to upper gastrointestinal endoscope) upon quarterly review under the alternative pathway with an effective date of July 1, 2024. We noted that C1606 was established for an adapter for attaching an ultrasound system to an upper GI endoscope that can only be used for a single procedure and cannot be reprocessed. As such, C1606 only describes devices that cannot be reprocessed.

We invited public comment on whether the UDK–T component of the EVS™ meets the eligibility criterion at § 419.66(b)(3).

Comment: The applicant submitted a comment reiterating that the EVS™ is used for one patient, comes into contact with human tissue, and is surgically implanted or inserted. The applicant clarified that the C1606 device component (*i.e.,* the UDK–T component) of the EVS™ meets the § 419.66(b)(3) criteria and is integral to the function and operation of the EVS™. The applicant further commented that C1606 was established for an adapter for attaching an ultrasound system to an upper GI endoscope that can only be used for a single procedure and cannot be reprocessed. The applicant asserted that the C1606 device component of the EVS™ meets the eligibility criterion at 42 CFR 419.66(b)(3).

Response: We appreciate the applicant's clarification. We agree with the applicant that the UDK–T component of the EVS™ is integral to the function and operation of the EVS™ and that the device is used for one patient only, comes into contact with human tissue, and is surgically implanted or inserted. After consideration of the applicant's comments and our review of the application we have determined that the UDK–T component of the EVS™ meets the eligibility requirement at § 419.66(b)(3).

With respect to the exclusion criterion at § 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker). The applicant claimed that the UDK–T meets the device eligibility requirements because it is not equipment or an item for which depreciation and financing expenses are recovered. In addition, the applicant asserted that the UDK–T is not a supply or material.

We invited public comment on whether the UDK–T component of the EVS™ meets the exclusion criterion at § 419.66(b)(4).

Comment: The applicant submitted a comment reiterating that the UDK–T component of the EVS™ is not equipment or an item for which depreciation and financing expenses are recovered and is not a supply or material.

Response: We appreciate the applicant's input. We agree with the applicant that the UDK–T component of the EVS™ is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets, or a material or supply furnished incident to a service. After consideration of the applicant comments we received and our review of the application, we have determined that the UDK–T component of the EVS™ meets the eligibility criterion at § 419.66(b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), the criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. According to the applicant, the EVS™ is an ultrasound system designed to externally attach to an upper GI endoscope (gastroscope/upper (EGD) endoscope). According to the applicant, no previous or existing device categories for pass-through payment appropriately describe the UDK–T. Per the applicant, device category C1748 (Endoscope, single-use (*i.e.,* disposable), Upper GI, imaging/illumination device (insertable)) does not appropriately describe the EVS™, inclusive of the UDK–T, because: (1) the EVS™, inclusive of the UDK–T, enables an endoscope that a hospital has to have added functionalities such as the ability to perform an EUS procedure, but is not an endoscope like the devices in C1748; (2) the EVS™, inclusive of the UDK–T, when used with an endoscope allows EUS procedures to be done without an elevator, unlike the other devices described in C1748; and (3) the EVS™, inclusive of the UDK–T, and the devices described in C1748 are used in different procedures. The applicant explained that CMS indicated that C1748 should always be billed with a HCPCS code in the ranges of 43260–43265 and 43274–43278, but there is no overlap between those HCPCS codes billed with C1748 and the HCPCS codes the applicant stated that the EVS™ would be reported with as shown in Table 48 of the CY 2025 OPPS/ASC proposed rule.

We did not identify an existing pass-through payment category that describes the UDK–T component of the EVS™.

We invited public comment on whether the UDK–T component of the EVS™ meets the device category criterion at § 419.66(c)(1).

Comment: The applicant agreed with CMS' assessment that there are no existing pass-through payment categories that describe the UDK–T component of the EVS™. The applicant further asserted that there is no other product similar in how the EVS™ assembles, operates, and functions and that, therefore, the device meets the criteria in 42 CFR 419.66(c)(1).

Response: We appreciate the applicant's input. After consideration of the comment and our review of the application, we continue to believe that there is no existing category or category previously in effect that appropriately describes the UDK–T component of the EVS™. Therefore, we have determined that the UDK–T component of the EVS™ meets the device category eligibility criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough

Device designation. The EVS™, inclusive of the UDK–T, has a Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation (as explained in more detail in the discussion of the newness criterion) and therefore is not evaluated for substantial clinical improvement.

We invited public comment on whether the EVS™, inclusive of the UDK–T component, meets the device category criterion at § 419.66(c)(2)(ii).

Comment: The applicant reiterated that the EVS™ and its components were granted Breakthrough Device designation and received FDA marketing authorization for the indication covered by the Breakthrough Device designation, and therefore, meets the criteria at 42 CFR 419.66(c)(2)(ii).

Response: We appreciate the applicant's comment. The EVS™ and its components have a Breakthrough Device designation effective July 29, 2021, and marketing authorization from FDA effective December 27, 2023, for the indication covered by the Breakthrough designation. Therefore, the EVS™ meets the criterion at § 419.66(c)(2)(ii) and is not evaluated for substantial clinical improvement at § 419.66(c)(2)(i). Based on our review of the application and the applicant's comments, we have determined that the EVS™ meets the device category criterion at § 419.66(c)(2).

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the EVS™ would be reported with HCPCS codes as shown in Table 117.

TABLE 117: HCPCS CODES REPORTED WITH THE EVS™

HCPCS Code	Long Descriptor	SI	APC
43231	Esophagoscopy, flexible, transoral; with endoscopic ultrasound examination	J1	5302
43232	Esophagoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s)	J1	5302
43237	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic ultrasound examination limited to the esophagus, stomach or duodenum, and adjacent structures	J1	5302
43238	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s), (includes endoscopic ultrasound examination limited to the esophagus, stomach or duodenum, and adjacent structures)	J1	5302
43242	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s), (includes endoscopic ultrasound examination limited to the esophagus, stomach and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastamosis)	J1	5302
43259	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic ultrasound examination, including the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis	J1	5302
43240	Esophagogastroduodenoscopy, flexible, transoral; with transmural drainage of pseudocyst (includes placement of transmural drainage catheter[s]/stent[s], when performed, and endoscopic ultrasound, when performed)	J1	5331
43253	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided transmural injection of diagnostic or therapeutic substance(s) (eg, anesthetic, neurolytic agent) or fiducial marker(s) (includes endoscopic ultrasound examination of the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis)	J1	5302

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). We noted that the applicant used the CY 2024 payment rates for the three tests of the cost criterion. For our calculations,

we used APC 5302, which had a CY 2024 payment rate of $1,812.99 at the time the application was received. HCPCS code 43232 in APC 5302 had a CY 2024 device offset amount of $14.50 at the time the application was received.[35] According to the applicant, the cost of the disposable, single-use UDK–T component of the EVS™ is $500.00.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The average reasonable cost of $500.00 for the UDK–T is 27.59 percent of the applicable APC payment amount for the service related to the category of devices of $1,812.99 (($500.00/$1,812.99) × 100 = 27.59 percent). Therefore, we stated that we believe the UDK–T component of the EVS™ meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $500.00 for the UDK–T is 3,448.28 percent of the cost of the device-related portion of the APC payment amount for the related service of $14.50 (($500.00/$14.50) × 100 = 3,448.28 percent). Therefore, we stated that we believe the UDK–T component of the EVS™ meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $500.00 for the UDK–T and the portion of the APC payment amount for the device of $14.50 is 26.78 percent of the APC payment amount for the related service of $1,812.99 (((($500.00 − $14.50)/$1,812.99) × 100 = 26.78 percent). Therefore, we stated that we believe the UDK–T component of the EVS™ meets the third cost significance requirement.

We invited public comment on whether the UDK–T component of the EVS™ meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

Comment: With respect to the cost criterion, the applicant agreed that the UDK–T component of the EVS™ meets all three of the cost criterion outlined in 42 CFR 419.66(c)(3) and (d)(1) through (3).

Response: We appreciate the applicant's input. After consideration of the comment we received and our findings from the first, second, and third cost significance tests, we agree that the UDK–T component of the EVS™ meets the cost significance criteria specified at § 419.66(d).

As discussed, the UDK–T component of the EVS™ pass-through application was preliminarily approved for transitional pass-through payment under the alternative pathway effective July 1, 2024. After considering the applicant comment received and our review of the device pass-through application, we have determined that the UDK–T component of EVS™ meets the requirements for device pass-through status described at § 419.66. We are finalizing approval for device pass-through payment status for the UDK–T component of the EVS™ under the alternative pathway for devices that have an FDA Breakthrough Device designation and have received FDA marketing authorization for the indication covered by the Breakthrough Device designation.

Comment: The applicant commented that HCPCS codes 43240 and 43253 should be added to the list of procedures that can be reported with C1606. The applicant stated that in Table 48 of the CY 2025 OPPS/ASC proposed rule, there are 6 primary HCPCS procedures codes reported with the nominated device, including HCPCS codes 43231, 43232, 43237, 43238, 43242, and 43259. The applicant stated that in the July 2024 ASC code pairs file,[36] dated June 14, 2024, 8 primary HCPCS procedures codes were listed with HCPCS code C1606, which included the HCPCS codes listed included those listed in proposed rule, with the addition of HCPCS codes 43240 and 43253. The applicant agreed with the preliminary approval of pass-through status for the nominated device and requested that it should be made clear that the 8 procedures codes on the July 2024 ASC code pairs file for C1606 are the procedures that can be reported with C1606.

Response: We thank the applicant for the comment. We will evaluate this request and add HCPCS codes 43240 and 43253 to the list of procedures that can be reported with C1606 if appropriate.

(e) iFuse Bedrock Granite™ Implant System

SI–BONE submitted an application for a new device category for transitional pass-through payment status for the iFuse Bedrock Granite™ Implant System for CY 2025. According to the applicant, the iFuse Bedrock Granite™ Implant System consists of iFuse Granite™ implants of various lengths and diameters and associated instruments sets. The titanium (Ti-6Al-4V ELI) iFuse Granite™ implant consists of a porous fusion sleeve with threaded length attached to a solid post that has connection and implant placement features of a typical pedicle fixation screw. The iFuse Granite™ implant is intended to provide sacropelvic fusion of the sacroiliac joint (when placed in the sacral-alar-iliac (SAI) trajectory) and fixation to the pelvis when used in conjunction with commercially available pedicle screw fixation systems as a foundational element for segmental spinal fusion only when performing both a lumbar and a sacroiliac joint (SIJ) fusion procedure in the same operative session. The applicant asserted that joint fusion occurs as a result of the device's porous surface and interstices and fixation occurs through the device's helical threaded design and traditional posterior fixation rod connection.

Per the applicant, the device can be placed into the pelvis in two trajectories: the SAI trajectory (*i.e.,* into the sacrum, across the SIJ and into the ilium), or directly into the ilium. The applicant explained that the iFuse Granite™ implant is typically placed in the SAI trajectory, bilaterally, and

[35] We noted that the applicant selected the APC payment rate of $1,814.88 and the APC level device offset amount of $178.95 for APC 5302. However, the values selected are inconsistent with the APC payment rate and the APC level device offset amount found in CY 2024 OPPS APC Offset File, which were corrected as described in the CY 2024 OPPS/ASC final rule with comment period correction (89 FR 9002). The HCPCS/CPT code level device offset amounts for the HCPCS/CPT codes provided by the applicant are available in the corrected Addendum P to the CY 2024 OPPS/ASC final rule with comment period. For our calculation, we selected the APC payment rate of $1,812.99 and the HCPCS/CPT code level device offset amount of $14.50 related to HCPCS 43232 in APC 5302 found in the corrected Addendum P, which are the accurate values for these codes. Based on our initial assessment in the proposed rule, using the APC payment rate of $1,812.99 and the device offset amount of $14.50 would result in the EVS™ meeting the cost significance requirement.

[36] July 2024 ASC code pairs file: *https://www.cms.gov/license/ama?file=/files/zip/july-2024-asc-codepairs.zip.*

oftentimes stacked to achieve two points of fusion and fixation/stabilization across each SIJ. According to the applicant, the iFuse Granite™ implant may also be used in a single, but bilateral, configuration, where only two implants may be required when replacing traditional pedicle screws in either a SAI trajectory or iliac trajectory. The applicant asserted that the iFuse Bedrock Granite™ Implant System is always used in addition to lumbar fusion instrumentation when used to perform lumbar and SIJ fusion at the same time.

Please refer to the online application posting for the iFuse Bedrock Granite™ Implant System, available at *https://mearis.cms.gov/public/publications/device-ptp/DEP240220LPFNM,* for additional detail describing the device and the disease treated by the device.

Comment: One commenter strongly encouraged CMS to consider the iFuse Bedrock Granite™ Implant System as having met all requirements for transitional pass-through payment status for CY 2025 and noting that that the device has Breakthrough Device designation for lumbar spinal deformity indications and was granted with New Technology Add-on Payment status effective in FY 2023 (87 FR 48780).

Response: We appreciate the commenters' input and support for the iFuse Bedrock Granite™ Implant System application for transitional pass-through payment. We have taken these comments into consideration in our final determination for pass-through status for the iFuse Bedrock Granite™ Implant System.

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), the iFuse Bedrock Granite™ Implant System received FDA Breakthrough Device designation effective November 23, 2021, as a treatment of the acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine, including: (1) degenerative disc disease (DDD), as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies; (2) severe spondylolisthesis (Grades 3 and 4) of the L5–S1 vertebra; (3) skeletally mature patients receiving fusions by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion; (4) spondylolisthesis; (5) trauma (*i.e.,* fracture or dislocation); (6) spinal stenosis; (7) deformities or curvatures (*i.e.,* scoliosis, kyphosis, and/or lordosis); (8) spinal tumor; and (9) pseudarthrosis, and/or failed previous fusion. Subsequently, FDA also granted the applicant 510(k) clearance for the iFuse Bedrock Granite™ Implant System on May 26, 2022, and December 22, 2022, for the indication covered by the Breakthrough Device designation with one additional indication for use: SIJ dysfunction that is a direct result of SIJ disruption and degenerative sacroiliitis, including conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months. We noted that the 510(k) clearance dated December 22, 2022, expanded the previously cleared indication of the iFuse Bedrock Granite™ Implant System to include general compatibility with certain compatible pedicle screw systems, whereas the indications under the May 26, 2022, 510(k) clearance only addressed compatibility of the iFuse Bedrock Granite™ Implant System with the SeaSpine Mariner Pedicle Screw System. Each 510(k) clearance, the May 26, 2022, and the December 22, 2022, are covered by the November 23, 2021, Breakthrough Device designation for the iFuse Bedrock Granite™ Implant System. We received the application for a new device category for transitional pass-through payment status for the iFuse Bedrock Granite™ Implant System on February 20, 2024, which is within 3 years of the dates of the May 26, 2022, and December 22, 2022, FDA marketing authorizations for the iFuse Bedrock Granite™ Implant System.

We invited public comment on whether the iFuse Bedrock Granite™ Implant System meets the newness criterion at § 419.66(b)(1).

Comment: With respect to the newness criterion at § 419.66(b)(1), the applicant reiterated that the iFuse Bedrock Granite™ Implant System received FDA marketing authorization on May 26, 2022. The applicant requested that CMS begin the newness period for the iFuse Bedrock Granite™ Implant System using the FDA Breakthrough Device designation of November 23, 2021, and the earlier market availability date of May 26, 2022, for the 510(k) marketing authorization.

Response: We appreciate the applicant's input. We agree with the applicant that the market availability date for the iFuse Bedrock Granite™ Implant System should be May 26, 2022, rather than December 22, 2022, because that is when the device became commercially available. We received the application for a new device category for transitional pass-through payment status for the iFuse Bedrock Granite™ Implant System on February 20, 2024, which is within 3 years of May 26, 2022, the date of 510(k) clearance. After consideration of the public comments received and our review of the application, we have determined that the iFuse Bedrock Granite™ Implant System meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criterion at § 419.66(b)(3), the device must be an integral part of the service furnished, used for one patient only, come in contact with human tissue, and be surgically inserted or implanted, or applied in or on a wound or other skin lesion. The applicant did not indicate if the iFuse Bedrock Granite™ Implant System is integral to the service furnished. The applicant provided that the iFuse Bedrock Granite™ Implant System is single-use, permanently implanted, and surgically inserted into the patient. However, we noted that we do not have sufficient information to determine if the associated instruments sets included in the iFuse Bedrock Granite™ Implant System meet the eligibility criterion at § 419.66(b)(3).

We invited public comment on whether the iFuse Bedrock Granite™ Implant System meets the eligibility criterion at § 419.66(b)(3).

Comment: The applicant submitted a comment clarifying that the iFuse Bedrock Granite™ Implant System, including the associated instrument sets included in the iFuse Bedrock Granite™ Implant System, meet the eligibility criterion at § 419.66(b)(3). Specifically, the applicant stated that the iFuse Bedrock Granite™ Implant System technology, including the associated instrument sets is integral to the service furnished, is single-use, permanently implanted, and surgically inserted into the patient, aligning fully with § 419.66(b)(3).

Response: We thank the applicant for the additional information. We agree with the applicant that the iFuse Bedrock Granite™ Implant System, including the associated instrument sets, is an integral part of the service furnished, used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted, or applied in or on a wound or other skin lesion. After consideration of the public comments received and our review of the application, we have determined that the iFuse Bedrock Granite™ Implant System meets the criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 419.66(b)(4), a device is not eligible to be considered for device pass-through

payment if it is any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker). The applicant did not indicate whether the iFuse Bedrock Granite™ Implant System is equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered, or if the iFuse Bedrock Granite™ Implant System is a supply or material furnished incident to a service.

We invited public comment on whether the iFuse Bedrock Granite™ Implant System meets the exclusion criterion at § 419.66(b)(4).

Comment: The applicant submitted a comment clarifying that the iFuse Bedrock Granite™ Implant System is not a material or supply furnished incident to a service and meets the eligibility criterion at § 419.66(b)(4) because neither the implant nor its associated instrument sets are a material or supply furnished incident to a service, and that the iFuse Bedrock Granite™ Implant System operates like a vast majority of spine and orthopedic hardware typically used in surgery of this type. The applicant also confirmed that the iFuse Bedrock Granite™ Implant System is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets.

Response: We appreciate the applicant's input. We agree with the applicant that the iFuse Bedrock Granite™ Implant System, including the associated instruments, is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets, or a material or supply such as a suture or clip furnished incident to a service. After consideration of the public comments received and our review of the application, we have determined that the iFuse Bedrock Granite™ Implant System meets the eligibility criterion at § 419.66(b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), the criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. According to the applicant, no previous or existing device categories for pass-through payment appropriately describe the iFuse Bedrock Granite™ Implant System. Per the applicant, the device category C1821 (Interspinous process distraction device) does not appropriately describe the iFuse Bedrock Granite™ Implant System because the iFuse Bedrock Granite™ Implant System is used to fixate and fuse, while the devices described in C1821 are interspinous spacers which, after implantation, are opened or expanded to distract the neural foramina and decompress the nerves. The applicant asserted that device category C1713 (Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable)) also does not appropriately describe the iFuse Bedrock Granite™ Implant System because the iFuse Bedrock Granite™ Implant System allows for simultaneous fusion of the SIJ and fixation of the pelvis by connecting via the Tulip Connector to the base of the stabilizing rods within the lumbosacral spinal construct, while C1713 includes implantable pins and/or screws that are used to oppose soft tissue-to-bone, tendon-to-bone, or bone-to-bone. Per the applicant, the device category C1889 (Implantable/insertable device, not otherwise classified) also does not appropriately describe the iFuse Bedrock Granite™ Implant System because it does not describe any specific device category, and therefore does not uniquely describe the device category proposed for the iFuse Bedrock Granite™ Implant System.

We noted that, according to the applicant, the iFuse Bedrock Granite™ Implant System is intended to provide sacropelvic fusion of the sacroiliac joint (when placed in the SAI trajectory) and fixation to the pelvis when used in conjunction with commercially available pedicle screw fixation systems as a foundational element for segmental spinal fusion only when performing both a lumbar and SIJ fusion procedure in the same operative session. The applicant asserted that joint fusion occurs as a result of the device's porous surface and interstices and fixation occurs through the device's helical threaded design and traditional posterior fixation rod connection. We stated that we believe that the device category C1713 may appropriately describe the iFuse Bedrock Granite™ Implant System and questioned whether a transfixing device utilizing the Tulip Connector is sufficiently distinguishable from traditional implantable pins or screws that it is meant to replace. In this context, based on the description the applicant provided, we stated that we believe the iFuse Bedrock Granite™ Implant System may be similar to the devices described by C1713, and therefore, the iFuse Bedrock Granite™ Implant System may also be appropriately described by C1713.

In addition, we stated that we believe the device category C1889 may appropriately describe the iFuse Bedrock Granite™ Implant System because C1889 may be used to describe any implantable/insertable device that is not otherwise described by a more specific device category and is, therefore, sufficiently broad to include implantable devices that allow for simultaneous fusion of the SIJ and fixation of the pelvis. We noted that in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79562), CMS created C1889 with the specific intent to recognize devices furnished during a device intensive procedure that are not described by a specific Level II HCPCS Category C-code. In this context, we stated that we believe the iFuse Bedrock Granite™ Implant System may be appropriately described by either C1713 or C1889.

We invited public comment on whether the iFuse Bedrock Granite™ Implant System meets the device category criterion at § 419.66(c)(1).

Comment: In response to our concerns that the iFuse Bedrock Granite™ Implant System may be appropriately described by the device pass-through category C1713, the applicant and a few other commenters asserted that the iFuse Bedrock Granite™ Implant System is not described by C1713. Specifically, the applicant relied upon the C1713 descriptor and supporting guidance: C1713: Anchor for opposing bone-to-bone or soft tissue-to-bone—Implantable pins and/or screws that are used to oppose soft tissue-to-bone, tendon-to-bone, or bone-to-bone. Screws oppose tissues via drilling as follows: soft tissue-to-bone, tendon-to-bone, or bone to-bone fixation. Pins are inserted or drilled into bone, principally with the intent to facilitate stabilization or oppose bone-to-bone. This may include orthopedic plates with accompanying washers and nuts. This category also applies to synthetic bone substitutes that may be used to fill bony void or gaps (*i.e.,* bone substitute implanted into a bony defect created from trauma or surgery). The applicant and commenters clarified that, unlike

devices described by C1713, the iFuse Bedrock Granite™ Implant System's intended use is not to anchor bone to bone, or soft tissue, tendons, or ligaments to bone, but to promote simultaneous pelvic stabilization and fusion across the SI joint space, via a unique and proprietary Tulip Connector that attaches to the spinal fusion construct. The applicant and another commenter further provided that the typical use scenarios for reporting C1713 include orthopedic procedures involving bone sutures, anchors, small plastic polyether ether ketone (PEEK) screws for bone-to-bone or bone-to-tendon/tissue connections, often in anatomic areas outside of the spine (including the extremities, shoulders, knees and small bones). Furthermore, the applicant and commenter noted that C1713 is used to report procedures that are mostly non-fusion applications with the intent to restore motion or function to anatomy(ies) and that C1713 can also include bone void filler or bone substitute materials (*e.g.,* demineralized bone matrix, Subchondroplasty, etc.).

The applicant and commenters specified that other implanted devices in this category restore motion while the iFuse Bedrock Granite™ Implant System immobilizes; and that the iFuse Bedrock Granite™ Implant System is intended to traverse an articulating joint space and fuse two bones via bridging the joint to immobilize it so bony fusion may occur.

Response: We appreciate the applicant and commenters' clarifications and the additional information. We agree that the ability to simultaneously fuse the SIJ and fixate the pelvis to the spinal fusion construct distinguishes the iFuse Bedrock Granite™ Implant System from other implant devices described by C1713 that anchor bone-to-bone, or soft tissue-to-bone, tendons-to-bone, or ligaments-to-bone. We also agree that the iFuse Bedrock Granite™ Implant System is distinguishable from other implant devices described by C1713 because it secures bone to a metal rod via the Tulip Connector, and that typical C1713 implants do not include joint fusion technologies, and are not specific to anatomic areas, nor do they function similarly to the iFuse Bedrock Granite™.

After consideration of the public comments we received and our review of the application, we agree that existing device category C1713 does not appropriately describe the iFuse Bedrock Granite™.

Comment: In response to our concerns that the iFuse Bedrock Granite™ Implant System may be appropriately described by C1889, the applicant and a few commenters noted that C1889 is not, and has not been, a device pass-through category code, and that it is not included in the complete list of device pass-through category codes.

Response: We appreciate the commenters' input. We agree that C1889 is not a device pass-through category code, and therefore, agree that it is not relevant to our determination at § 419.66(c)(1).

After consideration of the public comments received and our review of the application, we agree there is no existing category or category previously in effect that appropriately describes the iFuse Bedrock Granite™ Implant System. Based on this information, we have determined that the iFuse Bedrock Granite™ Implant System meets the eligibility criterion at § 419.66(c)(1).

The second criterion for establishing a device category at § 419.66(c)(2) provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The iFuse Bedrock Granite™ Implant System has a Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation (as explained in the discussion of the newness criterion) and therefore is not evaluated for substantial clinical improvement.

We invited public comment on whether the iFuse Bedrock Granite™ Implant System meets the device category criterion at § 419.66(c)(2)(ii).

We did not receive any public comment regarding whether the iFuse Bedrock Granite™ Implant System meets the device category criterion at § 419.66(c)(2)(ii). The iFuse Bedrock Granite™ Implant System has a Breakthrough Device designation effective November 23, 2021, and marketing authorization from FDA effective May 26, 2022, for the indication covered by the Breakthrough Device designation. Based on our review of the application, we have determined that the iFuse Bedrock Granite™ Implant System meets the device category criterion at § 419.66(c)(2)(ii) and is not evaluated for substantial clinical improvement at § 419.636(c)(2)(i).

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the iFuse Bedrock Granite™ Implant System would be reported with HCPCS codes shown in Table 118.

TABLE 118: HCPCS CODES REPORTED WITH THE IFUSE BEDROCKGRANITE™ IMPLANT SYSTEM

HCPCS Code	Long Descriptor	SI	APC
27279	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device	J1	5116
22612	Arthrodesis, posterior or posterolateral technique, single interspace; lumbar (with lateral transverse technique, when performed)	J1	5116
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace, lumbar	J1	5116
22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace, lumbar	J1	5116

According to the applicant, the iFuse Bedrock Granite™ Implant System is only used when both a SIJ fusion procedure and a lumbar fusion procedure are performed in the same operative session. The applicant stated that the iFuse Bedrock Granite™ Implant System is not utilized when only a SIJ fusion procedure is performed (HCPCS code 27279) or when only a lumbar fusion procedure is performed (HCPCS code 22612, 22630, or 22633). Rather, per the applicant, the appropriate coding of the procedure where the iFuse Bedrock Granite™ Implant System is used should include the HCPCS code for SIJ fusion (HCPCS code 27279) *and* a HCPCS code for lumbar fusion (HCPCS code 22612, 22630, or 22633). Per the applicant, the selection of the primary lumbar fusion HCPCS code (HCPCS code 22612, 22630, or 22633) is dependent on the procedure performed.

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). We noted that the applicant utilized the CY 2024 payment rates for the three tests of the cost criterion. For our calculations, we used APC 5116, which had a CY 2024 payment rate of $17,756.28 at the time the application was received. The applicant stated the iFuse Bedrock Granite™ Implant System device should be reported with the SIJ fusion procedure HCPCS code 27279 along with one of the three lumbar fusion procedures (HCPCS code 22612, 22630 or 22633). While the applicant utilized HCPCS code 22612 for the device offset amount for test two of the cost criterion, we stated that we believe that HCPCS code 27279 is the appropriate HCPCS code for the offset and subsequent calculation. Specifically, we understood that code 27279 is always reported when the iFuse Bedrock Granite™ Implant System is used along with only one of the three specified lumbar fusion codes and that the SIJ fusion procedure described by code 27279 is always performed when the iFuse Bedrock Granite™ is used along with just one of three possible lumbar procedures, depending on the specific surgical approach used. Therefore, we stated that we believe that neither HCPCS codes 22612, 22630, nor 22633 is appropriate to use for the cost criterion calculation. As such, we used HCPCS code 27279, the code that should always be reported with the iFuse Bedrock Granite™ Implant System, for our calculations. HCPCS code 27279 in APC 5116 had a CY 2024 device offset amount of $12,264.26 at the time the application was received. According to the applicant, the cost of the iFuse Bedrock Granite™ Implant System is $11,689.00.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The average reasonable cost of $11,689.00 for the iFuse Bedrock Granite™ Implant System is 65.83 percent of the applicable APC payment amount for the service related to the category of devices of $17,756.28 (($11,689.00/$17,756.28) × 100 = 65.83 percent). Therefore, we stated that we believe the iFuse Bedrock Granite™ Implant System meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $11,689.00 for the iFuse Bedrock Granite™ Implant System is 95.31 percent of the cost of the device-related portion of the APC payment amount for the related service of $12,264.26 (($11,689.00/$12,264.26) × 100 = 95.31 percent). Therefore, we stated that we believe the iFuse Bedrock Granite™ Implant System does not meet the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $11,689.00 for the iFuse Bedrock Granite™ Implant System and the portion of the APC payment amount for the device of $12,264.26 is negative 3.24 percent of the APC payment amount for the related service of $17,756.28 ((($11,689.00 − $12,264.26)/$17,756.28) × 100 = − 3.24 percent). Therefore, we stated that we believe the iFuse Bedrock

Granite™ Implant System does not meet the third cost significance requirement.

We invited public comment on whether the iFuse Bedrock Granite™ Implant System meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

Comment: In response to our proposal to utilize HCPCS code 27279 for evaluation of cost criteria for the iFuse Bedrock Granite™ Implant System, the applicant and another commenter asserted that the most appropriate HCPCS code to evaluate the criterion for the iFuse Bedrock Granite™ Implant System is HCPCS code 22612. The applicant and another commenter provided several reasons: (1) The intended indication and use of the nominated device in the hospital outpatient and ASC setting will be in support of the lumbar spinal construct for lumbar fusion cases; (2) The typical patient for the nominated device has severe lumbar spinal pathology, such as scoliosis or kyphosis of the lumbar spine, as the primary diagnosis, whereas sacroiliac joint disease or dysfunction is not the primary diagnosis or procedure indication for these patients; and (3) As evidence of the consensus on this type of pelvic fixation to support lumbar patients, numerous commercial payers across the U.S. agree and have published medical coverage policies stating that SI joint fusion at the bottom of a long construct is covered for treatment of lumbar disease or dysfunction.[37] The applicant claimed that in the outpatient setting, the iFuse Bedrock Granite™ Implant System would always be used in conjunction with one of three spinal fusion procedures and would always be considered as a secondary procedure. The applicant stated that of the four relevant HCPCS codes in its application (HCPCS codes 22612, 22630, 22633, and 27279), the threshold for HCPCS code 22612 is the most appropriate for evaluating the cost criterion for the iFuse Bedrock Granite™ Implant System. The applicant provided the following reasons: (1) HCPCS code 22612 is the only lumbar spinal fusion procedure payable by Medicare in both hospital outpatient and ASC settings; (2) HCPCS code 22612 has a lower device offset, consistent with CMS' policies; and (3) HCPCS code 22612 is the primary code in spinal fusion procedures in which the iFuse Bedrock Granite™ will always be used as an adjunctive technology, when connected to compatible posterior spinal rods, to improve the potential outcome of the lumbar fusion case. Finally, the applicant argued that HCPCS code 22612 would also be appropriate from a primary assignment rank perspective, stating that since the nominated device will have multiple J1 HCPCS codes, it would be appropriate to determine which HCPCS code has the highest primary assignment ranking. The applicant referenced Addendum J of the CY 2024 final rule and the CY 2025 proposed rule stating that HCPCS code 22612 has a higher ranking for primary assignment purposes than HCPCS code 27279. The applicant claimed that it would be consistent with CMS' policy on assignment of primary procedures to select the cost threshold for HCPCS code 22612, as opposed to HCPCS code 27279, to assess the cost criterion for the iFuse Bedrock Granite™ Implant System.

Response: We thank the commenters for the additional information. Based on the updated information provided in the comments, we agree HCPCS code 22612 is an appropriate procedure code for the evaluation of the cost criterion for the iFuse Bedrock Granite™ Implant System. As such, we have updated our calculations accordingly for the second and third cost significance requirements, at § 419.66(d)(2) and (3), respectively as below.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The average reasonable cost of $11,689 for the iFuse Bedrock Granite™ Implant System is 136.75 percent of the cost of the device-related portion of the APC payment amount for the related service of $8,547.88 (($11,689.00/$8,547.88) × 100 = 136.75 percent). Therefore, we agree that the iFuse Bedrock Granite™ Implant System meets the second cost significant requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $11,689.00 for the iFuse Bedrock Granite™ Implant System and the portion of the APC payment amount for the device of $8,547.88 is 17.70 percent of the APC payment amount for the related service of $17,756.28 ((($11,689.00 − $8,547.88)/$17,756.28) × 100 = 17.70 percent). Therefore, we agree that the iFuse Bedrock Granite™ Implant System meets the third cost significance requirement.

Comment: The applicant and another commenter stated that they believe it is appropriate for CMS to use the lowest APC payment rate applicable for use with the nominated device regarding the iFuse Bedrock Granite™ Implant System, stating that this is consistent with increasing probability that the device will pass the cost significance test. The applicant and another commenter asserted that CMS should likewise use the offset amount that gives the nominated device the best opportunity to pass the test, arguing that HCPCS code 22612 is the most appropriate code for assessing the cost threshold in this context.

Response: We thank the commenters for their input. As we explained in the CY 2005 OPPS/ASC final rule with comment period (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion. We note that in both the original evaluation of cost in the proposed rule as well as in the re-evaluation in this final rule, we followed this procedure by selecting the lowest, and in this case only, APC payment rate applicable for APC 5116 of $17,756. While we note that since 2017, we calculate the device offset amount at the HCPCS/CPT® code level instead of the APC level (89 FR 79657), we disagree that we are bound by the same policy to select the HCPCS code with the lowest offset amount. We believe that doing so would potentially conflict with our stated policy of selecting the lowest APC payment rate, which is intended to increase the probability the device will pass the cost significance test. We do, however, agree to use HCPCS code 22612 and its device offset amount for the evaluation of the cost criterion for the iFuse Bedrock Granite™ Implant System, based on the updated information we received in the comments.

Comment: The applicant requested that the iFuse Bedrock Granite™ Implant System be approved for the transitional pass-through status and the

[37] Anthem CG–SURG–111: ''Open sacroiliac joint fusion procedures are considered medically necessar y. . . *during multisegment spinal constructs (for example, correction of deformity in scoliosis or kyphosis surgery) extending to the ilium.*'' Ref: *https://www.anthem.com/dam/medpolicies/abcbs/active/guidelines/gl_pw_e001136.html* (accessed August 24, 2024).

device offset amount should be set to $0. The applicant asserted that the costs of the iFuse Bedrock Granite™ Implant System are not included as part of the device-related portion of the APC 5116 payment supporting hospitals performing a primary lumbar fusion procedure. The applicant stated that hospital outpatient departments and ASCs do not typically support combination lumbar fusion with SI joint fusion procedures performed in the same operative session, and claims data reveals an extremely low volume of these codes being reported together each year in the HOPD setting relative to other code pairings. In addition, the applicant stated that the iFuse Bedrock Granite™ Implant System cannot be used as a stand-alone device; rather, it will only be used in conjunction with one of three lumbar spinal fusion procedures. The applicant referred to the CY 2024 and CY 2025 Addendum J files and stated that all three HCPCS codes describing lumbar fusion which are eligible for payment in the hospital outpatient setting (HCPCS 22612, 22630, and 22633) are all ranked higher for primary assignment purposes than HCPCS code 27279. The applicant therefore argued that the device costs of the iFuse Bedrock Granite™ Implant System have not been appropriately included in the device offset of any of the fusion procedures. The applicant further stated that, since the costs of the iFuse Bedrock Granite™ Implant System are purely additive for hospitals currently performing lumbar spinal fusion procedures (HCPCS codes 22612, 22630, or 22633) mapping to Comprehensive APC 5116, the applicant requested that CMS set the device offset to $0 when granting transitional pass-through status for the iFuse Bedrock Granite™ Implant System for CY 2025.

Response: After further review, we are persuaded by commenters that the iFuse Bedrock Granite™ Implant System cannot be used as a stand-alone device and that it is only used in conjunction with the existing device costs for the lumbar spinal fusion procedures. Therefore, we agree that the device is not included in the existing APC payment amount for these procedures and a device offset amount under 42 CFR 419.66(h) would not be appropriate at this time. For CY 2025, for the procedures we described that are performed with this new transitional pass-through device category, we are accepting the commenter's recommendation to apply a $0 offset for the iFuse Bedrock Granite™ Implant System. We refer the reader to Addendum B of this CY 2025 OPPS/ASC final rule with comment period for APC payment rates.

After consideration of the public comments we received and our findings from the first, second, and third cost significance tests, we agree that the iFuse Bedrock Granite™ meets the cost significance criteria specified at § 419.66(d).

After consideration of the public comments we received and our review of the device pass-through application, we have determined that the iFuse Bedrock Granite™ Implant System meets the criteria for device pass-through status described at § 419.66. We are finalizing approval for device pass-through payment status for the iFuse Bedrock Granite™ Implant System effective January 1, 2025, under the alternative pathway for devices that have an FDA Breakthrough Device Designation and have received FDA marketing authorization for the indication covered by the Breakthrough Device designation.

(f) Paradise® Ultrasound Renal Denervation (RDN) System

ReCor Medical, Inc. submitted an application for a new device category for transitional pass-through payment status for the Paradise® Ultrasound RDN System for CY 2025. Per the applicant, the Paradise® Ultrasound RDN System is a catheter-based system that delivers ultrasound energy in the location of sympathetic nerves surrounding the renal arteries. The applicant explained that the Paradise® Ultrasound RDN System is indicated to reduce blood pressure as an adjunctive treatment in patients with hypertension in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure. According to the applicant, the Paradise® Catheter, when used with the other Paradise® Ultrasound RDN System components, provides complete 360-degree energy delivery and targeted ablation depth with each energy emission with the goal of disrupting the nerves and consequently achieving a reduction in systemic arterial blood pressure. The applicant asserted that the Paradise® Catheter protects the artery walls using a cooling system during periods of ultrasound energy emission (also called sonications).

Per the applicant's instructions for use, the Paradise® Ultrasound RDN System includes the following components: (1) Paradise® Generator, which circulates coolant fluid and electrical energy to the Paradise® Catheter via the Paradise® Cable and Paradise® Cartridge; (2) Paradise® Catheter, which connects with the Paradise® Generator and has a distal balloon (available in six different diameters that correspond to varying artery diameter ranges) that is pressurized using coolant fluid; (3) Paradise® Cartridge, which controls the fluid flow into and out of the Paradise® Catheter when used in conjunction with the Paradise® Generator; (4) Paradise® Connection Cable, which transfers electrical energy from the Paradise® Generator to the Paradise® Catheter; (5) Paradise® Remote, included with the Paradise® Generator for optional use; and (6) Paradise® Cart, an optional wheeled cart to which the Paradise® Generator can be mounted to stabilize the Paradise® Generator during a procedure and to transport the Paradise® Generator from one location to another. Per the applicant, additional items required for the procedure include: (1) a bag of coolant fluid for inflation and cooling of balloon; (2) a 0.014 inch guidewire to track the Paradise® Catheter into position for delivery of ultrasound energy; (3) a push/pull style hemostasis valve; (4) a 6 French (Fr) or larger guide sheath; and (5) a 7 Fr or larger guide catheter. According to the applicant, the Paradise® Catheter, Paradise® Cartridge, and Paradise® Connection Cable are single-patient, one-time use components of the system. According to the applicant, key steps for operating the Paradise® Ultrasound RDN System include: (1) gaining access to the femoral artery using standard interventional techniques and placing a 7 Fr (or larger) guide catheter; (2) advancing the 7 Fr guide catheter into the left or right renal artery under fluoroscopic guidance; (3) performing an angiogram to verify the patency of the left or right renal artery; (4) measuring the distal, mid, and proximal artery diameters and selecting the appropriate Paradise® Catheter balloon size; (5) preparing and attaching the Paradise® Cartridge, Paradise® Connection Cable, and sterile water supply, and connecting the Paradise® Cartridge extension tubing to the Paradise® Catheter; (6) preparing and flushing the Paradise® Catheter; removing access devices from the lumen of the guide catheter and inserting a 0.014 inch guidewire; (7) verifying the balloon on the Paradise® Catheter is deflated; (8) tracking the Paradise® Catheter over the guidewire and gently inserting the Paradise® Catheter into the push/pull style hemostasis valve and guide catheter; (9) advancing and positioning the Paradise® Catheter in desired locations within the renal arteries; (10) inflating the balloon via

the Paradise® Generator; (11) verifying the position of the balloon and catheter transducer via fluoroscopy and contrast injection; (12) performing denervation of the left and/or right renal artery by delivery of ultrasound energy; (13) verifying balloon deflation via fluoroscopy before moving to the next location; (14) withdrawing the Paradise® Catheter back into the guide catheter prior to moving the device into an alternate artery or accessory vessel, continuing to another position and exchanging the balloon catheter, as needed; (15) removing the Paradise® Catheter, ensuring that Paradise® Catheter balloon is in a deflated state prior to removal, by slowly withdrawing the Paradise® Catheter through the guide catheter, until completely withdrawn, and removing the guidewire and guide catheter; and (16) closing the wound per standard of practice.

Please refer to the online application posting for the Paradise® RDN System, available at *https://mearis.cms.gov/public/publications/device-ptp/DEP231128137E1,* for additional detail describing the device and the disease treated by the device.

Comment: Many commenters expressed their support for the approval of the Paradise® Ultrasound RDN System for transitional pass-through payment. In addition, many commenters shared their positive experiences with the Paradise® Ultrasound RDN System.

Response: We appreciate the commenters' input and support for the Paradise® Ultrasound RDN System application for transitional pass-through payment. We have taken these comments into consideration in our final determination for pass-through status for the Paradise® Ultrasound RDN System.

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), the Paradise® Ultrasound RDN System received FDA Breakthrough Device designation effective December 4, 2020, as a device with the indicated use to reduce blood pressure in adult (≥22 years of age) patients with uncontrolled hypertension, who may be inadequately responsive to, or who are intolerant to anti-hypertensive medications. FDA approved the premarket approval application (PMA) for the Paradise® Ultrasound RDN System on November 7, 2023, for the indicated use to reduce blood pressure as an adjunctive treatment in hypertension patients in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure. We noted that while the indication for the FDA Breakthrough Device designation and the indication for the FDA premarket approval vary slightly, we believed that FDA premarket approval indication is the one covered by the Breakthrough Device designation. We received the application for a new device category for transitional pass-through payment status for the Paradise® Ultrasound RDN System on November 28, 2023, which is within 3 years of the date of the initial FDA marketing authorization.

We invited public comment on whether the Paradise® Ultrasound RDN System meets the newness criterion at § 419.66(b)(1).

Comment: With respect to the newness criterion at § 419.66(b)(1), the applicant reiterated that the Paradise® Ultrasound RDN System received Breakthrough Device designation and later FDA approval on November 7, 2023, and CMS received the application for a new device category for transitional pass-through payment status on November 28, 2023, which is within 3 years of FDA approval. A few commenters stated the Paradise® Ultrasound RDN System meets the newness criterion, with one commenter specifically noting that the Paradise® Ultrasound RDN System meets the newness criterion based on its FDA Breakthrough Device designation.

Response: We appreciate the commenters' input. We agree with the applicant and commenters that the Paradise® Ultrasound RDN System meets the device eligibility requirements of § 419.66(b)(1); however, while we agree that the Paradise® Ultrasound RDN System meets the eligibility criterion specified at § 419.66(b)(1), we note that a device's uniqueness or FDA designation does not alone qualify a device for transitional pass-through payment. Specifically, when we adopted the alternative pathway for device pass-through payments under the OPPS, we stated that applications for devices that have received FDA marketing authorization and are part of the FDA Breakthrough Devices Program would not be evaluated in terms of the current substantial clinical improvement criterion at § 419.66(c)(2) for purposes of determining device pass-through payment status, but would continue to need to meet the other requirements for pass-through payment status in our regulations at § 419.66(c)(1) (84 FR 61295).

The Paradise® Ultrasound RDN System received Breakthrough Device designation on December 4, 2020. We received the application for a new device category for transitional pass-through payment status for the Paradise® Ultrasound RDN System on November 28, 2023, which is within 3 years of November 7, 2023, the date of FDA PMA. Based on our review of the application, we have determined that the Paradise® Ultrasound RDN System meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criteria at § 419.66(b)(3), the device must be an integral part of the service furnished, be used for one patient only, come in contact with human tissue, and be surgically inserted or implanted, or applied in or on a wound or other skin lesion. The applicant did not explicitly state whether the Paradise® Ultrasound RDN System is integral to the service furnished. With respect to whether the Paradise® Ultrasound RDN System is used for one patient only, the applicant asserted that the Paradise® Catheter, Paradise® Cartridge, and Paradise® Connection Cable are single-patient use. However, the Paradise® Generator, Paradise® Remote, and Paradise® Cart are reusable and are capital equipment. While the applicant did not explicitly state whether the Paradise® Ultrasound RDN System comes into contact with human tissue, the applicant provided that the Paradise® Catheter is placed within the renal artery. According to the applicant, the Paradise® Ultrasound RDN System is an implantable device. We noted that the Paradise® Generator, Paradise® Remote, and Paradise® Cart are reusable, do not come in contact with the patient's tissue, are not surgically implanted or inserted, or applied in or on a wound or other skin lesion, as required by § 419.66(b)(3).

We invited public comment on whether the Paradise® Ultrasound RDN System meets the eligibility criterion at § 419.66(b)(3).

Comment: The applicant submitted a comment clarifying that the Paradise® Ultrasound RDN System is an integral part of the service furnished and meets the eligibility criterion at § 419.66(b)(3) because the Paradise® Ultrasound RDN System performs the ablations via ultrasound which produce the therapeutic effect to reduce blood pressure. The applicant also clarified that the Paradise® Ultrasound RDN System comes into contact with human tissue and meets the eligibility criterion at § 419.66(b)(3) because the Paradise® Ultrasound RDN System's ablation catheter comes in contact with human tissue and is surgically inserted into the body and removed at the end of the procedure. Finally, the applicant reiterated that the Paradise® Connector

Cable, Paradise® Cartridge, and Paradise® Catheter components of the Paradise® Ultrasound RDN System are single-use only and the Paradise® Catheter is surgically inserted into the body and removed at the end of the procedure.

Response: We appreciate the applicant's input. We agree with the applicant that the Paradise® Ultrasound RDN System is an integral part of the service furnished, and is surgically implanted or inserted, or applied in or on a wound or other skin lesion. In addition, we agree that the Paradise® Connector Cable, Paradise® Cartridge, and Paradise® Catheter components of the Paradise® Ultrasound RDN System are used for one patient only and come in contact with human tissue. We continue our discussion and final determination of the criterion at § 419.66(b)(3) in our response below.

With respect to the exclusion criterion at § 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker). While the applicant did not explicitly state whether the Paradise® Ultrasound RDN System, or select components, is equipment, an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, per the applicant, the Paradise® Catheter, Paradise® Cartridge, and Paradise® Connection Cable are single-use only. The applicant further explained that the Paradise® Generator, Paradise® Cart, and Paradise® Remote are capital equipment; as such, they are excluded from device pass-through payment eligibility under § 419.66(b)(4). The applicant did not explicitly state whether the Paradise® Ultrasound RDN System is a supply or material furnished incident to a service.

The applicant requested pass-through payment for the Paradise® Ultrasound RDN System, but we questioned whether only the Paradise® Catheter component of the Paradise® Ultrasound RDN System, as opposed to the whole system, is eligible for pass-through payments under § 419.66(b)(3) or at § 419.66(b)(4). We stated that we do not believe the Paradise® Generator, Paradise® Cable, Paradise® Cartridge, Paradise® Connection Cable, Paradise® Remote, or Paradise® Cart meet the eligibility requirements under § 419.66(b)(3) or at § 419.66(b)(4), and, as such, are not eligible for pass-through payments.

We invited public comment on whether the Paradise® Ultrasound RDN System meets the exclusion criterion at § 419.66(b)(4).

Comment: The applicant submitted a comment clarifying that the Paradise® Cartridge and Paradise® Connector Cable meet the eligibility criterion at § 419.66(b)(4) because they are critical parts of a single piece of equipment, they are not sold without the Paradise® Catheter, and because these two components are not separable from the Paradise® Catheter component. With regard to our question as to whether only the Paradise® Catheter component of the Paradise® Ultrasound RDN System is eligible for pass-through payments under § 419.66(b)(3) or at § 419.66(b)(4), the applicant stated that the Paradise® Cartridge and Paradise® Connector Cable are eligible for pass-through payment because the procedure cannot be performed without all three components, *i.e.,* the Paradise® Catheter, the Paradise® Cartridge, and the Paradise® Connector Cable. The applicant further stated that while the Paradise® Connector Cable and Paradise® Cartridge are not inserted into the body, the Paradise® Catheter that is inserted into the body will not function without them. Therefore, the applicant asserted that the Paradise® Connector Cable and Paradise® Cartridge should also be eligible for transitional pass-through status along with the Paradise® Catheter. The applicant also confirmed that the Paradise® Generator, Paradise® Remote, and Paradise® Cart components of the Paradise® Ultrasound RDN System are capital equipment and are not eligible for pass-through payment. With regard to our question about whether the Paradise® Ultrasound RDN System is a supply or material furnished incident to a service, the applicant submitted a comment clarifying that the Paradise® Ultrasound RDN System is not a supply or material furnished incident to a service because the purpose of the procedure is to use the Paradise® Ultrasound RDN System to treat the patient with renal denervation; therefore, it is integral and essential and it is not a supply that is used incident to or for the purpose of doing another procedure.

Response: We thank the applicant for the clarification and agree with the applicant that the Paradise® Catheter, Paradise® Cartridge, and Paradise® Connection Cable components of the Paradise® Ultrasound RDN System meet the eligibility requirements under § 419.66(b)(3) and (4) because the Paradise® Connector Cable and Paradise® Cartridge are required parts of a single piece of equipment, they are not sold without the Paradise® Catheter, they are single-use and they are not separable. We also agree with the applicant that the Paradise® Generator, Paradise® Remote, or Paradise® Cart are capital equipment and do not meet the eligibility requirements under § 419.66(b)(3) or (4). Finally, we agree with the applicant that the Paradise® Ultrasound RDN System is not a material or supply furnished incident to a service. After consideration of the public comments we received and our review of the application, we have determined that the applicable components of the Paradise® Ultrasound RDN System meet the eligibility criteria at § 419.66(b)(3) and (4).

In addition to the criteria at § 419.66(b)(1) through (4), the criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. Per the applicant, the Paradise® Ultrasound RDN System is a catheter-based system that delivers ultrasound energy in the location of sympathetic nerves surrounding the renal arteries. According to the applicant, no previous or existing device categories for pass-through payment have encompassed the Paradise® Ultrasound RDN System. Per the applicant, device categories C1753 (Catheter, intravascular ultrasound) and C1888 (Catheter, ablation, noncardiac, endovascular (implantable)) do not appropriately describe the Paradise® Ultrasound RDN System. The applicant asserted that C1753 does not appropriately describe the Paradise® Ultrasound RDN System because the Paradise® Ultrasound RDN System is used to treat a disease and denervates renal nerves, whereas C1753 was created to describe ultrasound catheter devices that are not used to treat a disease and are used for imaging of the vessel. According to the applicant, C1888 does not appropriately describe the Paradise® Ultrasound RDN System because the Paradise® Ultrasound RDN System is intended to denervate renal nerves by using ultrasound energy that does not otherwise affect the blood vessel tissue, whereas C1888 was

created to describe devices that use radiofrequency or laser technologies to occlude or obliterate blood vessels.[38]

We did not identify an existing pass-through payment category that describes the Paradise® Ultrasound RDN System. We invited public comment on whether the Paradise® Ultrasound RDN System meets the device category criterion at § 419.66(c)(1).

Comment: The applicant and a few other commenters agreed with CMS' assessment that there are no existing pass-through payment categories that describe the Paradise® Ultrasound RDN System.

Response: We appreciate the commenters' input. After consideration of the public comments we received and our review of the application, we continue to believe that there is no existing category or category previously in effect that appropriately describes the Paradise® Ultrasound RDN System. Therefore, we have determined that the Paradise® Ultrasound RDN System meets the device category eligibility criterion at § 419.66(c)(1).

We noted that the applicant indicated the Paradise® Ultrasound RDN System is the only device authorized by FDA with an indication for renal denervation using ultrasound energy to achieve reductions in blood pressure. However, we noted that the Symplicity Spyral™ Catheter (Symplicity Spyral™ RDN System) device, for which we also received an application for transitional pass-through payments for CY 2025 as discussed in the proposed rule (89 FR 59312 through 59315) and this final rule with comment, is also authorized by FDA with an indication for renal denervation using a radiofrequency modality to achieve reductions in blood pressure. Accordingly, we noted that while the Paradise® Ultrasound RDN System device may have a different modality (*i.e.,* ultrasound compared to radiofrequency) than that of the Symplicity Spyral™ Catheter device, the Paradise® Ultrasound RDN System device may have a similar mechanism of action to that of the Symplicity Spyral™ Catheter device. We questioned whether the device descriptions provided in the respective applications support establishing two modality specific pass-through payment device categories or a single device category that would encompass both RDN device modalities. We address this question in section (i) in detail immediately following the full discussion of all other applicable eligibility criteria for both the Paradise® Ultrasound RDN System and the Symplicity Spyral™ RDN System applications.

For the summary of public comments received and our final decision on the question of whether the device descriptions provided in the respective applications support establishing two modality-specific pass-through payment device categories or a single device category that would encompass both RDN device modalities, please see section (i) immediately following the Symplicity Spyral™ RDN System application determination.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. As previously stated, the Paradise® Ultrasound RDN System has Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation (as explained in more detail in the discussion of the newness criterion) and therefore is not evaluated for substantial clinical improvement.

We invited public comment on whether the Paradise® Ultrasound RDN System meets the device category criterion at § 419.66(c)(2)(ii).

Comment: A few commenters stated that the Paradise® Ultrasound RDN System meets the eligibility criterion at § 419.66(c)(2)(ii), with one commenter asserting that the Paradise® Ultrasound RDN System meets the clinical improvement criterion based on its FDA Breakthrough Device designation.

Response: We appreciate the commenter's input. We agree with the commenters that the Paradise® Ultrasound RDN System has a Breakthrough Device designation effective December 4, 2020, and marketing authorization from FDA effective November 7, 2023, for the indication covered by the Breakthrough Device designation and therefore, meets the criterion at § 419.66(c)(2)(ii) and is not evaluated for substantial clinical improvement at § 419.66(c)(2)(i). Based on our review of the application and consideration of the public comments we received, we have determined that the Paradise® Ultrasound RDN System meets the device category criterion at § 419.66(c)(2).

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the Paradise® Ultrasound RDN System would be reported with HCPCS codes shown in Table 119.

[38] The applicant referenced the Medicare Claims Processing Manual, Chapter 4 to support these assertions.

TABLE 119: HCPCS CODES REPORTED WITH THE PARADISE® ULTRASOUND RDN SYSTEM

HCPCS Code	Long Descriptor	SI	APC
0338T**	Transcatheter renal sympathetic denervation, percutaneous approach including arterial puncture, selective catheter placement(s) renal artery(ies), fluoroscopy, contrast injection(s), intraprocedural roadmapping and radiological supervision and interpretation, including pressure gradient measurements, flush aortogram and diagnostic renal angiography when performed; unilateral	J1	5192
0339T**	Transcatheter renal sympathetic denervation, percutaneous approach including arterial puncture, selective catheter placement(s) renal artery(ies), fluoroscopy, contrast injection(s), intraprocedural roadmapping and radiological supervision and interpretation, including pressure gradient measurements, flush aortogram and diagnostic renal angiography when performed; bilateral	J1	5192

**Denotes a HCPCS code that was not included in Addendum P to the CY 2023 OPPS/ASC final rule with comment period, with no CY 2023 HCPCS/CPT code level device offset amount available. We noted the applicant used the CY 2023 payment rates for the three tests of the cost criterion. Since neither of the HCPCS/CPT codes provided by the applicant had a CY 2023 HCPCS/CPT code level device offset amount available at the time the application was received, we used the CY 2023 APC level device offset amount to assess whether the device meets the cost significance criterion.

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). We noted that the applicant used the CY 2023 payment rates for the three tests of the cost criterion. For our calculations, we used APC 5192, which had a CY 2023 payment rate of $5,215.40 at the time the application was received. We used the CY 2023 APC level device offset amount of $1,491.08 for APC 5192, since HCPCS codes 0338T and 0339T were not included in Addendum P to the CY 2023 OPPS/ASC final rule with comment period and no CY 2023 HCPCS/CPT code level device offset amount was available at the time the application was received.[39] According to the applicant, the operating cost[40] of the Paradise® Ultrasound RDN System is $23,000.00.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The average reasonable cost of $23,000.00 for the Paradise® Ultrasound RDN System is 441.00 percent of the applicable APC payment amount for the service related to the category of devices of $5,215.40 (($23,000.00/$5,215.40) × 100 = 441.00 percent). Therefore, we stated that we believe the Paradise® Ultrasound RDN System meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $23,000.00 for the Paradise® Ultrasound RDN System is 1,542.51 percent of the cost of the device-related portion of the APC payment amount for the related service of $1,491.08 (($23,000.00/$1,491.08) × 100 = 1,542.51 percent). Therefore, we stated that we believe the Paradise® Ultrasound RDN System meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $23,000.00 for the Paradise® Ultrasound

[39] The applicant stated as neither HCPCS code 0338T nor 0339T had a device offset amount listed in Addendum P to the CY 2023 OPPS/ASC final rule with comment period, it selected a device offset amount of $0.00. However, for our calculation, we selected the CY 2023 APC level device offset amount of $1,491.08 for APC 5192 found in CY 2023 NFRM OPPS APC Offset File, as no CY 2023 HCPCS/CPT code level device offset amount was available at the time the application was received. Based on our initial assessment for the proposed rule, using the device offset amount of $1,491.08 would result in the Paradise® Ultrasound RDN System meeting the cost significance requirement.

[40] According to the applicant, the current total cost of the Paradise® Ultrasound RDN System device is $23,235.00. For the cost criteria estimates, the applicant submitted an operating cost of $23,000.00 for the Paradise® Ultrasound RDN System device. Per the applicant, the individual component costs are as follows: Paradise® Remote (capital equipment) is $5.00; Paradise® Cart (capital equipment) is $5.00; Paradise® Generator (capital equipment) is $225.00; Paradise® RDN Catheter Kit (one time use) is $22,000.00; Paradise RDN Cable (one time use) is $250.00; and the Paradise® RDN Cartridge (one time use) is $750.00.

RDN System and the portion of the APC payment amount for the device of $1,491.08 is 412.41 percent of the APC payment amount for the related service of $5,215.40 ((($23,000.00 − $1,491.08)/$5,215.40) × 100 = 412.41 percent). Therefore, we stated that we believe the Paradise® Ultrasound RDN System meets the third cost significance requirement.

We invited public comment on whether the Paradise® Ultrasound RDN System meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

Comment: With respect to cost significance criteria, the applicant and a few other commenters reiterated that the Paradise® Ultrasound RDN System meets all three of the cost significance criteria. The applicant further clarified that the Paradise® Ultrasound RDN System meets the cost criteria regardless of whether the Paradise® Cartridge and Paradise® Connection Cable are deemed eligible for pass-through or excluded from the calculation. The applicant stated that the Paradise® Cartridge and Paradise® Connection Cable should be included when evaluating the cost criteria because they are both single-use items that are required for the Paradise® Ultrasound RDN System to function as intended and are essential to complete each patient treatment.

Response: We appreciate the applicant's and commenters' input. We agree with the applicant that the Paradise® Catheter, Paradise® Cartridge, and Paradise® Connection Cable are single-use components that are required for the Paradise® Ultrasound RDN System to function as intended and are essential to complete each patient treatment and should be included when evaluating the cost criteria. After consideration of the public comments we received and our findings from the first, second, and third cost significance tests, we agree that the Paradise® Catheter, Paradise® Cartridge, and Paradise® Connection Cable components of the Paradise® Ultrasound RDN System meet the cost significance criteria specified at § 419.66(d).

After consideration of the public comments we received and our review of the device pass-through application, we have determined that the Paradise® Catheter, Paradise® Cartridge, and Paradise® Connection Cable components of the Paradise® Ultrasound RDN System meet the requirements for device pass-through status described at § 419.66. Therefore, effective beginning January 1, 2025, we are finalizing approval for device pass-through payment status for the applicable components of the Paradise® Ultrasound RDN System under the alternative pathway for devices that have an FDA Breakthrough Device designation and have received FDA marketing authorization for the indication covered by the Breakthrough Device designation.

(g) Precision GI

Limaca Medical submitted an application for a new device category for transitional pass-through payment status for Precision GI for CY 2025. According to the applicant, Precision GI is a motorized, battery operated, single-use, fully disposable endoscopic ultrasound-guided (EUS) fine needle biopsy device used to obtain biopsies of tissue for definitive diagnosis of pancreatic cancer and other life-threatening gastrointestinal (GI) abnormalities. Per the applicant, Precision GI is untethered and battery operated with an internally powered and controlled motor, featuring a long flexible shaft transferring the proximal force of the motor through the inserted endoscope to the needle circumferential cutting tip. The device is controlled by a physician, who inserts the device into the patient's GI tract via the ultrasound endoscope. Upon reaching the designated biopsy site, the physician operates the device's motorized mechanism that automatically rotates the needle (which is included in the device's package) to cut and extract tissue. The biopsy site is accessed through the instrument channel of an ultrasound imaging endoscope that detects the device's echogenic needle tip.

Please refer to the online application posting for Precision GI, available at *https://mearis.cms.gov/public/publications/device-ptp/DEP23113023REE,* for additional detail describing the device and the disease treated by the device.

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), Precision GI received FDA Breakthrough Device designation effective March 24, 2022, as a device used with an ultrasound endoscope for fine needle biopsy of submucosal lesions, mediastinal masses, lymph nodes, and intraperitoneal masses within or adjacent to the GI tract. FDA granted the applicant 510(k) clearance for Precision GI on August 28, 2023, for the indication covered by the Breakthrough Device designation. We received the application for a new device category for transitional pass-through payment status for Precision GI on November 30, 2023, which is within 3 years of the date of the initial FDA marketing authorization.

We invited public comment on whether Precision GI meets the newness criterion at § 419.66(b)(1).

Comment: With respect to the newness criterion at § 419.66(b)(1), the applicant and one commenter agreed with CMS' assessment and the applicant noted that CMS raised no concerns about Precision-GI meeting the criterion at § 419.66(b)(1).

Response: We appreciate the applicant's and the commenter's input. We received the application for a new device category for transitional pass-through payment status for Precision GI on November 30, 2023, which is within 3 years of August 28, 2023, the date of FDA 510(k) clearance. Based on our review of the application and public comments received, we have determined that Precision GI meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criteria at § 419.66(b)(3), the device must be an integral part of the service furnished, used for one patient only, come in contact with human tissue, and be surgically inserted or implanted, or applied in or on a wound or other skin lesion. The applicant did not indicate whether Precision GI is an integral part of the service furnished. The applicant stated that the device is intended for single use. While the applicant did not explicitly state whether Precision GI comes in contact with human tissue and is surgically inserted or implanted, the applicant noted that Precision GI is used to sample targeted submucosal lesions, mediastinal masses, lymph nodes, and intraperitoneal masses within or adjacent to the GI tract and this is achieved by a physician who inserts Precision GI into the patient's GI tract using an ultrasound endoscope. However, we noted that, while the needle (which is a component of the device and is included in the device's package) does come into contact with human tissue and is surgically inserted, the motorized mechanism of the Precision GI device itself may not come in contact with human tissue and may not be surgically implanted or inserted (either permanently or temporarily), or applied in or on a wound or other skin lesion, as required at § 419.66(b)(3).

We invited public comment on whether Precision GI meets the eligibility criterion at § 419.66(b)(3).

Comment: In response to our concern about whether Precision GI is integral to the service furnished and meets the eligibility criterion at § 419.66(b)(3), the

applicant clarified that Precision GI is an integral part of the service furnished because the Precision GI device is an endoscopic ultrasound-guided fine needle biopsy (EUS–FNB) medical device and is the essential device that physicians must use to enable the procedures for the services the applicant identified. The applicant clarified that physicians use Precision GI for procedures that are reported using the following HCPCS codes: 43238 (Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s), (includes endoscopic ultrasound examination limited to the esophagus, stomach or duodenum, and adjacent structures), and 43242 (Esophagogastroduodenoscopy, flexible, transoral with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s), (includes endoscopic ultrasound examination limited to the esophagus stomach and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis)) and Precision GI is clearly integral to performing both of these services, given that these procedures are intended to extract suspected cancerous tissue and that Precision GI is the essential device used to obtain and remove the tissue. A commenter stated that based on the Precision GI application, they believe Precision GI would be integral to the procedures with which it is associated. The applicant reiterated that Precision GI is a single-use device and clarified that it is used for one patient only.

Response: We appreciate the applicant's and the commenter's input. Based on the information provided in the comments we agree with the applicant and commenter that Precision GI is an essential device that physicians must use to enable the procedures for the services the applicant identified and, as such, Precision GI is an integral part of the service furnished. After consideration of the public comments received and our review of the application, we have determined that Precision GI is integral to the service furnished and is used for one patient only. We have taken this information into consideration in making our final determination of whether Precision GI meets the requirements of § 419.66(b)(3).

Comment: In response to our concerns about whether Precision GI comes in contact with human tissue and meets the eligibility criterion at § 419.66(b)(3), the applicant and a commenter submitted comments clarifying that Precision GI comes in contact with human tissue when the device enters the patient and extracts suspected tumor tissue from the body. The applicant and commenter explained that after the Precision GI device is advanced through the mouth via the working channel of the upper GI endoscope to the section of the gastric wall located closest to the mass or tumor as identified by endoscopic ultrasound, the rotating needle component of Precision GI goes through the gastric wall to acquire tissue from the tumor. The applicant clarified that Precision GI operates as a single unit, which includes the needle and emphasized that Precision GI is not provided in separate components, does not require assembly, and does not require any additional supplies or materials to operate. As such, the applicant and the commenter asserted that Precision GI comes into contact with human tissue as required.

In response to our concerns about whether Precision GI is surgically inserted or implanted the applicant and another commenter clarified that Precision GI is surgically inserted when Precision GI is inserted through a natural orifice (the mouth) to access the biopsy site, and therefore it meets the eligibility criterion at § 419.66(b)(3). Specifically, the applicant clarified that the surgical path to the tumor is created by the endoscope which is passed through the mouth (natural orifice) where Precision GI is then used to access the site and to extract tissue in or adjacent to the GI tract, meeting the requirements of § 419.66(b)(3).

Response: We appreciate the applicant's and the commenter's input. Based on the clarifying information provided in the comments, we agree with the applicant that Precision GI comes in contact with human tissue and is surgically implanted or inserted as required by § 419.66(b)(3). Specifically, we relied upon the clarification that Precision GI functions collectively as a single unit with no separate components and the device enters the patient via an endoscope to extract human tissue from the body, and as such, we believe that Precision GI comes into contact with human tissue. In addition, we agree with the applicant and commenter that Precision GI is surgically inserted when it is advanced through a natural orifice (*i.e.,* the mouth) via an endoscope to create a surgical path to the tumor. After consideration of the public comments received and our review of the application, we have determined that Precision GI comes in contact with human tissue and is surgically inserted in accordance with the eligibility criterion at § 419.66(b)(3).

We agree with the applicant and commenter that Precision GI is an integral part of the service furnished, used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted, or applied in or on a wound or other skin lesion. After consideration of the public comments received and our review of the application, we have determined that Precision GI meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker). The applicant indicated that Precision GI is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets; the applicant noted that Precision GI is a motorized, single-use, fully disposable EUS fine needle biopsy device that functions with no related capital component. The applicant stated that Precision GI is not a material or supply furnished incident to a service. However, based on the applicant's description of Precision GI as a biopsy device, we questioned whether Precision GI may be considered a supply or material furnished incident to a service and excluded from device pass-through payment eligibility under § 419.66(b)(4).

Specifically, in the CY 2001 OPPS interim final rule with comment period (65 FR 67804 through 67805), we explained how we interpreted § 419.43(e)(4)(iv). We stated that we consider a device to be surgically implanted or inserted if it is introduced into the human body through a surgically created incision. We also stated that we do not consider an item used to cut or otherwise create a surgical opening to be a device that is surgically implanted or inserted. We consider items used to create incisions, such as scalpels, electrocautery units, biopsy apparatuses, or other commonly used operating room instruments, to be supplies or capital equipment not eligible for transitional pass-through payments. We stated that we believe the function of these items is different and distinct from that of devices that are

used for surgical implantation or insertion. Finally, we stated that, generally, we would expect that surgical implantation or insertion of a device occurs after the surgeon uses certain primary tools, supplies, or instruments to create the surgical path or site for implanting the device. Further, in the CY 2006 OPPS final rule with comment period (70 FR 68629 through 68630), we adopted as final our interpretation that the surgical insertion or implantation criterion can be met by devices that are surgically inserted or implanted via a natural or surgically created orifice, as well as those devices that are inserted or implanted via a surgically created incision. We reiterated that we maintain all of the other criteria in § 419.66 of the regulations, namely, that we do not consider an item used to cut or otherwise create a surgical opening to be a device that is surgically implanted or inserted. We reiterated this interpretation in the CY 2024 OPPS final rule (88 FR 81543, 81743).

We noted that Precision GI, is inserted into the patient's GI tract via the ultrasound endoscope to reach the designated biopsy site where the device's motorized mechanism is then used for cutting and extraction of tissue endoscopically from within or adjacent to the patient's GI tract. However, we questioned whether Precision GI, which is described as a biopsy device, may be considered a supply or material furnished incident to a service consistent with our previous interpretation of § 419.43(e)(4)(iv) and therefore excluded from device pass-through payment eligibility under § 419.66(b)(4).

We welcomed additional evidence regarding whether Precision GI should be considered a material or supply incident to a service based on our previous interpretation of § 419.43(e)(4)(iv) as it has been applied to biopsy devices and we invited public comments on whether Precision GI meets the exclusion criterion at § 419.66(b)(4).

Comment: The applicant submitted a comment stating that there is agreement that Precision GI is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets.

Response: We appreciate the applicant's input. We agree with the applicant that Precision GI is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets. We have taken this information into consideration in making our final determination of whether Precision GI meets the requirements of § 419.66(b)(4).

Comment: The applicant submitted a comment clarifying that Precision GI is not a material or supply incident to a service and meets the eligibility criterion at § 419.66(b)(4) because Precision GI does not create incisions and is not used to create a surgical opening, rather Precision GI is used to capture and extract a diagnostically relevant portion of the tumor. The applicant stated that Precision GI's cutting function does not make the device a commodity supply and that Precision GI should not be placed in the same category as simple cutting or basic commodity tools (*e.g.,* such as scalpel, biopsy forceps, simple exchangeable needles, etc.).

Additionally, the applicant stated that Precision GI is not a generic biopsy device as defined by CMS for pass-through devices, referencing section 60.4.3, Chapter 4 of the Medicare Claims Processing Manual. In support, the applicant compared Precision GI to devices described by C1782 (Morcellator), which like Precision GI are also used for tissue removal. The applicant explained that because C1782 devices are used for laparoscopic tissue removal, per the CMS guidance in the Medicare Claims Processing Manual, they are not considered generic biopsy devices.[41] Thus, the applicant asserted its belief that, similar to C1782 devices, Precision GI is not a generic biopsy device because it is used for tissue removal. Furthermore, the applicant noted that C1782 would not appropriately describe Precision GI because C1782 is specific to laparoscopic removal of tissue, whereas Precision GI is endoscopically inserted to remove tissue within or adjacent to the GI tract.

The applicant asserted that CMS previously created a pass-through device category C1830 (Powered bone marrow biopsy needle), effective October 1, 2011, and that the device in this category functions similarly to Precision GI in complexity of operation and is not a biopsy needle as the applicant stated CMS defines this term. The applicant further commented that suggesting that Precision GI is a supply ignores the complexity of the device compared to commonly used endoscopic biopsy forceps and interchangeable commodity operating instruments.

One commenter stated that, per the application, Precision GI is a single, disposable, mechanized unit that would be integral to the procedures with which it is associated and for this reason, it should not be categorized with scalpels, needles, and other commonly used operating room instruments as a supply furnished incident to a service and should not be excluded from device pass-through eligibility under § 419.66(b)(4).

The applicant asserted that the FDA Breakthrough Designation implicitly recognizes the innovative nature of Precision GI and that it would be unlikely to have received this designation if it were deemed a supply. The applicant also asserted that Precision GI obtains tumor tissue in a superior method compared to today's non-motorized EUS–FNB devices, providing consistently higher quality core tumor tissue for the anatomic pathologist to more confidently diagnose.

Response: We appreciate the applicant's and commenter's input and the additional information. We agree with the applicant that Precision GI is not a supply or material furnished incident to a service because the device does not appear to be an item used to cut or otherwise create a surgical opening, rather it is inserted through a natural orifice (*i.e.,* the mouth) via an endoscope to create a surgical path to reach the designated biopsy site where the device's motorized mechanism is used for cutting and extraction of tissue endoscopically from within or adjacent to the patient's GI tract.

We also agree with the applicant that similar to devices described by C1782 and C1830, Precision GI appears to be distinct from biopsy devices as defined by section 60.4.3, Chapter 4 of the Medicare Claims Processing Manual.

In response to the applicant's comment that FDA Breakthrough Designation implicitly recognizes the innovative nature of Precision GI and that it would be unlikely to have received this designation if it were deemed a supply, we note that a device's FDA designation does not alone qualify a device for transitional device pass-through payment; the criteria FDA utilizes to grant medical device approvals differ from the criteria CMS has established to evaluate device eligibility for OPPS device pass-through payments. As such, CMS must evaluate all information submitted for each device pass-through application for each applicable criterion as it applies to the nominated device. In response to the

[41] According to the Medicare Claims Processing Manual (60.4.3), the device pass-through category C1782 (Morcellator) is specific to devices used for cutting, coring, and extracting tissue in laparoscopic procedures. These are distinct from biopsy devices because morcellators are used for the laparoscopic removal of tissue.

applicant's comment that Precision GI obtains tumor tissue in a superior method compared to today's non-motorized EUS–FNB devices, providing consistently higher quality core tumor tissue for the anatomic pathologist to more confidently diagnose, we note that § 419.66(b)(4) does not require that a device is superior to other available devices.

Based on the additional information provided in the comments, we agree with the applicant and commenter that Precision GI is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets, or a material or supply furnished incident to a service. After consideration of the public comments received and our review of the application, we have determined that Precision GI meets the eligibility criterion at § 419.66(b)(4).

Comment: With respect to our concerns about the eligibility criterion at § 419.66(b)(3), the applicant sought to distinguish Precision GI from the CytoCore device, which was denied pass-through status in CY 2024 (88 FR 81744). The applicant stated that Precision GI differs from CytoCore in two ways: unlike the CytoCore device, Precision GI does not have a separate needle component and Precision GI comes into contact with human tissue. Specifically, the applicant commented that the needle attached to the CytoCore is a separate needle, and not part of the CytoCore device and the needle is the only portion of the device that comes in contact with human tissue, whereas Precision GI's needle is an integral part of the Precision GI device that works in conjunction with Precision GI's long flexible shaft fully driven by its control system and motor, to transfer the proximal driving force of the motor to the highly specialized circumferential cutting and capturing tip to access the tumor tissue and perform the biopsy. The applicant further clarified that the Precision GI's needle is not only an integrated part of the device, but it is also a specifically and uniquely designed cannula with circumferential internal sharpening to enable superior tumor tissue capture when driven by Precision GI as a motor and microchip control program. The applicant stated that Precision GI enables the physician to accomplish motorized, automated, and synchronized axial advancement and rotational cutting and extraction of tissue at the target tissue site. Finally, the applicant noted that the needle used with Precision GI cannot be swapped out for other generic needles.

Response: We appreciate the applicant's input and agree that because Precision GI does not have separate components, functions collectively as a single device, and is surgically inserted when it is advanced through a natural orifice (*i.e.,* the mouth) via an endoscope, creating a surgical path to the tumor, the device comes into contact with human tissue and is surgically inserted as required by § 419.66(b)(3).

Comment: With regard to our discussion about the eligibility criterion specified at § 419.66(b)(4), a commenter stated that the Precision GI transitional pass-through payment application raises an important policy question about the definition of a biopsy apparatus. According to the commenter, items used to create incisions, such as biopsy apparatuses, or other commonly used operating room instruments, that CMS classified as supplies in in the CY 2006 OPPS final rule (70 FR, 68629 through 68630) [42] are substantially different from the targeted mechanical core biopsies of today. The commenter explained that technological advances in incision devices began in the late 2010s with various alterations to needle shapes and have continued to improve and progress to the current, mechanical, EUS-guided devices, which do not merely create incisions and should not be classified along with biopsy forceps or even aspiration needles. Therefore, the commenter requested that CMS consider the definition of a supply and consider re-classification of mechanical tissue extraction apparatuses such as Precision GI into a new category of devices outside of the existing definition. The commenter stated their belief that this would enable CMS to determine the benefits and costs of single-use devices and future innovations in this space and determine their role in therapeutic decision-making and associated improvements in patient outcomes.

Response: We thank the commenter for their feedback. We will continue to consider issues related to the definition of a biopsy apparatus as it relates to the criterion at § 419.66(b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), the criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. The applicant asserted that Precision GI is authorized by FDA with an indication to sample targeted submucosal lesions, mediastinal masses, lymph nodes, and intraperitoneal masses within or adjacent to the GI tract. Per the applicant, the device category C1830 (Powered bone marrow biopsy needle) does not appropriately describe Precision GI because Precision GI is not targeting bone marrow and instead is targeting sub-mucosal and extramural GI lesions. According to the applicant, the device category C1782 (Morcellator) also does not appropriately describe Precision GI because that device category, per Medicare Claims Processing Manual, Ch. 4, section 60.4.3, is only for laparoscopic procedures. The applicant added that Precision GI cuts and extracts tissue endoscopically, not laparoscopically.

We did not identify an existing pass-through payment category that describes Precision GI. We invited public comment on whether Precision GI meets the device category criterion at § 419.66(c)(1).

Comment: With respect to the device category criterion at § 419.66(c)(1), the applicant agreed with our assessment that there are no existing pass-through payment categories that describe Precision GI.

Response: We appreciate the applicant's input. After consideration of the public comments received and our review of the application, we continue to believe there is no existing category or category previously in effect that appropriately describes Precision GI. Therefore, we have determined that Precision GI meets the device category eligibility criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. Precision GI has a Breakthrough Device designation and marketing authorization from FDA for

[42] Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates, 70 FR 68516 (November 10, 2005).

the indication covered by the Breakthrough Device designation (as explained in more detail in the discussion of the newness criterion) and therefore is not evaluated for substantial clinical improvement.

We invited public comment on whether Precision GI meets the device category criterion at § 419.66(c)(2)(ii).

Comment: With respect to the device category criterion at § 410.66(c)(2)(ii), the applicant reiterated that Precision GI received FDA Breakthrough Device designation and marketing authorization for the same indication. The applicant agreed with CMS that Precision GI meets the device category criterion at § 410.66(c)(2)(ii), and therefore, is not evaluated for substantial clinical improvement.

Response: We appreciate the applicant's input. FDA granted Precision GI Breakthrough Device designation effective March 24, 2022, and a marketing authorization effective August 28, 2023, for the indication covered by the Breakthrough Device designation. Therefore, Precision GI meets the criterion at § 419.66(c)(2)(ii) and is not evaluated for substantial clinical improvement at § 419.66(c)(2)(i). After consideration of public comments received and our review of the application, we have determined that Precision GI meets the device category criterion at § 419.66(c)(2).

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that Precision GI would be reported with HCPCS codes as shown in Table 120.

TABLE 120: HCPCS CODES REPORTED WITH PRECISION GI

HCPCS Code	Long Descriptor	SI	APC
43238	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s), (includes endoscopic ultrasound examination limited to the esophagus, stomach or duodenum, and adjacent structures)	J1	5302
43242	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s), (includes endoscopic ultrasound examination limited to the esophagus, stomach and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastamosis)	J1	5302

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). We noted that the applicant utilized the CY 2024 payment rates for the three tests of the cost criterion. For our calculations, we used APC 5302, which had a CY 2024 payment rate of $1,812.99 at the time the application was received. HCPCS code 43242 in APC 5302 had a CY 2024 device offset amount of $23.75 at the time the application was received.[43] According to the applicant, the cost of Precision GI is $1,400.00.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The average reasonable cost of $1,400.00 for Precision GI is 77.22 percent of the applicable APC payment amount for the service related to the category of devices of $1,812.99 (($1,400.00/$1,812.99) × 100 = 77.22 percent). Therefore, we stated that we believe Precision GI meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount. The estimated average reasonable cost of $1,400.00 for Precision GI is 5894.74 percent of the cost of the device-related portion of the APC payment amount for the related service of $23.75 (($1,400.00/$23.75) × 100 = 5894.74 percent). Therefore, we stated that we believe Precision GI meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of

[43] We noted that the applicant selected the APC payment rate of $1,814.88 and the APC level device offset amount of $178.95 for APC 5302. However, the values selected are inconsistent with the APC payment rate and the APC level device offset amount found in CY 2024 OPPS APC Offset File, which were corrected as described in the CY 2024 OPPS/ASC final rule with comment period correction (89 FR 9002). The HCPCS/CPT code level device offset amounts for the HCPCS/CPT codes provided by the applicant are available in the corrected Addendum P to the CY 2024 OPPS/ASC final rule with comment period. For our calculation, we selected the APC payment rate of $1,812.99 and the HCPCS/CPT code level device offset amount of $23.75 related to HCPCS 43242 in APC 5302 found in the corrected Addendum P, which are the accurate values for these codes. Based on our initial assessment for the proposed rule, using the APC payment rate of $1,812.99 and the device offset amount of $23.75 would result in Precision GI meeting the cost significance requirement.

$1,400.00 for Precision GI and the portion of the APC payment amount for the device of $23.75 is 75.91 percent of the APC payment amount for the related service of $1,812.99 ((($1,400 − $23.75)/$1,812.99) × 100 = 75.91 percent). Therefore, we stated that we believe Precision GI meets the third cost significance requirement.

We invited public comment on whether Precision GI meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

Comment: With respect to cost significance criteria, the applicant stated that they agree with CMS that Precision GI satisfies the cost criteria.

Response: We appreciate the applicant's input. After consideration of the public comment received and our findings from the first, second, and third cost significance tests, we have determined that Precision GI meets the cost significance criteria specified at § 419.66(d).

After consideration of the public comments received, and our review of the device pass-through application, we have determined that Precision GI meets the requirements for device pass-through status described at § 419.66, and we are finalizing approval for device pass-through payment status for Precision GI effective January 1, 2025, under the alternative pathway for devices that have an FDA Breakthrough Device designation and have received FDA marketing authorization for the indication covered by the Breakthrough Device designation.

(h) Symplicity Spyral™ Renal Denervation (RDN) System

Medtronic submitted an application for a new device category for transitional pass-through payment status for the Symplicity Spyral™ RDN System for CY 2025. The applicant is seeking a new device category for transitional pass-through payment status only for the Symplicity Spyral™ Multi-Electrode RDN Catheter (hereinafter Symplicity Spyral™ Catheter) component of the Symplicity Spyral™ RDN System. According to the applicant, the Symplicity Spyral™ RDN System consists of the Symplicity Spyral™ Catheter and the Symplicity G3™ generator; however, the applicant requested device pass-through status for the catheter component of the system only. The applicant further explained that the Symplicity Spyral™ RDN System is indicated to reduce blood pressure as an adjunctive treatment in hypertension patients in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure. Per the applicant, the Symplicity Spyral™ Catheter, when used with the Symplicity G3™ generator, delivers radiofrequency (RF) energy through the wall of the renal artery to disrupt the surrounding renal nerves with the aim of modulating or suppressing sympathetic nerve hyperactivity. According to the applicant, the Symplicity Spyral™ Catheter is a single-use catheter used to deliver multiple ablations in both kidneys, in the renal main, accessory, and branch arteries, based on a patient's artery anatomy and size.

Per the applicant, the Symplicity Spyral™ Catheter is designed to be used with the Symplicity G3™ generator and includes the following components: (1) four gold radiopaque electrodes at the spiral (helical) distal end that are deployed into a spiral (helical) shape by partially retracting the guidewire proximal to the spiral section of the catheter; (2) self-expanding electrode array assembly which radially spaces the four gold electrodes for quadratic ablation; (3) rapid exchange port; (4) straightening tool intended to facilitate safe insertion of the guidewire into the catheter; (5) cable connector attached to the catheter handle that connects the catheter to the generator; (6) catheter handle; and (7) femoral marker. Per the applicant, additional components of the Symplicity Spyral™ RDN System include the: (1) Symplicity G3™ generator, which is only compatible with the Symplicity Spyral™ Catheter, which includes a remote control, power cable, and output for the Symplicity Spyral™ Catheter; (2) Symplicity G3™ generator cart, an optional mobile cart; and (3) foot switch, an optional component. Per the applicant, additional items required for the procedure include: (1) a 0.36 mm (0.014 in) guidewire, preferably without hydrophilic coating; (2) a dispersive electrode; (3) a sterile bag to cover the remote control if used in the sterile field; (4) a 6 French (Fr) guide-catheter; (5) an introducer sheath; (6) a stopcock sidearm; (7) a Tuohy-Borst adapter; and (8) other standard items used to aid percutaneous transluminal catheterization in renal arteries.

According to information submitted by the applicant, key steps for operating the Symplicity Spyral™ Catheter include: (1) connecting the Symplicity Spyral™ Catheter to the Symplicity G3™ generator; (2) inserting the Symplicity Spyral™ Catheter through a small femoral incision and guiding it to the renal artery via the abdominal aorta; (3) advancing the Symplicity Spyral™ Catheter until the distal electrode is located in the desired position within the renal artery; (4) retracting the guidewire, allowing the self-expanding catheter to expand and fit the renal arterial vessel walls; (5) delivering the treatment of RF energy to ablate the renal nerves through the activation of the catheter electrodes, which is controlled using the generator; (6) if treating another vessel, repositioning the guide catheter within the next vessel and repeating the procedure for positioning the catheter and delivering treatments; (7) upon completion of all treatments, straightening the distal end by advancing the guidewire and withdrawing both the guidewire and the straightened catheter from the guide catheter; (8) retracting the guide catheter from the sheath and removing the introducer sheath from the artery; (9) using standard of care procedures to achieve hemostasis at the puncture site; and (10) disposing of the devices.

Please refer to the online application posting for the Symplicity Spyral™ RDN System, available at *https://mearis.cms.gov/public/publications/device-ptp/DEP231130WPU4J,* for additional detail describing the device and the disease treated by the device.

Comment: Many commenters expressed their support for the approval of the Symplicity Spyral™ RDN System for transitional pass-through payment.

Response: We appreciate the commenters' input and support for the Symplicity Spyral™ RDN System application for transitional pass-through payment. We have taken these comments into consideration in our final determination for pass-through status for the Symplicity Spyral™ RDN System.

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), the Symplicity Spyral™ RDN System received FDA Breakthrough Device designation effective March 27, 2020, as a device with the following indicated use: the Symplicity Spyral™ multi-electrode renal denervation catheter and the Symplicity G3™ RF Generator are indicated for the reduction of blood pressure in patients with uncontrolled hypertension despite the use of anti-hypertensive medications or in patients who may have documented intolerance to anti-hypertensive medications. FDA approved the premarket approval application (PMA) for the Symplicity Spyral™ RDN System on November 17, 2023, for the indicated use to reduce blood pressure as an adjunctive treatment in patients with hypertension

in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure. We received the application for a new device category for transitional pass-through payment status for the Symplicity Spyral™ Catheter on November 30, 2023, which is within 3 years of the date of the initial FDA marketing authorization.

We invited public comment on whether the Symplicity Spyral™ Catheter meets the newness criterion at § 419.66(b)(1).

Comment: With respect to the newness criterion at § 419.66(b)(1), the applicant reiterated that the Symplicity Spyral™ Catheter received FDA marketing authorization on November 17, 2023, and the Symplicity Spyral™ RDN System was granted Breakthrough Device designation effective March 27, 2020. A few other commenters also stated that they believed the Symplicity Spyral™ RDN System meets the newness criterion.

Response: We appreciate the applicant's and commenters' input. The Symplicity Spyral™ RDN System received FDA Breakthrough Device designation on March 27, 2020. We received the application for a new device category for transitional pass-through payment status for the Symplicity Spyral™ Catheter on November 30, 2023, which is within 3 years of November 17, 2023, the date of FDA PMA. After consideration of the public comments received and our review of the application, we have determined that the Symplicity Spyral™ Catheter meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criteria at § 419.66(b)(3), the device must be an integral part of the service furnished, used for one patient only, come in contact with human tissue, and be surgically inserted or implanted, or applied in or on a wound or other skin lesion. The applicant did not indicate whether the Symplicity Spyral™ Catheter is integral to the service furnished. Per the applicant, the Symplicity Spyral™ Catheter is intended for single-patient use only. While the applicant did not explicitly state whether the Symplicity Spyral™ Catheter comes into contact with human tissue, the applicant asserted that the Symplicity™ Catheter ablates renal nerve tissue by positioning the catheter within the renal artery, which expands and fits the renal arterial vessel walls. While the applicant did not explicitly state if the Symplicity Spyral™ Catheter is surgically inserted or implanted, per the device description, the Symplicity Spyral™ Catheter is inserted through a small femoral incision, after which it is inserted into the renal arterial vessel.

We invited public comment on whether the Symplicity Spyral™ Catheter meets the eligibility criterion at § 419.66(b)(3).

Comment: The applicant submitted a comment stating that the Symplicity Spyral™ catheter meets all eligibility criteria as laid out at § 419.66(b)(3). The applicant clarified that the Symplicity Spyral™ Catheter is required to ablate the renal sympathetic nerves in this procedure, is integral to the service furnished, and meets the eligibility criterion at § 419.66(b)(3). The applicant further clarified that the Symplicity Spyral™ Catheter comes into contact with human tissue because it is inserted through the skin and into the arterial system, and is then introduced into the renal artery.

Response: We appreciate the applicant's input. We agree with the applicant that the Symplicity Spyral™ Catheter is an integral part of the service furnished, used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted, or applied in or on a wound or other skin lesion because the Symplicity Spyral™ Catheter is a single-use catheter and is inserted through a small femoral incision, after which it is inserted into the renal arterial vessel. After consideration of the public comments we received and our review of the application, we have determined that the Symplicity Spyral™ Catheter meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker). The applicant did not state whether the Symplicity Spyral™ Catheter is equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered, or whether the Symplicity Spyral™ Catheter is a supply or material furnished incident to a service.

We invited public comment on whether the Symplicity Spyral™ Catheter meets the exclusion criterion at § 419.66(b)(4).

Comment: The applicant submitted a comment confirming that the Symplicity Spyral™ Catheter meets the eligibility criterion at § 419.66(b)(4) because it is not equipment, an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered as defined in Chapter 1 of the Medicare Provider Reimbursement Manual. The applicant clarified that the Symplicity Spyral™ Catheter is not a supply or material furnished incident to a service. The applicant commented that the Symplicity Spyral™ Catheter is used with the Symplicity G3™ generator, which may be considered depreciating equipment as defined at § 419.66(b)(4); however, the applicant noted that it is only seeking pass-through status for the single-use Symplicity Spyral™ Catheter.

Response: We thank the applicant for the clarification and agree with the applicant that the Symplicity Spyral™ Catheter is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets, or a material or supply furnished incident to a service. After consideration of the public comments we received and our review of the application, we have determined that the Symplicity Spyral™ Catheter meets the eligibility criterion at § 419.66(b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), the criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. According to the applicant, the Symplicity Spyral™ Catheter is a single-use catheter used to deliver multiple ablations in both kidneys, in the renal main, accessory, and branch arteries, based on a patient's artery anatomy and size. According to the applicant, no previous or existing device categories for pass-through payment appropriately describe the Symplicity Spyral™ Catheter. The applicant asserted that two categories, C1886 (Catheter, extravascular tissue ablation, any modality (insertable)) and C1888 (Catheter, ablation, noncardiac, endovascular (implantable)), do not appropriately describe the Symplicity Spyral™ Catheter. Per the applicant, C1886 does not appropriately describe the Symplicity Spyral™ Catheter because the Symplicity Spyral™

Catheter ablates renal nerve tissue via an endovascular approach by positioning the catheter within the renal artery and C1886 was created to describe devices that ablate extravascular tissue (via an extravascular approach).[44] According to the applicant, C1888 does not appropriately describe the Symplicity Spyral™ Catheter because the Symplicity Spyral™ Catheter does not ablate or otherwise affect the blood vessel tissue and C1888 was created to describe devices designed to occlude or obliterate blood vessels.[45]

We did not identify an existing pass-through payment category that describes the Symplicity Spyral™ Catheter. We invited public comment on whether the Symplicity Spyral™ Catheter meets the device category criterion at § 419.66(c)(1).

Comment: The applicant and a few other commenters agreed with CMS' assessment that there are no existing pass-through payment categories that describe the Symplicity Spyral™ Catheter.

Response: We appreciate the commenters' input. After consideration of the public comments we received and our review of the application, we continue to believe that there is no existing category or category previously in effect that appropriately describes the Symplicity Spyral™ Catheter. Therefore, we have determined that the Symplicity Spyral™ Catheter meets the device category eligibility criterion at § 419.66(c)(1).

We noted that the applicant indicated the Symplicity Spyral™ Catheter is not the only device authorized by FDA with an indication for renal denervation to achieve reductions in blood pressure. Paradise® Ultrasound RDN System, for which we also received an application for transitional pass-through payments for CY 2025 as discussed in more detail in the proposed rule (89 FR 59304 through 59307) and this final rule with comment, is also authorized by FDA with an indication for renal denervation using ultrasound energy to achieve reductions in blood pressure. Per the applicant, the Paradise® Ultrasound RDN System would also be described by the applicant's proposed pass-through payment category: Ablation catheter, renal nerve, via endovascular approach, any modality. Accordingly, we noted that while the Symplicity Spyral™ Catheter device may have a different modality (*i.e.,* radiofrequency compared to ultrasound), the Symplicity Spyral™ Catheter device may have a similar mechanism of action to that of the Paradise® Ultrasound RDN System device. We questioned whether the device descriptions provided in the respective applications support establishing two modality specific pass-through payment device categories or a single device category that would encompass both RDN device modalities. We address this question in section (i) in detail immediately following the full discussion of all other applicable eligibility criteria for the Symplicity Spyral™ RDN System application.

For the summary of public comments received and our final decision on the question of whether the device descriptions provided in the respective applications support establishing two modality-specific pass-through payment device categories or a single device category that would encompass both RDN device modalities, please see section (i) immediately following the Symplicity Spyral™ RDN System application determination.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. As previously stated, the Symplicity Spyral™ Catheter has Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation (as explained in more detail in the discussion of the newness criterion) and therefore is not evaluated for substantial clinical improvement.

We invited public comment on whether the Symplicity Spyral™ Catheter meets the device category criterion at § 419.66(c)(2)(ii).

Comment: The applicant submitted a comment confirming that the Symplicity Spyral™ Catheter meets the eligibility criterion at § 419.66(c)(2)(ii) because as an FDA Breakthrough Device, it meets the device category criterion as described at § 419.66(c)(2)(ii). A few commenters also stated that the Symplicity Spyral™ Catheter meets the eligibility criterion at § 419.66(c)(2)(ii).

Response: We appreciate the applicant's and commenters' input. The Symplicity Spyral™ RDN System has a Breakthrough Device designation, as stated by the applicant, effective March 27, 2020, and marketing authorization from FDA effective November 17, 2023, for the indication covered by the Breakthrough Device designation and therefore, meets the criterion at § 419.66(c)(2)(ii) and is not evaluated for substantial clinical improvement at § 419.66(c)(2)(i). Based on our review of the application and consideration of the public comments we received, we have determined that the Symplicity Spyral™ Catheter meets the eligibility criterion at § 419.66(c)(2).

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the Symplicity Spyral™ Catheter would be reported with HCPCS codes shown in Table 121.

[44] The applicant referenced CY 2013 OPPS FR (77 FR 68352) and Transmittal 2386, Change Request 7672 (Jan 13, 2012) to support these assertions.

[45] The applicant referenced the Medicare Claims Processing Manual, Chapter 4, section 60.4.3 to support these assertions.

TABLE 121: HCPCS CODES REPORTED WITH THE SYMPLICITY SPYRAL™ CATHETER

HCPCS Code	Long Descriptor	SI	APC
0338T**	Transcatheter renal sympathetic denervation, percutaneous approach including arterial puncture, selective catheter placement(s) renal artery(ies), fluoroscopy, contrast injection(s), intraprocedural roadmapping and radiological supervision and interpretation, including pressure gradient measurements, flush aortogram and diagnostic renal angiography when performed; unilateral	J1	5192
0339T	Transcatheter renal sympathetic denervation, percutaneous approach including arterial puncture, selective catheter placement(s) renal artery(ies), fluoroscopy, contrast injection(s), intraprocedural roadmapping and radiological supervision and interpretation, including pressure gradient measurements, flush aortogram and diagnostic renal angiography when performed; bilateral	J1	5192

**Denotes a HCPCS code that was not included in the corrected Addendum P to the CY 2024 OPPS/ASC final rule with comment period, with no CY 2024 HCPCS/CPT code level device offset amount available. We noted the applicant used the CY 2024 payment rates for the three tests of the cost criterion. We used the CY 2024 HCPCS/CPT code level device offset amount for the HCPCS/CPT code included in the corrected Addendum P to assess whether the device meets the cost significance criterion.

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). We noted that the applicant used the CY 2024 payment rates for the three tests of the cost criterion. For our calculations, we used APC 5192, which had a CY 2024 payment rate of $5,445.84 at the time the application was received. HCPCS code 0339T in APC 5192 had a CY 2024 device offset amount of $3,362.26 at the time the application was received.[46] According to the applicant, the cost of the Symplicity Spyral™ Catheter is $16,000.00.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The average reasonable cost of $16,000.00 for the Symplicity Spyral™ Catheter is 293.80 percent of the applicable APC payment amount for the service related to the category of devices of $5,445.84 (($16,000.00/$5,445.84) × 100 = 293.80 percent). Therefore, we stated that we believe the Symplicity Spyral™ Catheter meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $16,000.00 for the Symplicity Spyral™ Catheter is 475.87 percent of the cost of the device-related portion of the APC payment amount for the related service of $3,362.26 (($16,000.00/$3,362.26) × 100 = 475.87 percent). Therefore, we stated that we believe the Symplicity Spyral™ Catheter meets the second cost significance requirement.

The third cost significance requirement at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $16,000.00 for the Symplicity Spyral™ Catheter and the portion of the APC payment amount for the device of $3,362.26 is 232.06 percent of the APC payment amount for the related service of $5,445.84 ((($16,000.00 − $3,362.26)/$5,445.84) × 100 = 232.06 percent). Therefore, we stated that we believe the Symplicity Spyral™ Catheter meets the third cost significance requirement.

We invited public comment on whether the Symplicity Spyral™ Catheter meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

Comment: With respect to cost significance criteria, the applicant and a few other commenters reiterated that the Symplicity Spyral™ Catheter meets all three of the cost significance criteria.

Response: We appreciate the applicant's and commenters' input. After consideration of the public comments we received and our findings from the first, second, and third cost significance tests, we agree that the Symplicity Spyral™ Catheter meets the cost significance criteria specified at § 419.66(d).

After consideration of the public comments we received and our review of the device pass-through application, we have determined that the Symplicity

[46] We noted that the applicant selected the APC payment rate of $5,451.51 and the HCPCS/CPT code level device offset amount of $3,365.76 for HCPCS 0339T in APC 5192. However, the values selected are inconsistent with the APC payment rate and the device offset amount found in the corrected Addendum P to the CY 2024 OPPS/ASC final rule with comment period. For our calculation, we selected the APC payment rate of $5,445.84 and the HCPCS/CPT code level device offset amount of $3,362.26 for HCPCS 0339T in APC 5192 found in the corrected Addendum P, which are the accurate values for these codes. Based on our initial assessment for the proposed rule, using the APC payment rate of $5,445.84 and the HCPCS/CPT code level device offset amount of $3,362.26 would result in the Symplicity Spyral™ Catheter meeting the cost significance requirement.

Spyral™ Catheter meets the requirements for device pass-through status described at § 419.66. Therefore, effective beginning January 1, 2025, we are finalizing approval for device pass-through payment status for the Symplicity Spyral™ Catheter under the alternative pathway for devices that have an FDA Breakthrough Device designation and have received FDA marketing authorization for the indication covered by the Breakthrough Device designation.

(i) Paradise® Ultrasound RDN System and the Symplicity Spyral™ RDN System Device Category Code Establishment

As previously discussed, we received two applications for transitional device pass-through status for RDN devices: the Paradise® Ultrasound RDN System and the Symplicity Spyral™ RDN System (Symplicity Spyral™ Catheter). Per the applicants, both are RDN devices that use an endovascular approach to enter the renal arteries and ablate renal sympathetic nerves to achieve reductions in blood pressure. We questioned whether the information provided for each nominated device supported establishing two modality-specific device pass-through payment device categories or establishing a single device category that would encompass both RDN devices.

We noted that the Paradise® Ultrasound RDN System and the Symplicity Spyral™ RDN System are both authorized by FDA for the indicated use to reduce blood pressure as an adjunctive treatment in patients with hypertension in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure. In addition, based on the information provided in the respective applications, we stated that it appears that both devices use the same procedure (renal sympathetic denervation, also called renal sympathetic nerve ablation) with the same underlying mechanism of action (thermal ablation), treat the same disease (hypertension) in the same patient population (patients in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure), and aim to achieve the same therapeutic outcome (to reduce blood pressure). We noted that in addition to having the same indicated use, per the applicants, both devices may be used with the same HCPCS procedure codes: 0338T [47] or 0339T.[48]

We noted several differences in procedural technique with use of the Paradise® Ultrasound RDN System device compared to the Symplicity Spyral™ RDN System device. Per the applicants, the Paradise® Ultrasound RDN System delivers ablation while positioned in the main renal arteries only, whereas the Symplicity Spyral™ RDN System may deliver ablation while positioned in the main renal, accessory, and branch arteries and therefore may require advancing the catheter beyond the main renal arteries. According to the applicants, the Paradise® Ultrasound RDN System procedural technique requires the measurement of the main renal artery diameter to select an appropriate size cooling balloon catheter, whereas the Symplicity Spyral™ RDN System does not require a cooling balloon catheter nor this measurement. Similarly, per the applicants, the Paradise® Catheter's cooling balloon catheter requires additional procedural techniques to ensure the balloon is appropriately inflated and deflated during the procedure, but the Symplicity Spyral™ Catheter does not require this.

The two applicants proposed different device category descriptions. Based on the information submitted, we acknowledged that the device category proposed by the applicant for the Paradise® Ultrasound RDN System would not appropriately describe the Symplicity Spyral™ RDN System, but that the device category proposed by the applicant for the Symplicity Spyral™ RDN System would appropriately describe the Paradise® Ultrasound RDN System. Specifically, the applicant for the Paradise® Ultrasound RDN System proposed the following device category: *Catheter, intravascular renal denervation, ultrasound, with balloon cooling,*[49] while the applicant for the Symplicity Spyral™ RDN System proposed the following device category: *Ablation catheter, renal nerve, via endovascular approach, any modality.* The device category descriptor the applicant proposed for the Paradise® Ultrasound RDN System specifies the device's treatment or procedure (catheter renal denervation), the ablation modality (*i.e.,* ultrasound), and an attribute of the catheter (*i.e.,* the cooling balloon). We noted that while the device category descriptor the applicant proposed for the Symplicity Spyral™ RDN System device also specifies the device's treatment or procedure (catheter ablation of the renal nerves), it does not specify an ablation modality or any additional attributes of the catheter; rather, the proposed device category for the Symplicity Spyral™ RDN System more broadly describes any ablation modality (*e.g.,* radiofrequency or ultrasound).

The applicant for the Symplicity Spyral™ RDN System asserted that the use of a common thermal mechanism of action in both systems supported the establishment of a single device category irrespective of modality. However, we noted the applicant of the Paradise® Ultrasound RDN System stated a separate device category associated with ultrasound denervation is supported by possible differences in clinical efficacy between RDN devices using ultrasound and those using radiofrequency ablation. However, we noted that we did not evaluate the validity or generalizability of these claims, nor was it clear if the two different ablation modalities (*i.e.,* ultrasound and radiofrequency) would render different clinical results in larger studies or in the long term.[50] [51] We further noted that we discussed these claims solely for the purpose of

[47] HCPCS procedure code 0338T (Transcatheter renal sympathetic denervation, percutaneous approach including arterial puncture, selective catheter placement(s) renal artery(ies), fluoroscopy, contrast injection(s), intraprocedural roadmapping and radiological supervision and interpretation, including pressure gradient measurements, flush aortogram and diagnostic renal angiography when performed; unilateral).

[48] HCPCS procedure code 0339T (Transcatheter renal sympathetic denervation, percutaneous approach including arterial puncture, selective catheter placement(s) renal artery(ies), fluoroscopy, contrast injection(s), intraprocedural roadmapping and radiological supervision and interpretation, including pressure gradient measurements, flush aortogram and diagnostic renal angiography when performed; bilateral).

[49] The Paradise® Ultrasound RDN System device category does not explicitly describe using an endovascular approach; however, it does describe renal nerve ablation via a catheter. We stated that we believe the device category describes the intravascular sonication (ultrasound treatment) delivered by the catheter. We noted that the proposed device description does not preclude an endovascular approach, and that, per the applicant, the Paradise® Ultrasound RDN system is a catheter-based endovascular based system.

[50] Fengler, K., Rommel, K.-P., Kriese, W., Blazek, S., Besler, C., von Roeder, M., Desch, S., Thiele, H., & Lurz, P. (2023, February 13). Research Correspondence: 6- and 12-Month Follow-Up From a Randomized Clinical Trial of Ultrasound vs Radiofrequency Renal Denervation (RADIOSOUND–HTN). *JACC: Cardiovascular Interventions, 16*(3),: 367–369. *https://doi.org/10.1016/j.jcin.2022.10.058*

[51] Fengler, K., Rommel, K.-P., Blazek, S., Besler, C., Hartung, P., von Roeder, M., Petzold, M., Winkler, S., Höllriegel, R., Desch, S., Thiele, H., & Lurz, P. (2019). A Three-Arm Randomized Trial of Different Renal Denervation Devices and Techniques in Patients With Resistant Hypertension (RADIOSOUND–HTN). *Circulation: 139*(5), 590–600. *https://doi.org/10.1161/CIRCULATIONAHA.118.037654.*

determining whether the information provided supports establishing two modality-specific pass-through payment device categories or establishing a single device category that may encompass both RDN devices.

In seeking comment, we noted that in accordance with section 1833(t)(6)(B)(ii)(II) of the Act, new categories must be established in such a way that no medical device is described by more than one category. We further noted that CMS does not establish pass-through device categories for the purposes of describing specific devices, but rather, device categories which are intended to encompass all devices that can be appropriately described by a category. However, there are instances where CMS has defined specific ablation modalities (*e.g.,* high intensity ultrasound, microwave, and cryoablation) in HCPCS codes for use with the OPPS. In addition, we noted the existence of several modality-specific tissue ablation procedure codes in the Current Procedural Terminology (CPT®) 2024. However, there are examples where CMS has established device categories with additional granularity to differentiate similar devices with special characteristics (*e.g.,* implantable neurostimulators). Further, there are examples where CMS has created HCPCS codes specifying the modality of ablation (*e.g.,* ultrasound, microwave). Finally, we noted that the intent of transitional device pass-through payment, as implemented at § 419.66, is to facilitate access for beneficiaries to the advantages of new and truly innovative devices by allowing for adequate payment for these new devices while the necessary cost data is collected to incorporate the costs for these devices into the procedure APC rate (66 FR 55861). We questioned whether two modality-specific device category codes may facilitate the collection of more accurate data for incorporating the costs of these two devices into the procedure APC rate as well as foster the tracking of efficacy data for these two ablation modalities.

As such, we invited public comment on whether the device descriptions provided in the Paradise® Ultrasound RDN System and the Symplicity Spyral™ RDN System applications support establishing two modality-specific pass-through payment device categories or a single device category that would encompass both RDN device modalities.

Comment: Commenters, including the Paradise® Ultrasound RDN System applicant, overwhelmingly supported establishing two pass-through payment device categories. However, some commenters suggested that the device category codes be specific to the physical device characteristics while other commenters suggested the device category codes be specific to modality. Specifically, the applicant for the Paradise® Ultrasound RDN System and many other commenters stated that two device categories are more appropriate for many reasons such as documented procedural differences between the two treatment modalities, differences in the prices between the two technologies, CMS's previous creation of separate and distinct device categories for similar technologies, CMS's recent creation of different ICD–10–PCS codes for radiofrequency and ultrasound renal denervation modalities in the FY 2025 IPPS final rule, and to facilitate the tracking of each device's efficacy data.

We received a few comments, including from the Symplicity Spyral™ RDN System applicant, who suggested that CMS establish a single device category that would encompass both RDN device modalities. The Symplicity Spyral™ RDN System applicant and a few other commenters supported the establishment of an energy modality-agnostic RDN device pass-through payment device category for several reasons. Specifically, the Symplicity Spyral™ RDN System applicant emphasized the similarities between the two devices and procedures, opinions from the physician community, existing policy and coding standards, and potential future consequences of this determination. The Symplicity Spyral™ RDN System applicant also disagreed with many of the reasons for separate pass-through payment device categories provided by the Paradise® Ultrasound RDN System applicant that were outlined in the proposed rule.

Response: We appreciate the feedback provided by the applicants and the commenters on this topic. We have taken the points raised into consideration in our final decision.

Comment: Commenters, including the Paradise® Ultrasound RDN System applicant noted many procedural differences between the two treatment modalities. For example, the radiofrequency system (*i.e.,* Symplicity Spyral™ RDN System) requires ablation of the main renal artery and branches of the main renal artery, whereas the Paradise® Ultrasound RDN System normally requires ablation of only the main renal artery, leading to significantly fewer ablations [52] [53] and the Paradise® Ultrasound RDN System requires the estimation of the size of the patient's renal artery to ensure the correct balloon size is utilized, which may require additional equipment or procedural steps at the discretion of the operator compared to the Symplicity Spyral™ RDN System procedure, where this is not required. In addition, the applicant and many commenters noted that the Symplicity Spyral™ RDN System procedure takes longer than the overall procedure for the Paradise® Ultrasound RDN System, and the Paradise® Ultrasound RDN System applicant specified this difference in procedure time as approximately 30 percent.[54] [55] [56] [57] [58] Many other commenters also indicated additional potential procedural differences between the two devices, including variation in the number of catheters used, pre- and post-procedure scheduling and workflow protocols, complexity of the procedure, depth of ablation, specialized training requirements, patient selection and management issues, and recovery time.

With respect to procedural and device similarities, the Symplicity Spyral™ RDN System applicant and another commenter reiterated that both devices share the same intended use, for the same patient population, with identical

[52] Fengler, et al. (2019). A Three-Arm Randomized Trial of Different Renal Denervation Devices and Techniques in Patients With Resistant Hypertension (RADIOSOUND–HTN). *Circulation, 139*(5), 590–600. *https://doi.org/10.1161/CIRCULATIONAHA.118.037654.*

[53] Fengler, et al. (2023). Research Correspondence: 6- and 12-Month Follow-Up From a Randomized Clinical Trial of Ultrasound vs Radiofrequency Renal Denervation (RADIOSOUND–HTN). *JACC: Cardiovascular Interventions, 16*(3): 367—369. *https://doi.org/10.1016/j.jcin.2022.10.058.*

[54] Fengler, et al. (2019).

[55] Fengler, et al. (2023).

[56] Symplicity Spyral renal denervation system Instructions for Use. Medtronic.

[57] Azizi, M., Schmieder, R.E., Mahfoud, F., Weber, M.A., Daemen, J., Davies, J., Basile, J., Kirtane, A.J., Wang, Y., Lobo, M.D., Saxena, M., Feyz, L., Rader, F., Lurz, P., Sayer, J., Sapoval, M., Levy, T., Sanghvi, K., Abraham, J., Sharp, A.S.P., Fisher, N.D.L., Bloch, M.., Reeve-Stoffer, H., Coleman, L., Mullin, C., & Mauri, Laura on behalf of the RADIANCE–HTM Investigators (2018). Endovascular ultrasound renal denervation to treat hypertension (RADIANCE–HTN SOLO): a multicentre, international, single-blind, randomised, sham-controlled trial. *Lancet, 391*(10137), P2335–P2345. *https://doi.org/10.1016/S0140-6736(18)31082-1.*

[58] Azizi, M., Sanghvi, K., Saxena, M., Gosse, P., Reilly, J.P., Levy, T., Rump, L.C., Persu, A., Basile, J., Bloch, M.J., Daemen, J., Lobo, M.D., Mahfoud, F., Schmieder, R.E., Sharp, A.S.P., Weber, M.A., Sapoval, M., Fong, P., Pathak, A., Lantelme, P., Hsi, D., Bangalore, S., Witkowski, A., Weil, J., Kably, B., Barman, N.C., Reeve-Stoffer, H., Coleman, L., McClure, C.K., Kirtane, A.J. on behalf of the RADIANCE–HTN Investigators (2021). Ultrasound renal denervation for hypertension resistant to a triple medication pill (RADIANCEHTN TRIO): a randomised, multicentre, single-blind, sham-controlled trial. Lancet, 397(10293), P2476–P2486. *https://doi.org/10.1016/S0140-6736(21)00788-1.*

or nearly identical FDA-approved indications, and are deployed similarly, on the same anatomy. The Symplicity Spyral™ RDN System applicant further stated that the two devices have the same mechanism of action (thermal ablation of renal sympathetic nerves using heat energy), a similar form factor and product composition (single use endovascular catheters, connected to a generator, and delivered over a wire to the renal arteries, with distal ends containing heat energy emitting implements which ablate nerve tissue), and that the RDN procedure performed with either technology is fundamentally the same. The Symplicity Spyral™ RDN System applicant also asserted that even though there may be small differences in the placement of each device along the renal arterial vasculature, they believe these small differences can be expected for devices that are inherently similar but not identical in form factor, size, and deliverability. The Symplicity Spyral™ RDN System applicant asserted that the RDN procedure performed by both devices is also fundamentally the same, as both include catheter-based femoral access and closure, intraprocedural imaging, physician wire skills and expertise, and the ablation targeting of the sympathetic renal nerves to achieve the identical therapeutic goal of reducing blood pressure.

The Symplicity Spyral™ RDN System applicant reiterated that the Paradise® Catheter's cooling balloon requires specific procedural techniques to ensure the balloon is appropriately inflated and deflated during the procedure, noting that the Symplicity Spyral™ Catheter does not have this requirement. The applicant stated that the Symplicity Spyral™ Catheter does not require a cooling balloon as the non-occlusive spiral design of the radiofrequency catheter allows for continued collateral blood flow to cool the artery wall during ablation. Further, while use of the Paradise® Catheter's cooling balloon does require some different considerations when compared to the Symplicity Spyral™ Catheter, particularly related to vessel size, the cooling balloon itself is not providing the therapeutic effect (*i.e.* ablation of the nerves); rather, the balloon is preventing vessel damage from heat energy. The applicant stated this distinction makes it similar to many medical devices which provide the same treatment but require slightly different considerations based on manufacturer-specific equipment differences, and while the energy modality has driven some differences in the Symplicity Spyral™ Catheter and the Paradise® Catheter designs, the overall procedure is substantially similar between the two technologies.

With respect to the differences in procedural technique described in the proposed rule that the Paradise® Ultrasound RDN System only ablates in the main renal arteries, while the Symplicity Spyral™ RDN System typically involves ablation in the main renal arteries, accessories, and branches, the applicant stated that according to the Paradise® Ultrasound RDN System instructions for use (IFU),[59] the Paradise® Ultrasound RDN System is recommended for treatment of branches and accessory arteries, provided they are of appropriate size to accommodate the balloon and meet specific spacing requirements. The Symplicity Spyral™ RDN System applicant explained that the Symplicity Spyral™ RDN System IFU[60] do not specify or require that distal branches be treated (only a size range for vessel diameters is specified). Furthermore, per the applicant, a thorough treatment strategy typically including distal branches is recommended for the Symplicity Spyral™ RDN System. The applicant noted that this recommendation is based on available knowledge of renal sympathetic nerve anatomy, to increase the likelihood of thorough and complete denervation up to the size limitations of the device, given that the current procedure and technology do not yet have an intraprocedural way to validate successful denervation. Additionally, the Symplicity Spyral™ RDN System applicant noted that several studies, including a sub-analysis of the Paradise® Ultrasound RDN System applicant's RADIANCE–HTN SOLO[61] study, point to the importance of thorough ablation, including appropriate branch and accessory renal arteries, to achieving optimal nerve ablation and blood pressure reduction with RDN.[62] [63] Further, the Symplicity Spyral™ RDN System applicant stated that proceduralists with both devices seek to denervate to the greatest extent possible up to the limitations of the RDN technology used, and there are many considerations in how proceduralists may determine where to denervate, and with how many energy emissions, based on clinical experience and patient anatomical considerations.

The Symplicity Spyral™ RDN System applicant disagreed with some assertions provided in the Paradise application and discussed in some of the comments supporting the creation of two device category codes. Primarily, the applicant asserted that the differences in intraprocedural metrics cited in the proposed rule noted are not accurate comparisons. For example, the Symplicity Spyral™ RDN System applicant stated that the average procedure times from respective pooled analyses suggest that the total procedure time is 85 minutes for the Symplicity Spyral™ RDN System[64] and 78 minutes for the Paradise® Ultrasound RDN but the total procedure times attributed to using either device are variable across studies, and, due to differing trial procedural requirements and physician experience, it is difficult to compare procedure times across studies. In addition, the applicant further stated other intraprocedural metrics, such as total ablation time and ablation time per cycle, are not necessarily reflective of additional resources involved in the procedures. The Symplicity Spyral™ RDN System applicant noted that in the proposed rule CMS stated that the Symplicity Spyral™ Catheter required more ablations per patient at 46.9, compared to 5.4 ablations for the Paradise® Ultrasound RDN System. However, the applicant stated that as a quadripolar device, each of the Symplicity Spyral™ Catheter's four electrodes may be activated independently for focal treatments, causing the difference in the number of ablations. The applicant clarified that the SPYRAL HTN–OFF MED

[59] ReCor Paradise Ultrasound RDN Instructions for Use. *https://mearis.cms.gov/public/publications/device-ptp/DEP231128137E1* (accessed July 26, 2024).

[60] Symplicity Spyral Indications for Use. Available at: *https://www.accessdata.fda.gov/cdrh_docs/pdf22/P220026D.pdf*. Accessed Sept 2024.

[61] Saxena, M., Schmieder, R.E., Kirtane, A.J., Mahfoud, F., Daemen, J., Basile, J., Lurz, P., Gosse, P., Sanghvi, K., Fisher, N.D.L., Rump, L.C., Pathak, A., Blakenstjn, P.J., Mathur, A., Wang, Y., Weber, M.A., Sharp, A.S.P., Bloch, M.J., Barman, N.C., Claude, L., Song, Y., Aziz, M. & Lobo, M.D. (2022). Predictors of blood pressure response to ultrasound renal denervation in the RADIANCE–HTN SOLO study. *Journal of Human Hypertension, 36*(7), 629–639. *https://doi.org/10.1038/s41371-021-00547-y*.

[62] Sato, Y., Kawakami, R., Jinnouchi, H., Sakamoto, A., Cornelissen, A., Mori, M., Kawai, K., Guo, L., Coleman, L., Nash, S., Claude, L., Barman, N.C., Romero, M., Kolodgie, F.D., Virmani, R., & Finn, A.V. (2001). Comprehensive Assessment of Human Accessory Renal Artery Periarterial Renal Sympathetic Nerve Distribution. *JACC: Cardiovascular Interventions, 14*(3), 304–15. *https://doi.org/10.1016/j.jcin.2020.09.043*.

[63] Struthoff, H., Lauder, L, Hohl, M., Hermens, A., Rami Tzafriri, A., Edelman, E.R., Kunz, M., Böhm, M., Tschernig, T., & Mahfoud, F. (2023). Histological examination of renal nerve distribution, density, and function in humans. *EuroIntervention, 19*(7), 612–620. *https://doi.org/10.4244/eij-d-23-00264*.

[64] Podium presentation. Mahfoud. Pooled, 12-month Blood Pressure Reductions Using the Symplicity Spyral Radiofrequency Renal Denervation Catheter. Transvascular Cardiotherapuetics Conference. October 2023.

randomized controlled trial [65] counted ablations from each of the four electrodes of the Symplicity Spyral™ Catheter as a separate ablation, although most ablation cycles would have counted the four ablations simultaneously as a single ablation. The applicant indicated that given this design difference, it is misleading to draw comparisons between those two data points for each system. The applicant also clarified that regarding ablation depth, cadaveric studies found that >90 percent of the renal nerves lie within 6.39 mm of the arterial lumen.[66] While the applicant stated that it cannot independently confirm the 1–6 mm ablation depth cited for the Paradise® Ultrasound RDN System, a histological study of radiofrequency RDN in porcine models using the Symplicity Spyral™ RDN System found a comparable mean lesion depth of 6.26 mm (+/- 1.62) in the main renal segment.[67] The Symplicity Spyral™ RDN System applicant also stated that regardless of modality, ablation depth is not uniform and occurs asymmetrically as a result of heating different tissue types surrounding the renal artery (given the presence of other organs surrounding the renal artery, and anatomical variability between patients, this heat energy is variably dissipated). Therefore, the applicant asserted that ablation depth, by itself, is an incomplete two-dimensional measure of a three-dimensional phenomenon.

Response: We thank the commenters and the applicants for the information. We agree with commenters that the Paradise® Ultrasound RDN System and the Symplicity Spyral™ RDN System have the same underlying thermal mechanism of action, have the same intended use for the same patient population, and have identical FDA-approved primary indications. However, we continue to believe that, while there are similarities, the devices are not identical and warrant separate device categories. We note that commenters, including the applicants, addressed potential clinical impacts, efficacy, and outcomes in the comments. While we have included some of those details in our discussion for the purposes of illustrating the procedural comparison of the two devices and determining whether the information provided supports establishing two modality-specific pass-through payment device categories or establishing a single device category that may encompass both RDN devices, we note that we did not evaluate the validity or generalizability of these claims, nor was it is clear if the two different ablation modalities (*i.e.,* ultrasound and radiofrequency) would render different clinical results in larger studies or in the long term. In regard to comments on the differences in clinical trial data between the Paradise® Ultrasound RDN System and the Symplicity Spyral™ RDN System, we are not evaluating any evidence submitted in relation to the devices' clinical outcomes or the comparison of clinical outcomes to other similar devices because both devices meet the requirements at § 419.66(c)(2)(ii) and are not required to prove substantial clinical improvement for pass-through payment, as discussed in this final rule.

With regard to the procedural differences we noted in the proposed rule, we agree with commenters that there are some procedural differences between the two RDN technologies and that the long-term impact of these differences on patient outcomes is unknown. We appreciate that differences between the two treatment modalities may result in different resource requirements such as operating room time, more anesthetic, and more contrast medium. We also agree with the many commenters who stated the Paradise® Ultrasound RDN System may require additional equipment or procedural steps to determine the estimation of the size of the patient's renal artery to ensure the correct balloon size is utilized.

With regards to comments stating the cooling balloon itself is not providing the therapeutic effect (*i.e.* ablation of the nerves); rather, the balloon is preventing vessel damage from heat energy, we appreciate that the cooling balloon does not constitute a difference in mechanism of action. However, we believe the different considerations of resources due to the differences of the cooling balloon may be considered a significant difference in modalities that could reasonably suggest a need for separate device codes.

Comment: The Paradise® Ultrasound RDN System applicant and many commenters stated that the difference in price between the two technologies also warrants two device categories. The Paradise® Ultrasound RDN System applicant and many other commenters stated that while the transitional pass-through payment calculation is based on hospital charges, having only one device category could lead to undercharging for one technology and overcharging for the other. The Paradise® Ultrasound RDN System applicant and many other commenters further stated that having two distinct device categories would allow hospitals to set charges that accurately reflect the cost of each procedure, thereby enabling CMS to more accurately calculate the costs of each procedure. The applicant and a few commenters further stated two distinct device categories would provide additional flexibility for CMS to more fully evaluate both modalities over the pass-through period to determine the most appropriate APC assignment when transitional pass-through payment expires.

The Symplicity Spyral™ RDN System applicant commented that it appreciates CMS' intent to facilitate access for beneficiaries to innovative technologies by allowing for adequate payment while cost data is collected for APC assignments, and that the payment calculation methodology for transitional device pass-through provides for adequate payments based on charges on individual hospital claims adjusted to costs during the 3-year eligibility period, regardless of device category assignment. The applicant further commented that when the pass-through period expires and CMS packages the procedures into an APC, payment will be calculated at the level of the CPT code, which both RDN technologies share. The applicant claimed that the RDN device costs for both technologies will be packaged into the payment for the same CPT code, whether these costs are similar or not. The Symplicity Spyral™ RDN System applicant therefore questioned the utility of using separate device categories for cost tracking. The Symplicity Spyral™ RDN System applicant also opined that tracking efficacy data for the two devices is beyond the fundamental purpose of establishing device categories and should not be a primary consideration. The applicant stated that both manufacturers are engaged in post-

[65] Böhm, M., Kario, K., Kandzari, D.E., Mahfoud, F., Weber, M.A., Schmieder, R.E., Tsioufis, K., Pocock, S., Konstantinidis, D., Choi, J.W., East, C., Lee, D.P., Ma, A., Ewen, S., Cohen, D.L., Wilensky, R., Devireddy, C.M., Lea, J., Schmid, A., Weil, J., Agdirlioglu, T., Reedus, D., Jefferson, B.K., Reyes, D., D'Souza, R., Sharp, A.S.P., Sharif, F., Fahy, M., DeBruin, V., Cohen, S.A., Brar, S., & Townsend, R.R. on behalf of the SPYRAL HTN–OFF MED Pivotal Investigators (2020). Efficacy of catheter-based renal denervation in the absence of antihypertensive medications (SPYRAL HTN–OFF MED Pivotal): a multicentre, randomised, sham-controlled trial. *Lancet, 395*(10234), 1444–1451. *https://doi.org/10.1016/s0140-6736(20)30554-7.*

[66] Sakakura, K., Ladich, E., Cheng, Q., Otsuka, F., Yahagi, K., Fowler, D.R., Kolodgie, F.D., Virmani, R., & Joner, M. (2014). Anatomic assessment of sympathetic peri-arterial renal nerves in man. *Journal of American College of Cardiology, 64*(7), 635–43. *https://doi.org/10.1016/j.jacc.2014.03.059.*

[67] Wolf, M., Hubbard, B., Sakaoka, A., Rousselle, S., Tellez, A., Jiang, X., Kario, K., Hohl, M., Böhm, M., & Mahfoud, F. (2018). Procedural and anatomical predictors of renal denervation efficacy using two radiofrequency renal denervation catheters in a porcine model. *Journal of Hypertension, 36*(12), 2453–2459. *https://doi.org/10.1097/hjh.0000000000001840.*

market research to continue building the body of evidence for RDN specific to each technology, and the research will continue independent of the establishment of pass-through device categories. The applicant urged CMS to prioritize and maintain an OPPS policy-based rationale in establishing new device categories, with focus on the payment-driven mechanisms and purposes of the device category codes.

Response: In response to comments on the difference in price between the two technologies and whether that difference warrants two device categories, we note that while price difference considerations are generally outside the scope of the traditional pass-through payment program, we agree with commenters that two distinct device categories will provide an easier mechanism for hospitals to set charges that reflect the price differences between the two device categories which will enable CMS to more accurately calculate the costs of each procedure for future rulemaking.

Comment: The Paradise® Ultrasound RDN System applicant and many commenters asserted that CMS has previously created separate and distinct device categories for similar technologies. The applicant suggested the most notable of these are the neurostimulators, where CMS created categories to differentiate rechargeable, non-rechargeable, high-frequency, and closed feedback loop neurostimulators for the treatment of chronic pain.[68] The Paradise® Ultrasound RDN System applicant stated that other neurostimulator categories have also been created for phrenic nerve stimulation, paired stimulation, and carotid sinus baroreceptor stimulation. Further, the applicant stated that there are also currently five device categories[69] that are all electrophysiology catheters. The applicant stated that they believe that these device categories appropriately capture the characteristics among these groups of technologies to allow for the most accurate reporting of device costs. The Paradise® Ultrasound RDN System applicant opined that the situation with respect to the Paradise® Ultrasound RDN System and the Symplicity™ Spryal RDN System is similar to the examples presented, and therefore, it is appropriate to have two device categories to differentiate tracking of ultrasound and radiofrequency renal denervation. Several other commenters also referenced device categories that were differentiated due to their unique characteristics, including examples related to cardiology, neurostimulators, catheters, and ablation modalities (*i.e.,* high-intensity ultrasound, microwave, and cryoablation), to support their position that the Paradise® Ultrasound RDN System and the Symplicity™ Spryal RDN System should be classified within two different pass-through payment device categories.

Further, the Paradise® Ultrasound RDN System applicant and many commenters noted that CMS recently created different ICD–10–PCS codes that differentiate between radiofrequency and ultrasound renal denervation modalities for the new technology add-on payments confirmed in the IPPS final rule for FY 2025. The applicant and several commenters opined that it is important to be consistent across inpatient and outpatient settings as the same rationale for separation and independent tracking of costs applies in both instances. A few commenters stated that the use of separate ICD–10–PCS codes for the two devices reflect their unique contributions to the treatment of hypertension.

The applicant for the Symplicity Spyral™ RDN System argued that pass-through device categories are not established for the purpose of describing specific devices; rather, device categories are intended to encompass all devices that can be appropriately described by a category (89 FR 59316). The applicant acknowledged that, as stated in the proposed rule, CMS has established energy-specific device categories in the past; however, the applicant asserted that the establishment of device categories requires a nuanced approach, balancing appropriate granularity without becoming manufacturer- or device-specific. The applicant asserted that CMS must assess each situation on a case-by-case basis, in the context of the procedure and device in question, the existing code set, and established policy. The applicant asserted its belief that a single device category for the two RDN technologies is consistent with the considerations put forth by CMS in the proposed rule and consistent with past precedent, whereas the creation of two categories may conflict with these policy standards. Another commenter stated a preference for a simple single code to be used on claims when performing RDN, regardless of which device is chosen.

With regard to broader device category definitions, the Symplicity Spyral™ RDN System applicant asserted that RDN ablation catheters in the future may come with several combinations of modalities and cooling mechanisms, noting that there are other RDN devices currently in development, such as a radiofrequency RDN catheter with balloon cooling under study by Metavention, with an approved Investigational Device Exemption (IDE) in the United States. The applicant stated the belief that other manufacturers may eventually gain FDA authorization with various device structures and features employing either ultrasound or radiofrequency RDN, and thus believed that the specific category description proposed by the Paradise® Ultrasound RDN System applicant would establish a framework in which different iterations of RDN technology could be considered new by virtue of their brand-specific characteristics. The Symplicity Spyral™ RDN System applicant asserted that, in contrast, a broader device category definition for RDN technologies currently eligible for pass-through would provide flexibility for future RDN devices to be evaluated on their own merits and that, if those devices meet the newness and other criteria for pass-through payment status, a broad category code for RDN can be easily adapted to reflect the distinguishing characteristic that merits such recognition.

The Symplicity Spyral™ RDN System applicant noted that the RDN procedure used with either device is currently reported using the same energy modality-agnostic Category III CPT® codes. This applicant further opined that the broader physician community views RDN as fundamentally a single procedure with multiple technologies

[68] HCPCS codes C1826 (Generator, neurostimulator (implantable), includes closed feedback loop leads and all implantable components, with rechargeable battery and charging system), C1827 (Generator, neurostimulator (implantable), non-rechargeable, with implantable stimulation lead and external paired stimulation controller), C1821 (Interspinous process distraction device (implantable)), C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system), C1823 (Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads), C1767 (Generator, neurostimulator (implantable), non-rechargeable), C1820 (Generator, neurostimulator (implantable), with rechargeable battery and charging system), and C1825 (Generator, neurostimulator (implantable), non-rechargeable with carotid sinus baroreceptor stimulation lead(s).

[69] HCPCS codes C1730 (Catheter, electrophysiology, diagnostic, other than 3D mapping (19 or fewer electrodes)), C1731 Catheter, electrophysiology, diagnostic, other than 3D mapping (20 or more electrodes)), C1732 (Catheter, electrophysiology, diagnostic/ablation, 3D or vector mapping), C1733 (Catheter, electrophysiology, diagnostic/ablation, other than 3D or vector mapping, other than cool-tip), and C2630 (Catheter, electrophysiology, diagnostic/ablation, other than 3D or vector mapping, cool-tip).

available in the same class.[70] [71] [72] [73] Specifically, the applicant commented that in a Society for Cardiovascular Angiography & Interventions (SCAI) expert consensus statement published in August 2023, the operator training and experience recommended for the RDN procedure is the same, regardless of which technology is used, with the only device-specific training noted in the statement being operator familiarity with the functionality of each technology's generator and knowledge regarding balloon sizing with ultrasound RDN,[74] while the European Society of Cardiology/European Society of Hypertension (ESC/ESH) Guidelines refer only to RDN as a class and do not distinguish between radiofrequency and ultrasound technologies.[75] [76] A commenter stated that from a physician work perspective, the two systems are similar in time and technique. The applicant further asserted that this issue was addressed at the September 2023 American Medical Association CPT® Editorial Panel meeting, where a request for a CPT® code for an energy modality-specific ultrasound RDN procedure was ultimately rejected by the Panel.

Response: As commenters stated, we have established precedent for creating both broad and distinct device categories for similar technologies. In fact, there have been many scenarios is which we have established distinct device categories to differentiate between various neurostimulators, electrophysiology catheters, and ablation modalities to ensure that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect due as required by § 419.66(c)(1). We agree with the Symplicity™ Spryal RDN System applicant that the establishment of device categories requires a nuanced approach, and that CMS must assess each situation on a case-by-case basis in accordance with established policy. We believe that we have followed not only our established policy, but our precedent in our evaluation of the device category code determination for the two nominated RDN devices. We agree with commenters that this situation with respect to the Paradise® Ultrasound RDN System and the Symplicity™ Spryal RDN System is similar to the examples presented.

The Symplicity™ Spryal RDN System applicant noted that manufacturers may gain FDA authorization for other RDN devices with various device characteristics employing either ultrasound or radiofrequency RDN and establishing device category codes that are device characteristic specific, like the code descriptor proposed by the Paradise® Ultrasound RDN System applicant. This, according to the Symplicity™ Spryal RDN System applicant, would establish a framework in which different iterations of RDN technology could be considered new by virtue of their brand-specific characteristics. We acknowledge that concern and agree that the device category codes established for the nominated devices should not typically be differentiated by the specific device characteristics, rather, consistent with the options in the proposed rule, we believe that in this instance the device pass-through payment device categories should be modality-specific.

With respect to a comment on the September 2023 AMA CPT® Editorial Panel meeting, where the Symplicity™ Spryal RDN System applicant stated that a request for a CPT® code specific to an energy modality ultrasound RDN procedure was ultimately rejected, as of the date this final rule with comment period is issued, we are not aware of any decision made by the AMA CPT® Editorial Panel regarding this issue.

Comment: The Paradise® Ultrasound RDN System applicant and many commenters also stated creating two categories may facilitate tracking modality-specific efficacy data and shared their belief that having the ability to identify and track which RDN device modality Medicare patients receive via claims data may be beneficial for CMS in the future.

The Symplicity Spyral™ RDN System applicant stated that tracking efficacy data for the two devices is beyond the fundamental purpose of establishing device categories and should not be a primary consideration.

Response: In response to comments on tracking of long-term efficacy data for the nominated devices, while we note that collecting long-term efficacy data is always a priority of CMS and other interested parties, we agree with the Symplicity Spyral™ RDN System applicant that we do not believe the tracking of long-term efficacy is a fundamental purpose of establishing

[70] Mancia, G., Kreutz, R., Brunström, M., Burnier, M., Grassi, G., Januszewicz, A., Muiesan, M.L., Tsioufis, K., Agabiti-Rosei, E., Algharably, E.A.E., Azizi, M., Benetos, A., Borghi, C., Hitij, J.B., Cifkova, R., Coca, A., Cornelissen, V., Cruickshank, J.K., Cunha, P.G., Danser, A.H.J., Pinho, R.M., Delles, C., Dominiczak, A.F., Dorobantu, M., Doumas, M., Fernández-Alfonso, M.S., Halimi, J.M., Járai, Z., Jelaković, B., Jordan, J., Kuznetsova, T., Laurent, S., Lovic, D., Lurbe, E., Mahfoud, F., Manolis, A., Miglinas, M., Narkiewicz, K., Niiranen, T., Palatini, P., Parati, G., Pathak, A., Persu, A., Polonia, J., Redon, J., Sarafidis, P., Schmieder, R., Spronck, B., Stabouli, S., Stergiou, G., Taddei, S., Thomopoulos, C., Tomaszewski, M., Van de Borne, P., Wanner, C., Weber, T., Williams, B., Zhang, Z.Y., & Kjeldsen, SE (2023). 2023 ESH Guidelines for the management of arterial hypertension: The Task Force for the management of arterial hypertension of the European Society of Hypertension. *Journal of Hypertension, 41*(12), 1874–2071. *https://doi.org/10.1097/HJH.0000000000003480*.

[71] Barbato, E., Azizi, M., Schmieder, R.E., Lauder, L., Böhm, M., Brouwers, S., Bruno, R.M., Dudek, D., Kahan, T., Kandzari, D.E., Lüscher, T.F., Parati, G., Pathak, A., Ribichini, F.L., Schlaich, M.P., Sharp, A.S.P., Sudano, I., Volpe, M., Tsioufis, C., Wijns, W., & Mahfoud, F. (2023). Renal denervation in the management of hypertension in adults. A clinical consensus statement of the ESC Council on Hypertension and the European Association of Percutaneous Cardiovascular Interventions (EAPCI). *European Heart Journal, 44*(15), 1313–1330. *https://doi.org/10.1093/eurheartj/ehad054*.

[72] Swaminathan, R.V., East, C.A., Feldman, D.N., Fisher, N.D., Garasic, J.M., Giri, J.S., Kandzari, D.E., Kirtane, A.J., Klein, A., Kobayashi, T., Koenig, G., Li, J., Secemsky, E., Townsend, R.R., & Aronow, H.D. (2023). SCAI Position Statement on Renal Denervation for Hypertension: Patient Selection, Operator Competence, Training and Techniques, and Organizational Recommendations. *Journal of the Society for Cardiovascular Angiography & Interventions, 2*(6), 101121. *https://doi.org/10.1016/j.jscai.2023.101121*.

[73] Kandzari DE, Townsend RR, Bakris G, Basile, J., Bloch, M.J., Cohen, D.L., East, C., Ferdinand, K.C., Fisher, N., Kirtane, A., Lee, D.P., Puckrein, G., Rader, F., Vassalotti, J.A., Weber, M.A., Willis, K., & Secemsky, E. (2021). Renal denervation in hypertension patients: Proceedings from an expert consensus roundtable cosponsored by SCAI and NKF. *Catheterization & Cardiovascular Interventions, 98*(3), 416–426. *https://doi.org/10.1002/ccd.29884*.

[74] Swaminathan, R.V., East, C.A., Feldman, D.N., Fisher, N.D., Garasic, J.M., Giri, J.S., Kandzari, D.E., Kirtane, A.J., Klein, A., Kobayashi, T., Koenig, G., Li, J., Secemsky, E., Townsend, R.R., & Aronow, H.D. (2023). SCAI Position Statement on Renal Denervation for Hypertension: Patient Selection, Operator Competence, Training and Techniques, and Organizational Recommendations. *Journal of the Society for Cardiovascular Angiography & Interventions, 2*(6), 101121. *https://doi.org/10.1016/j.jscai.2023.101121*.

[75] Mancia, G., Kreutz, R., Brunström, M., Burnier, M., Grassi, G., Januszewicz, A., Muiesan, M.L., Tsioufis, K., Agabiti-Rosei, E., Algharably, E.A.E., Azizi, M., Benetos, A., Borghi, C., Hitij, J.B., Cifkova, R., Coca, A., Cornelissen, V., Cruickshank, J.K., Cunha, P.G., Danser, A.H.J., Pinho, R.M., Delles, C., Dominiczak, A.F., Dorobantu, M., Doumas, M., Fernández-Alfonso, M.S., Halimi, J.M., Járai, Z., Jelaković, B., Jordan, J., Kuznetsova, T., Laurent, S., Lovic, D., Lurbe, E., Mahfoud, F., Manolis, A., Miglinas, M., Narkiewicz, K., Niiranen, T., Palatini, P., Parati, G., Pathak, A., Persu, A., Polonia, J., Redon, J., Sarafidis, P., Schmieder, R., Spronck, B., Stabouli, S., Stergiou, G., Taddei, S., Thomopoulos, C., Tomaszewski, M., Van de Borne, P., Wanner, C., Weber, T., Williams, B., Zhang, Z.Y., & Kjeldsen, SE (2023). 2023 ESH Guidelines for the management of arterial hypertension: The Task Force for the management of arterial hypertension of the European Society of Hypertension. *Journal of Hypertension, 41*(12), 1874–2071. *https://doi.org/10.1097/HJH.0000000000003480*.

[76] Barbato, E., Azizi, M., Schmieder, R.E., Lauder, L., Böhm, M., Brouwers, S., Bruno, R.M., Dudek, D., Kahan, T., Kandzari, D.E., Lüscher, T.F., Parati, G., Pathak, A., Ribichini, F.L., Schlaich, M.P., Sharp, A.S.P., Sudano, I., Volpe, M., Tsioufis, C., Wijns, W., & Mahfoud, F. (2023). Renal denervation in the management of hypertension in adults. A clinical consensus statement of the ESC Council on Hypertension and the European Association of Percutaneous Cardiovascular Interventions (EAPCI). *European Heart Journal, 44*(15), 1313–1330. *https://doi.org/10.1093/eurheartj/ehad054*.

device category codes, as such, we did not consider this topic in our final decision.

We thank the commenters for their feedback and took into account all of the points raised in our final decision.

Comment: The applicant for the Symplicity Spyral™ RDN System, Medtronic, submitted another application for its device, PulseSelect™, for transitional pass-through payment during CY 2025. The proposed rule stated that PulseSelect™ is used to achieve catheter ablation to treat atrial fibrillation, and thus, could be appropriately described by C1733. The Symplicity Spyral™ RDN System applicant stated that the PulseSelect™ application involved the interpretation of an existing device category description, but the applicant stated CMS's conclusion for that application is consistent with the logic for establishing a single device category to describe the two RDN devices. Following the publication of the proposed rule, the applicant withdrew its application for transitional pass-through payment for PulseSelect™.

Response: With respect to the application for the PulseSelect™ included in the CY 2025 notice of proposed rulemaking, we note that we invited comment on whether the PulseSelect™ PFA System was described by C1733 (89 FR 59310 through 59311). We noted that based on the description the applicant provided, the PulseSelect™ PFA System is used to achieve catheter ablation to treat atrial fibrillation, and thus could be appropriately described by C1733. However, because the application was withdrawn prior to making a final determination on the device category criterion at § 419.66(c)(1), we are unable to address whether we would have ultimately determined that the PulseSelect™ PFA System was described by C1733.

We thank both applicants and the many commenters for their input. We note that we received overwhelming support in favor of establishing two device category codes to reflect the nominated devices. After review of the applications and the comments we received, we agree with majority of the commenters that we should establish two pass-through payment device categories. We believe that there are procedural differences and potential resource requirement differences between the two treatment modalities that warrant separate device categories. In addition, we believe that the circumstances presented by the nominated devices are sufficiently similar to the previous scenarios in which we established device category codes to differentiate similar devices with different modalities. However, we disagree with the suggestion that the device category codes should be specific to the physical device characteristics rather than modality-specific device categories. As such, consistent with our proposal and our final determination to approve both the Paradise® Ultrasound RDN System and the Symplicity Spyral™ RDN System for device pass-through payment status effective January 1, 2025, we are finalizing our decision to create two modality-specific pass-through payment device categories for RDN devices: radiofrequency and ultrasound.

(2) Traditional Device Pass-Through Applications

(a) Ambu® aScope™ Gastro

Ambu Inc. submitted an application for a new device category for transitional pass- through payment status for the Ambu® aScope™ Gastro for CY 2025. Per the applicant, the Ambu® aScope™ Gastro is a sterile, single-use, flexible gastroscope intended to be used for: (1) endoscopic access to and examination of the upper gastrointestinal (GI) anatomy; and (2) upper GI endoscopy or esophagogastroduodenoscopy (EGD) to diagnose and treat problems in the upper GI tract, including dysphagia, gastroesophageal reflux disease, narrowing or blockages, esophageal varices, inflammation, ulcers, tumors, hiatal hernia, Celiac disease, Crohn's disease, and infections of the upper GI tract in adult patients.

According to the applicant, the Ambu® aScope™ Gastro works with the Ambu® aBox™ 2, a compatible, reusable displaying unit. The Ambu® aScope™ Gastro endoscope is inserted into the upper GI anatomy airway through the mouth, while the Ambu® aBox™ 2 is a non-sterile digital monitor intended to display live imaging data from Ambu visualization devices. The applicant is only seeking a new device category for transitional pass-through payment status for the Ambu® aScope™ Gastro.

Please refer to the online application posting for the Ambu® aScope™ Gastro, available at *https://mearis.cms.gov/public/publications/device-ptp/DEP2305305795M*, for additional detail describing this device and the disease treated by the device.

Comment: A few commenters expressed general support for the application for transitional pass-through payments for the Ambu® aScope™ Gastro.

Response: We appreciate the commenters' input and recognize the commenters' support for the approval of the Ambu® aScope™ Gastro for transitional pass-through payment.

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), on February 3, 2022, the applicant received 510(k) clearance from FDA for the Ambu® aScope™ Gastro, Ambu® aBox™ 2, as a sterile, single-use, flexible gastroscope intended to be used for endoscopic access to and examination of the upper GI anatomy. The Ambu® aScope™ Gastro is intended to provide visualization via a compatible Ambu displaying unit and to be used with endotherapy accessories and other ancillary equipment. We received the application for a new device category for transitional pass-through payment status for the Ambu® aScope™ Gastro on May 30, 2023, which is within 3 years of the date of the initial FDA marketing authorization.

We invited public comment on whether the Ambu® aScope™ Gastro meets the newness criterion at § 419.66(b)(1).

Comment: With respect to the newness criterion at § 419.66(b)(1), the applicant reiterated that the Ambu® aScope™ Gastro meets the newness requirement for transitional pass-through payment.

Response: We appreciate the applicant's input. We received the application for a new device category for transitional pass-through payment status for the Ambu® aScope™ Gastro on May 30, 2023, which is within 3 years of February 3, 2022, the date of FDA 510(k) approval to market for the Ambu® aScope™ Gastro. As such we have concluded that the Ambu® aScope™ Gastro meets the newness criterion.

With respect to the eligibility criteria at § 419.66(b)(3), the device must be an integral part of the service furnished, used for one patient only, come in contact with human tissue, and be surgically inserted or implanted, or applied in or on a wound or other skin lesion. The applicant did not indicate whether the Ambu® aScope™ Gastro is integral to the service furnished. The applicant stated that the device was single-use and is intended to be used with one patient only. We noted that the Ambu® aScope™ Gastro, based on the device description provided by the applicant and the evidence provided in support of the substantial clinical improvement as discussed in detail in the § 419.66(c)(2) analysis in this

application summary write-up, explicitly provides that the nominated device is intended to be used on one patient, for a single procedure and then disposed of. As such, we noted that our evaluation and final decision as it relates to this potential category of devices (gastroscopes) would be based on the understanding that devices included in this device category (gastroscopes) can only be used for a single procedure, on a single patient, and cannot be reprocessed. While the applicant did not explicitly state whether the device comes in contact with human tissue or is surgically inserted, per the device description, the Ambu® aScope™ Gastro is a flexible gastroscope intended to be used for endoscopic access to and examination of the upper GI anatomy.

We invited public comment on whether the Ambu® aScope™ Gastro meets the eligibility criterion at § 419.66(b)(3).

Comment: With respect to the eligibility criterion at § 419.66(b)(3), the applicant submitted a comment confirming that the Ambu® aScope™ Gastro is used for one patient only, does come in contact with human tissue, and is surgically inserted during applicable procedures, and that the Ambu® aScope™ Gastro is a device that is an integral part of the service furnished.

Response: We appreciate the applicant's input. We agree with the applicant that the Ambu® aScope™ Gastro is an integral part of the service furnished, used for one patient only, comes in contact with human tissue, and is surgically inserted. After consideration of the public comment received and based on our review of the application, we have determined that the Ambu® aScope™ Gastro meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker). The applicant indicated that the Ambu® aScope™ Gastro is single-use equipment, not intended for use in multiple patients, for which depreciation and financing expenses are not recovered. The applicant explained that the Ambu® aScope™ Gastro is purely an operating cost and is not subject to capitalization or a depreciation schedule.

We noted that the applicant stated in the application that the Ambu® aScope™ Gastro is a supply furnished incident to a service rendered, as described, the Ambu® aScope™ Gastro would be considered a supply or material furnished incident to a service and excluded from device pass-through payment eligibility under § 419.66(b)(4).

We invited public comment on whether the Ambu® aScope™ Gastro meets the exclusion criterion at § 419.66(b)(4).

Comment: The applicant submitted a comment clarifying that the Ambu® aScope™ Gastro is not a material or supply furnished incident to the service and meets the eligibility criterion at § 419.66(b)(4) because it must be purchased for each patient and is a device that is integral to the procedure. The applicant reiterated that as a single-use scope, it is not subject to capital equipment depreciation schedules.

Response: We appreciate the applicant's input. We agree with the applicant that the Ambu® aScope™ Gastro is not a material or supply furnished incident to the service because it is single-use equipment, not intended for use in multiple patients, for which depreciation and financing expenses are not recovered. In addition, we agree that the Ambu® aScope™ Gastro is not a material or supply furnished incident to the service. After consideration of the public comment received and our review of the application, we have determined that the Ambu® aScope™ Gastro meets the eligibility criterion at § 419.66(b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), the criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determine that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. Per the applicant, the Ambu® aScope™ Gastro is a sterile, single-use, flexible, imaging/illumination gastroscope device that uses an integrated camera module and built-in dual light-emitting diode (LED) illumination to provide access to, illumination, and imaging of the upper GI anatomy for diagnostic and therapeutic purposes for a GI patient. According to the applicant, no previous or existing device categories for pass-through payment appropriately describe the Ambu® aScope™ Gastro. Per the applicant, the two device categories, C1747 (Endoscope, single-use (*i.e.,* disposable), urinary tract, imaging/illumination device (insertable)) and C1748 (Endoscope, single-use (*i.e.,* disposable), upper gastrointestinal tract (GI), imaging/illumination device, (insertable)), do not appropriately describe the Ambu® aScope™ Gastro. Specifically, the applicant asserted that the urinary tract scopes described in C1747 are not indicated for use in the GI system and therefore, do not appropriately describe Ambu® aScope™ Gastro. The applicant further asserted that while C1748 describes a single-use endoscopic device, C1748 is only appropriate for single-use duodenoscopes and endoscopic retrograde cholangiopancreatography (ERCP) services. While the long descriptor of C1748 describes disposable endoscopes with imaging and illumination capabilities intended for use in the upper GI and the applicant describes the Ambu® aScope™ Gastro as a single-use, gastroscope with illumination and imaging intended for use in the upper GI anatomy, we noted that C1748 only describes single-use duodenoscopes and ERCP services. As such, the Ambu® aScope™ Gastro is not described by C1748.

We did not identify an existing pass-through payment category that describes the Ambu® aScope™ Gastro. We invited public comment on whether the Ambu® aScope™ Gastro meets the device category criterion at § 419.66(c)(1).

Comment: The applicant and a commenter agreed with CMS' assessment that there are no existing pass-through payment categories that describe the Ambu® aScope™ Gastro. The applicant submitted a comment with supporting documents reiterating that C1747 for single-use ureteroscopes and C1748 for single-use duodenoscopes do not describe the Ambu® aScope™ Gastro because the Ambu® aScope™ Gastro is a gastroscope and not a duodenoscope.[77] The applicant also submitted a July 2020 CMS Medicare Learning Network memorandum (MM11842) as a supporting document to confirm that C1748 is specific to ERCP procedures, which does not apply to the Ambu®

[77] Please see the public posting at [*https://www.regulations.gov/document/CMS-2024-0199-0002/comment* for a complete list of evidence and background documents submitted by the applicant during the public comment process. Please note, that as in the proposed rule, we do not summarize background documents, which are documents that do not support the applicant's assertions.

aScope™ Gastro.[78] The other commenter indicated that endoscopic procedure codes, including those for EGD, were mostly created prior to the invention of single-use endoscopes. The commenter provided a detailed list of procedure codes for different types of endoscopes, including duodenoscopes and gastroscopes, to illustrate the differences in their applications. The commenter recommended the establishment of a new category to allow reporting specifically for gastroscopes, as their indications for use differ from other types of endoscopes like duodenoscopes.

However, a few other commenters stated that they believed that the existing code C1748 appropriately describes the Ambu® aScope™ Gastro technology. One of the commenters stated that this code was established to cover all single-use scopes for upper GI procedures, regardless of the camera orientation (forward-facing or side-facing). Another commenter noted that C1748 was established in 2020, following an application from Boston Scientific for its EXALT™ Model D Single-Use Duodenoscope.[79] The commenter noted that while the EXALT™ Model D Single-Use Duodenoscope is used primarily in ERCP, CMS updated C1748 by assigning additional transnasal procedure codes to C1748 to include devices like the EvoEndo Model LE Single-Use Gastroscope.[80] The commenter stated that the description of C1748 reflects the use of an upper GI imaging/illumination device and is not specific only to duodenoscopes.

Response: We appreciate the applicant's and commenters' input. We agree with the applicant that C1747 does not describe the Ambu® aScope™ Gastro because C1747 is intended to describe devices used in a different anatomical area (the urethra) of the patient. With regard to C1748, we continue to believe that C1748 does not describe the Ambu® aScope™ Gastro because C1748 describes devices intended to perform ERCP services and limited transnasal endoscopy services. Unlike the devices described by C1748, according to the description provided by the applicant, the Ambu® aScope™ Gastro is intended to be used for transoral endoscopy and is not indicated for transnasal endoscopy or ERCP services. Specifically, while we agree that C1748 describes upper GI imaging/illumination devices, which could describe the Ambu® aScope™ Gastro, C1748 does not include the types of procedures that the Ambu® aScope™ Gastro can perform, such as those described by HCPCS code 43205 (Esophagoscopy, flexible, transoral; with bandligation of esophageal varices). We acknowledge that a list of procedure codes associated with HCPCS code C1748 were updated in 2022 to include transnasal services and were assigned to APC 5301 (Level 1 Upper GI Procedures) and APC 5302 (Level 2 Upper GI Procedures), however, we do not believe that the addition of those codes to the codes for which C1748 can be reported describe the Ambu® aScope™ Gastro because, as previously indicated, it is our understanding that the Ambu® aScope™ Gastro is intended for transoral services only.[81] We note that the EvoEndo ® Model LE Single-use Gastroscope is indicated for use both as a transoral and transnasal gastroscope, while the Ambu® aScope™ Gastro is only indicated for transoral use. While we believe the devices are comparable for the transoral functions of the devices for the purposes of evaluating substantial clinical improvement as discussed below, we do not believe that adding a subset of applicable procedure codes to C1748 expanded the device category code in such a way that it describes the Ambu® aScope™ Gastro. After consideration of the public comments received and our review of the application, we agree that there is no previous or existing pass-through payment category that appropriately describes the Ambu® aScope™ Gastro because no current category appropriately describes a single-use, transoral gastroscope with illumination and imaging intended for use in the upper GI anatomy. Therefore, we have determined that the Ambu® aScope™ Gastro meets the device eligibility criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The applicant claimed that the Ambu® aScope™ Gastro represents a substantial clinical improvement over existing technologies in the diagnosis and management of endoscopic procedures and examination within the upper GI anatomy. The applicant outlined the following areas in which it claimed the Ambu® aScope™ Gastro would provide a substantial clinical improvement: (1) elimination of the risk of cross-contamination between patients and scopes, (2) elimination of the risk of cross-contamination for reusable gastroscopes, (3) elimination of the risk of resistant infections that originate from reusable gastroscopes, (4) avoidance of scope damage and debris after reprocessing, (5) avoidance of damaged and contaminated scopes from being used on patients, (6) elimination of the risk of patient-to-patient infections associated with contaminated scopes, and (7) avoidance of infection and death associated with reusable gastroscope contamination.

The applicant provided seven background articles about reusable GI endoscopes to support its claims. Table 122 summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for the Ambu® aScope™ Gastro for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

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[78] Centers for Medicare & Medicaid Services (2020). MLN Matters: July 2020 Update of the Ambulatory Surgical Center (ASC) Payment System (HHS–0938–2020–F–6667). U.S. Department of Health and Human Services. *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/MM11842.pdf.*

[79] Centers for Medicare & Medicaid Services (2020). MLN Matters: July 2020 Update of the Ambulatory Surgical Center (ASC) Payment System (HHS–0938–2020–F–6667). U.S. Department of Health and Human Services. *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/MM11842.pdf.*

[80] Centers for Medicare & Medicaid Services (2020). MLN Matters: July 2020 Update of the Ambulatory Surgical Center (ASC) Payment System (HHS–0938–2020–F–6667). U.S. Department of Health and Human Services. *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/MM11842.pdf.*

[81] Centers for Medicare & Medicaid Services (2020). MLN Matters: July 2020 Update of the Ambulatory Surgical Center (ASC) Payment System (HHS–0938–2020–F–6667). U.S. Department of Health and Human Services. *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/MM11842.pdf.*

TABLE 122: SUBSTANTIAL CLINICAL IMPROVEMENT ASSERTIONS

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments		
Applicant statements in support	**Supporting evidence provided by the applicant**	**Reference title***
The Ambu® aScope™ Gastro eliminates the risk of cross-contamination between patients and scopes between patients and scopes	The literature highlights six studies that show the contamination rate of gastroscopes to be 28.2 percent. Given the Ambu® aScope™ Gastro's disposable design, the contamination rate is eliminated since there is no reuse of the same scope. These positive cultures are a result of normally reprocessing standards being unable to fully sterilize a scope once it has been used.	Goyal, H., Larsen, S., Perisetti, A., Larsen, N. B., Ockert, L. K., Adamsen, S., Tharian, B., & Thosani, N. (2022). Gastrointestinal endoscope contamination rat–s - elevators are not only to blame: a systematic review and meta-analysis. Endoscopy international open, 10(6), E840–E853. https://doi.org/10.1055/a-1795-8883 *
The Ambu® aScope™ Gastro would eliminate the contamination MAUDE reports submitted for reusable gastroscopes	More adverse event reports involving potentially contaminated gastroscopes were submitted to the FDA from 2014 - 2021 than any other flexible endoscope. 1,135 MAUDE reports were submitted to the FDA for gastroscopes in 2021. Some cases involve patients infected with CRE or a related superbug.	Muscarella, L. F. (2022). Contamination of Flexible Endoscopes and Associated Infections: A Comprehensive Review and Analysis of FDA Adverse Event Reports. https://lfm-hcs.com/2022/01/contamination-of-flexible-endoscopes-and-associated-infections/
The Ambu® aScope™ Gastro would eliminate the risk of superbug related infections that originate from reusable gastroscopes	There have been multiple cases linking a reprocessed gastroscope to infections of resistant bacteria. In some cases, this has led to patient death. The aScope Gastro would have eliminated the risk of these infections since the scope would not be used on multiple patients.	Muscarella, L. F. (2023). Gastroscopes Have Been Linked to A Cluster of Resistant E. coli Infections — Is the Risk Sufficiently Recognized? https://lfm-hcs.com/2023/01/gastroscopes-have-been-linked-to-a-cluster-of-resistant-e-coli-infections-is-the-risk-sufficiently-recognized/
The Ambu® aScope™ Gastro would avoid damage and debris after reprocessing since it is not reused	Visible damage and debris/residue was found in all gastroscopes observed after reprocessing. After visual inspection, all gastroscopes needed to be either repaired or refurbished due to damage and/or debris. Additional issue observed after reprocessing were gapping of distal adhesive bands, leftover fluid, channel shredding, and droplet. All of these introduce issues to patients that may result in readmissions, infections, or deaths. The aScope Gastro avoids all of these issues.	Ofstead, C. L., Smart, A. G., Hopkins, K. M., & Wetzler, H. P. (2023). The utility of lighted magnification and borescopes for visual inspection of flexible endoscopes. American journal of infection control, 51(1), 2–10.
The Ambu® aScope™ Gastro avoids damaged and contaminated scopes from being used on patients	27 percent of gastroscopes were found to have positive microbial samples after reprocessing. Additional issues found were fluid retention, channel shredding, scratches, and debris after reprocessing. These issues pose several threats to	Wallace, M. M., Keck, T., Dixon, H., & Yassin, M. (2023). Borescope examination and microbial culture results of endoscopes in a tertiary care hospital led to changes in storage protocols to

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments		
Applicant statements in support	**Supporting evidence provided by the applicant**	**Reference title***
	patient safety. The aScope Gastro bypasses these issues since the scope is never reused.	improve patient safety. American journal of infection control, 51(4), 361–366.
The Ambu® aScope™ Gastro eliminates the risk of patient-to-patient infections associated with contaminated scopes	The all-cause infection rate for EGDs with reusable gastroscopes was found to be 3.0 per 1000 procedures. The aScope Gastro can eliminate the risk of infection associated with reusable gastroscopes since the design is single-use and will be thrown out after each use.	Wang, P., Xu, T., Ngamruengphong, S., Makary, M. A., Kalloo, A., & Hutfless, S. (2018). Rates of infection after colonoscopy and osophagogastroduodenoscopy in ambulatory surgery centres in the USA. Gut, 67(9), 1626–1636.
The Ambu® aScope™ Gastro 's single-use design avoids the issues associated with reusable gastroscope contamination such as infection and even death	3 died after testing positive (+) for antibiotic-resistant E coli after undergoing an EGD. 4 patients tested + for E coli after the gastroscope was used on them– one died. 6 patients became infected with the same superbug from the same scope–3 died. 2 patients treated with the same gastroscope tested + for CRE-NDM and E coli– 84 additional patients had procedures with the scope. A reusable gastroscope was used on a patient with Creutzfeldt-Jakob disease. A superbug remained after reprocessing.	The applicant provided FDA MAUDE Adverse Event Reports

*We noted this source does not assess, evaluate, or review the nominated device and only provides background information in support of the applicant's claims of substantial clinical improvement.

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After review of the information provided by the applicant, we stated we had the following concerns regarding whether the Ambu® aScope™ Gastro meets the substantial clinical improvement criterion.

First, we noted that the applicant identified 11 other devices that it believed are most like the Ambu® aScope™ Gastro: (1) Olympus GIF–HQ 190; (2) Olympus GIF–1TH190; (3) Olympus GIF–H190; (4) Olympus GIF–CP190N; (5) Fujifilm EG–760R; (6) Fujifilm EG–760CT; (7) Fujifilm EG–760Z; (8) Fujifilm EG–740N; (9) Pentax HD Video Gastroscope EG34 i10; (10) Pentax MagniView EG 2990Zi; and (11) Pentax G EYE. According to the applicant, these devices are used during the same specific procedure(s) and/or services with which the nominated device is used. The applicant stated that the nominated device's single-use feature is unique among the comparators because its single-use feature eliminates gastroscope reprocessing. The applicant also indicated that there are no HCPCS Level I and/or Level II code(s) used to identify these existing devices. While the evidence provided demonstrated that the Ambu® aScope™ Gastro may be different than the other 11 closely related devices, it does not provide any comparative data that demonstrates that the Ambu® aScope™ Gastro offers a substantial clinical improvement when compared to the other 11 devices.

Second, we noted that the nominated device was determined to be substantially equivalent to a predicate device: OLYMPUS EVIS EXERA II Gastrointestinal Videoscope GIF H180 (K100584). The FDA 510(k) summary indicated that both devices share the same technological characteristics such as insertion portion length, working channel diameter, direction of view and bending angles. We noted that the 510(k) summary indicated that, unlike the predicate device, the Ambu® aScope™ Gastro is a sterile, single-use device and not intended to be reprocessed. Again, while this demonstrated that the Ambu® aScope™ Gastro may be different than the predicate device, it is unclear whether this difference demonstrates substantial clinical improvement. No comparative data demonstrating that the Ambu® aScope™ Gastro provides a substantial clinical improvement when compared to the Olympus EVIS EXERA II Gastrointestinal Videoscope GIF–H180 was provided. We stated we would be interested in additional information to demonstrate whether the nominated device demonstrates a substantial clinical benefit in comparison to other existing devices.

Further, the applicant indicated that while other single-use endoscopes are available, there are no known competitive devices on the market that are single-use, transoral, and marketed in the U.S. The applicant compared the Ambu® aScope™ Gastro to the following two existing devices: (1) EndoFresh Single-Use Gastroscope; and (2) EvoEndo Model LE Single-Use Gastroscope. Specifically, the applicant noted that although EndoFresh Single-Use Gastroscope is FDA-cleared and a similar device that could also become eligible for transitional pass-through payment under the proposed additional category, it has no commercial activity in the U.S. According to the applicant, while EvoEndo® Model LE Single-Use Gastroscope is used during the same specific procedure(s) and/or services as the Ambu® aScope™ Gastro, the Ambu® aScope™ Gastro is different

from EvoEndo® Model LE Single-Use Gastroscope because the Ambu® aScope™ Gastro is a transoral scope, not transnasal. The applicant also indicated that there are no HCPCS Level I and/or Level II code(s) used to identify EvoEndo Model LE Single-Use Gastroscope. However, we noted that EvoEndo® Model LE Single-Use Gastroscope is both transoral and transnasal, which is indicated on the EvoEndo, Inc.'s website and on its FDA 510(k) clearance letter. We also noted that the applicant did not compare the Ambu® aScope™ Gastro to another single-use, FDA-cleared endoscope available on the market—EXALT™ Model D, Single-Use Duodenoscope—which we stated that we believe may be similar. We stated we were interested in additional information to demonstrate whether the nominated device demonstrates a substantial clinical improvement in comparison to similar single-use competitive devices such as the EvoEndo® Model LE Single-Use Gastroscope and the EXALT™ Model D, Single-Use Duodenoscope. In addition, we noted that the applicant's self-sponsored studies, which are background articles by Muscarella, L. F. (2022),[82] Muscarella, L.F. (2023),[83] and Ofstead, et. al. (2022),[84] lack direct comparison of the nominated device to other devices, and do not directly show any clinical improvement that results from the use of the nominated device compared to the use of other devices. In order to demonstrate substantial clinical improvement over currently available treatments, we consider supporting evidence, preferably published peer-reviewed clinical trials, that shows improved clinical outcomes, such as reduction in mortality, complications, subsequent interventions, future hospitalizations, recovery time, pain, or a more rapid beneficial resolution of the disease process compared to the standard of care. Additional supporting evidence, preferably published peer-reviewed clinical trials, that shows these improved clinical outcomes would help inform our assessment of whether the Ambu® aScope™ Gastro demonstrates substantial clinical improvement over existing technologies.

Moreover, while the details provided in the application and all the articles submitted as evidence of substantial clinical improvement discuss potential adverse events from reusable gastroscope procedures, they do not appear to directly show any clinical improvement that results from the use of the Ambu® aScope™ Gastro. Rather, the applicant provided evidence which seems to rely on indirect inferences from other sources of data. Specifically, the applicant included an FDA Manufacturer and User Facility Device Experience (MAUDE) report [85] which provides the details of multiple adverse event reports associated with the contamination or suspected contamination of reusable gastroscopes but does not directly show any clinical improvement that results from the use of the Ambu® aScope™ Gastro.

While the applicant claimed that the Ambu® aScope™ Gastro eliminates cross-contamination associated with reusable gastroscopes and eliminates the risk of infections that originate from reusable gastroscopes, we stated that we do not believe that we have sufficient information on the prevalence of infection to evaluate the applicant's substantial clinical improvement claims for the Ambu® aScope™ Gastro. We noted the analyses on adverse event reports and the FDA MAUDE report appear to apply to flexible, reprocessed gastroscope or endoscopes, broadly, but not to disposable, single-use devices comparable to the nominated device.[86] [87] [88] Therefore, we questioned the direct relevance of these background articles to the nominated device and the applicant's substantial clinical improvement claims. Further, we noted that many of the applicant's substantial clinical improvement claims rely on an assumption that inadequate reprocessing of reusable endoscopes is positively correlated with heightened risk of infection. We noted that the applicant's self-sponsored analyses of FDA adverse event reports and studies and the FDA MAUDE report do not provide evidence on the prevalence of infection, establish a clear relationship between infection risk and reprocessing procedures, or substantiate that single-use disposable scopes, or the nominated device specifically, would be a substantial clinical improvement over currently available devices.[89] [90] [91] [92] We stated that we would be interested in more information on the prevalence of infection due to incomplete/inadequate processing for gastroscopes in the U.S. and whether single-use gastroscopes reduce the infection rate in patients to identify the extent of the problem with existing technologies.

We invited public comment on whether the Ambu® aScope™ Gastro meets the device category criterion at § 419.66(c)(2).

Comment: In response to our concerns that the Ambu® aScope™ Gastro lacked comparative data demonstrating substantial clinical improvement compared to other available treatments, the applicant submitted a comment along with a multitude of articles and background documents.[93] The applicant submitted these documents as evidence to support the claim that the Ambu® aScope™ Gastro is as a single-use device which offers substantial clinical improvements compared to reusable gastroscopes by eliminating infection risks and ensuring consistent functionality, which they assert are significant issues with reusable gastroscopes. The applicant stated that the Ambu® aScope™ Gastro reduces infection risks and ensures consistent functionality. To support this claim, the applicant cited over 10,000

[82] Muscarella, L.F. (2022). Contamination of Flexible Endoscopes and Associated Infections: A Comprehensive Review and Analysis of FDA Adverse Event Reports. LFM Healthcare Solutions, LLC. *https://lfm-hcs.com/2022/01/contamination-of-flexible-endoscopes-and-associated-infections/*.

[83] Muscarella, L.F. (2023). Gastroscopes Have Been Linked to A Cluster of Resistant E. coli Infections—Is the Risk Sufficiently Recognized? LFM Healthcare Solutions, LLC. *https://lfm-hcs.com/2023/01/gastroscopes-have-been-linked-to-a-cluster-of-resistant-e-coli-infections-is-the-risk-sufficiently-recognized/*.

[84] Ofstead, C.L., Smart, A.G., Hopkins, K.M., & Wetzler, H.P. (2023). The utility of lighted magnification and borescopes for visual inspection of flexible endoscopes. *American Journal of Infection Control, 51*(1), 2–10. *https://doi.org/10.1016/j.ajic.2022.08.026*.

[85] MAUDE Adverse Event Report: AIZU OLYMPUS CO., LTD. EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE (*fda.gov*).

[86] Muscarella, L.F. (2022). Contamination of Flexible Endoscopes and Associated Infections: A Comprehensive Review and Analysis of FDA Adverse Event Reports. *https://lfm-hcs.com/2022/01/contamination-of-flexible-endoscopes-and-associated-infections/*.

[87] Muscarella, L.F. (2023). Gastroscopes Have Been Linked to A Cluster of Resistant E. coli Infections—Is the Risk Sufficiently Recognized? *https://lfm-hcs.com/2023/01/gastroscopes-have-been-linked-to-a-cluster-of-resistant-e-coli-infections-is-the-risk-sufficiently-recognized/*.

[88] MAUDE Adverse Event Report: AIZU OLYMPUS CO., LTD. EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE (*fda.gov*).

[89] Muscarella, L.F. (2022). Contamination of Flexible Endoscopes and Associated Infections: A Comprehensive Review and Analysis of FDA Adverse Event Reports. *https://lfm-hcs.com/2022/01/contamination-of-flexible-endoscopes-and-associated-infections/*.

[90] Muscarella, L.F. (2023). Gastroscopes Have Been Linked to A Cluster of Resistant E. coli Infections—Is the Risk Sufficiently Recognized? *https://lfm-hcs.com/2023/01/gastroscopes-have-been-linked-to-a-cluster-of-resistant-e-coli-infections-is-the-risk-sufficiently-recognized/*.

[91] Ofstead, C.L., Smart, A.G., Hopkins, K.M., & Wetzler, H.P. (2023). The utility of lighted magnification and borescopes for visual inspection of flexible endoscopes. American Journal of Infection Control, 51(1), 2–10.

[92] MAUDE Adverse Event Report: AIZU OLYMPUS CO., LTD. EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE (*fda.gov*).

[93] Please see the public posting at *https://www.regulations.gov/document/CMS-2024-0199-0002/comment* for a complete list of background documents submitted [by the applicant] during the public comment process.

Manufacturer and User Facility Device Experience (MAUDE) adverse event database reports for reusable scopes since May 2023 that include 1,500 related to contamination issues. The applicant noted that none of the MAUDE reports include adverse event reports for the Ambu® aScope™ Gastro. In addition, the applicant referenced studies showing problems with reusable scopes, such as inadequate cleaning and performance degradation.[94] [95] [96] [97] [98] The applicant claimed that single-use scopes could be used in various settings without reprocessing delays, potentially expanding access to care. Although no specific studies on the Ambu® aScope™ Gastro's impact on patient throughput exist, the applicant cited research on other single-use scopes indicating increased efficiency and reduced wait times, suggesting similar benefits.[99] [100] [101] In response to our concern about the lack of information identifying the extent of the problem with existing technologies, including the prevalence of infection due to incomplete and/or inadequate processing for gastroscopes in the U.S., and whether single-use gastroscopes reduce the infection rate in patients, the applicant stated that contamination issues are primarily relevant to reusable gastroscopes due to their complex reprocessing requirements, which are prone to human error and design flaws. The applicant referenced the studies and MAUDE reports again, reiterating that they show significant contamination rates and adverse events for reusable gastroscopes.[102] [103] The applicant indicated that one study found a 19.98 percent contamination rate in reprocessed endoscopes. The applicant argued that single-use devices, like the Ambu® aScope™ Gastro, eliminate cross-contamination risks, and noted there have been no MAUDE reports including the Ambu® aScope™ Gastro.[104] The applicant anticipated that FDA might recommend single-use gastroscopes, citing severe infections linked to reusable ones, including deaths from *Escherichia coli (E. coli)* and Carbapenem-resistant *Enterobacteriaceae* (CRE). The applicant emphasized that single-use gastroscopes would particularly benefit immunosuppressed patients by eliminating these risks.

In response to our concern about the lack of comparative data demonstrating that the Ambu® aScope™ Gastro provides substantial clinical improvement over the OLYMPUS EVIS EXERA II Gastrointestinal Videoscope GIF H180, the applicant submitted a study by Billy, et al. (2024), conducted at a Community Memorial Health Systems-Ventura, CA's endoscopic GI lab, that examined the difference in the degrees of retroflexion articulation achieved between an inventory of reusable diagnostic gastroscopes (RUDG: OLYMPUS GIF–HQ190 & H190) compared to that of two, single-use diagnostic gastroscopes (SUDG: Ambu® aScope™ Gastro).[105] Per the applicant, the study demonstrated that the Ambu® aScope™ Gastro has superior retroflexion compared to the OLYMPUS GIF–HQ190. The applicant believed that this is significant because articulation is crucial for the procedures these devices perform and reduced effectiveness in RUDGs can hinder optimal patient care.

However, one commenter stated that the applicant has not demonstrated substantial clinical improvement over existing technologies. The commenter stated that FDA clearance for the Ambu® aScope™ Gastro is based on equivalence to the earlier generation Olympus EVIS Exera II model 180 series. The commenter believed that the applicant has not provided comparative clinical documentation to support its claim.

In response to our concern about the lack of information demonstrating substantial clinical improvement with the use of the Ambu® aScope™ Gastro device compared to similar single-use competitive devices, such as the EXALT™ Model D, Single-Use Duodenoscope and the EvoEndo Model LE Single-Use Gastroscope, the applicant submitted a comment asserting that there are key differences between the Ambu® aScope™ Gastro and the EXALT™ Model D Single-Use Duodenoscope and the EvoEndo Model LE Single-Use Gastroscope. The applicant stated that the Ambu® aScope™ Gastro cannot be compared to the EXALT™ Model D because it is not indicated for ERCP procedures. The applicant noted that, compared to the EvoEndo Model LE Single-Use Gastroscope, the Ambu® aScope™ Gastro has a larger working channel (2.8 mm vs. 2.0 mm), allowing for more endoscopic accessories and broader capabilities. The applicant also claimed that while the EvoEndo® Model LE Single-Use Gastroscope can perform some of the same procedures, it is limited compared to the Ambu® aScope™ Gastro, which can perform 30 HCPCS procedures versus 10 for the EvoEndo® Model LE Single-Use Gastroscope.

A commenter agreed with CMS, noting that the EvoEndo® Model LE Single-Use Gastroscope is for both transoral and transnasal use, as stated on EvoEndo® Model LE Single-Use Gastroscope website and its FDA 510(k) clearance summary. The commenter highlighted similarities in FDA clearances between the Ambu®

[94] Haislip, I., Hoffman, D., Dehlholm-Lambertsen, E., & Cool, C. (20223) Single-Use Vs Reusable Endoscope Reprocessing: A Staff Survey on Safety and Effectiveness. *Value in Health, 26*(12): S434. *https://doi.org/10.1016/j.jval.2023.09.227.*

[95] Hoffman, D. & Cool, C. (2024). Gastrointestinal Endoscopy Volume, Efficiency, And Safety Issues: A Case Report. Ambu USA. *https://www.ambuusa.com/Files/Files/Downloads/Ambu%20USA/Gastrointestinal-endoscopy-volume_-efficiency_-and-safety-issues-a-case-report-poster.pdf.*

[96] Wallace, M.M., Keck, T., Dixon, H., & Yassin, M. (2025). Borescope examination and microbial culture results of endoscopes in a tertiary care hospital led to changes in storage protocols to improve patient safety. *American Journal of Infection Control, 51*(4): 361–366. *https://doi.org/10.1016/j.ajic.2022.09.009.*

[97] Ofstead, C.L., Smart, A.G., Hopkins, K.M., & Wetzler, H.P. (2022). The utility of lighted magnification and borescopes for visual inspection of flexible endoscopes. *American Journal of Infection Control, (22)*00660–5. *https://doi.org/10.1016/j.ajic.2022.08.026.*

[98] Billy, H. & Pradhan, S. (2024). Superior Backward Articulation in Disposable Gastroscopes versus Reusable Gastroscopes. *Surgery for Obesity and Related Diseases, 20*(6): S136. *https://doi.org/10.1016/j.soard.2024.04.426.*

[99] Johnson, B.A., Raman, J.D., Best, S.L., & Lotan, Y. (2023). Prospective Randomized Trial of Single-Use vs Reusable Cystoscope for Ureteral Stent Removal. *Journal of Endourology, 37*(10): 1139–1144. *https://doi.org/10.1089/end.2023.0134.*

[100] Göger, Y.E., Özkent, M.S., Kılınç M.T., Taşkapu, H.H., Göger, E., Aydın, A., Sönmez, M.G., & Karalezli, G. (2021). Efficiency of retrograde intrarenal surgery in lower pole stones: disposable flexible ureterorenoscope or reusable flexible ureterorenoscope? *World Journal of Urology, 39*(9): 3643–3650. *https://doi.org/10.1007/s00345-021-03656-y.*

[101] Bowen, A.J., Macielak, R.J., Fussell, W., Yeakel, S., McMillan, R., Goates, A, Awadallah, A., & Ekbom, DC (2024). Single-use versus reusable rhinolaryngoscopes for inpatient otorhinolaryngology consults: Resident and patient experience. *Laryngoscope: Investigative Otolaryngology, 9*(1): e1203. *https://doi.org/10.1002/lio2.1203.*

[102] Wallace, M.M., Keck, T., Dixon, H., & Yassin, M. (2025). Borescope examination and microbial culture results of endoscopes in a tertiary care hospital led to changes in storage protocols to improve patient safety. *American Journal of Infection Control, 51*(4): 361–366. *https://doi.org/10.1016/j.ajic.2022.09.009.*

[103] Goyal, H., Larsen, S., Perisetti, A., Larsen, N.B., Ockert, L.K., Adamsen, S., Tharian, B., & Thosani, N. (2002). Gastrointestinal endoscope contamination rates—elevators are not only to blame: a systematic review and meta-analysis. Endoscopy: International Open, 10(06): E840–E853. *https://doi.org/10.1055/a-1795-8883.*

[104] Goyal, H., Larsen, S., Perisetti, A., Larsen, N.B., Ockert, L.K., Adamsen, S., Tharian, B., & Thosani, N. (2002). Gastrointestinal endoscope contamination rates—elevators are not only to blame: a systematic review and meta-analysis. Endoscopy: International Open, 10(06): E840–E853. *https://doi.org/10.1055/a-1795-8883.*

[105] Billy, H. & Pradhan, S. (2024). Superior Backward Articulation in Disposable Gastroscopes versus Reusable Gastroscopes. *Surgery for Obesity and Related Diseases, 2 0*(6): S136. *https://doi.org/10.1016/j.soard.2024.04.426.*

aScope™ Gastro and the EvoEndo® Model LE Single-Use Gastroscope and noted that the applicant has not shown substantial clinical improvement of the nominated device over this existing device.

To bolster its claims that single-use gastroscopes have improved outcomes compared to reusable gastroscopes, the applicant submitted background articles and other documents about the potential adverse events from reusable gastroscope procedures as well as from other reusable types of endoscopes for different anatomy (*e.g.,* bronchoscopy). Many commenters noted numerous challenges and risks associated with the reprocessing of reusable endoscopes, emphasizing the need for single-use alternatives like the Ambu® aScope™ Gastro to improve patient safety. A few commenters pointed out that delays in reprocessing due to staffing shortages, union-related issues, and the need to transport scopes across hospitals are common. Several commenters stated that the cleaning process for endoscopes involves many complex steps, making the cleaning process prone to human error and creating difficulty in training staff effectively. One commenter stated that despite proper education, human error remains a significant barrier to successful reprocessing with observations of missed steps and shortcuts due to assumptions or mimicking others. A few commenters further explained that inadequate training and preparation, especially during after-hours procedures, contribute to poor cleaning practices and increased infection risks. Several commenters further noted that continuous cleaning without breaks due to staff shortages and high demand increases the likelihood of errors.

Many commenters identified specific reprocessing gaps, including blood dripping from reprocessed scopes, improper handling of Creutzfeldt-Jakob Disease (CJD) cases, non-compliance with cleaning guidelines, and failed competencies among reprocessing technicians. One commenter indicated that problems with automatic preprocessors, inconsistent reprocessing locations, and confusion over Automated Endoscope Reprocessors (AERs) filters add to the complexity and risk. One commenter stated that there is a positive correlation between inadequate reprocessing and increased infection risk. Specifically, the commenter asserted that single-use gastroscopes eliminate this risk, providing a higher standard of care. The commenter cited several FDA reports and peer-reviewed studies asserting that they link reusable gastroscopes to infections and outbreaks, thereby supporting the need for single-use alternatives. The commenter acknowledged that linking or associating a reusable gastroscope with an infection or outbreak does not confirm the gastroscope transmitted or otherwise caused the infection, as one or more other factors could be, in part or solely, responsible. The commenter suggested more data would be required to conclude more definitively that the endoscope caused an infection. The commenter also acknowledged that FDA's MAUDE database has limitations and that its housed adverse event reports may be incomplete, inaccurate, untimely, unverified, or biased.

The applicant and several commenters advocated for the adoption of disposable gastroscopes, such as the Ambu® aScope™ Gastro in healthcare settings, emphasizing their benefits in terms of efficiency, patient safety, and cost-effectiveness. Several commenters stated that single-use gastroscopes are always ready for use, eliminating delays caused by the need to reprocess reusable scopes because they can be set up quickly, facilitating continuous care, especially in critical situations. Multiple commenters stated that single-use gastroscopes eliminate the risk of cross-infection associated with reusable scopes, which can remain contaminated even after reprocessing. One commenter indicated that sterile single-use devices lower the infection risk for patients with compromised immune systems. Another commenter provided a scenario in which single-use gastroscopes are crucial for patients with diseases like CJD, where reusable scopes might need to be destroyed. Several commenters pointed out that single-use gastroscopes remove the financial and logistical burdens associated with reprocessing, sampling, culturing, and infection surveillance. One commenter considered the single-use gastroscopes serve as a bridge when reusable scopes are out for repair, ensuring uninterrupted patient care. Several commenters stated that the single-use scopes provide consistent performance as they are used only once, avoiding issues related to scope degradation. One commenter believed that single-use scopes can incorporate rapid design improvements, enhancing their clinical capabilities.

Response: We appreciate the applicant's and commenters' input and insights on efficiency, patient safety, and cost-effectiveness. However, we wish to reiterate the statement we made in CY 2024 (88 FR 81736) where we encouraged applicants to submit all relevant supporting evidence with their device pass-through application to allow us to adequately evaluate and include the data in the notice of proposed rulemaking. Further, we note that the information submitted by the applicant in support of its CY 2025 application during the comment period did not appear to provide information that demonstrates that the use of the Ambu® aScope™ Gastro improves clinical outcomes when compared to the use of similar reusable or single-use gastroscope devices. In order to evaluate substantial clinical improvement over currently available treatments to meet the transitional pass-through payment criterion at § 419.66(c)(2), we consider supporting evidence, preferably published peer-reviewed clinical trials, that demonstrates improved clinical outcomes, such as reduction in mortality, complications, subsequent interventions, future hospitalizations, recovery time, pain, or a more rapid beneficial resolution of the disease process comparing the nominated device to the standard of care.

Based on the information provided and our review, we note that the Ambu® aScope™ Gastro and the EvoEndo Model LE Single Use Gastroscope do perform at least 10 of the same procedures. We remain concerned with the lack of evidence comparing these devices' respective clinical outcomes. We further note that the applicant referenced the study by Billy, et al (2024), which compared the nominated device against OLYMPUS EVIS EXERA III GIF–HQ190, not the predicate device, OLYMPUS EVIS EXERA II Gastrointestinal Videoscope GIF H180 for retroflexion articulation (not clinical outcome). We also note that the Billy, et al. (2024) article is not a peer-reviewed publication and does not provide evidence of the Ambu® aScope™ Gastro's clinical improvement compared to other single-use gastroscopes. In addition to this study, the applicant submitted numerous background articles; however, these articles did not include evidence that demonstrated or supported the Ambu® aScope™ Gastro's substantial clinical improvement compared to other single-use gastroscopes. We also have concerns regarding the submitted articles' relevance and appropriateness. For example, we have concerns about the validity of the findings in the Haislip, et al. (2023) poster submitted as evidence by the applicant because it lacks a full description of the methods, and it is unknown where it was presented and the extent to which it was peer reviewed for the validity of its findings. In the Tomlinson publication, which primarily

discusses the complexity of Instructions For Use (IFUs) for noncritical devices but not semi-critical devices like endoscopes that require high-level disinfection, we note that the problematic IFUs mentioned pertain to physical therapy and ophthalmology, not endoscopy.[106] As such, we question the relevancy of the submitted materials and do not believe that the information provided supported the applicants claims of substantial clinical improvement.

Based on our review of the extensive MAUDE reports provided by one of the commenters, we found that the vast majority did not conclusively link reusable gastroscopes to infections and those with proven or highly likely cross-contamination were few in number. We also note that the references provided by the commenter were about bronchoscopes and duodenoscopes, which are different anatomical areas that may be more vulnerable to infection.

Comment: The applicant and a commenter urged CMS to follow precedents set with Uretero1, aScope5 Broncho HD, and other single-use endoscopes and to approve the Ambu® aScope™ Gastro for transitional pass-through payment status. The applicant argued that the existing evidence is consistent with the level of evidence provided for previously approved single-use endoscopes like Uretero1 and aScope 5 Broncho HD.

Response: We appreciate the applicant's and commenter's input. We evaluate documentation submitted for each application as it applies to that specific device. Due to inherent differences in the devices themselves and/or the supporting documentation submitted, we may have different concerns. In addition, we are not precluded from evaluating and expressing concerns regarding documentation submitted with an application because we have evaluated the document as part of a previous application. We approved the Uretero1 and the aScope5 Broncho HD applications for device pass-through status because the applicants submitted documentation of studies that directly demonstrated the nominated device's improved clinical outcomes compared to other devices. We do not believe that the applicant has submitted documentation that demonstrates a substantial clinical improvement with use of the Ambu® aScope™ Gastro compared to the use of other comparable devices.

Comment: In regard to our concern about using other sources of data and relying on indirect inferences as evidence, the applicant commented that we should call our attention to the volumes of literature concerning reprocessing issues. The applicant shared MAUDE reports to show that reusable devices have had outbreaks, while disposable gastroscopes, like the Ambu® aScope™ Gastro, have not. The applicant also noted a pattern of FDA advisories and subsequent CMS approvals for single-use endoscopes (single-use aScope 5 Broncho HD) suggesting that single-use gastroscopes offer substantial clinical improvements. Additionally, the applicant argued that single-use gastroscopes enhance availability and access to care, especially during equipment failures or staffing shortages.

In response to our concern about lack of studies that directly compare the Ambu® aScope™ Gastro device to other single-use devices, the applicant argued that due to the nature and relative newness of single-use endoscopes, extensive data is not yet available on the Ambu® aScope™ Gastro device specifically. The applicant emphasized reprocessing issues, submitting reports documenting challenges and risks, including bacterial transmission, even with meticulous adherence to instructions. The applicant further argued that conducting a full-scale randomized trial comparing single-use and reusable gastroscopes would be time-prohibitive. The applicant again cited the study by Billy, et al (2024) showing superior retroflexion of single-use devices over reusable ones. The applicant emphasized the sterile nature of the Ambu® aScope™ Gastro, eliminating infection risks associated with reprocessing reusable devices. The applicant reiterated that single-use endoscopes save time, improve morale, and reduce reprocessing risks, leading to increased patient throughput and reduced wait times, demonstrating clinical improvements over reusable options.

Response: We thank the applicant for its input. However, we continue to have concerns about the studies and evidence submitted, as most of these are background articles that do not directly assess, evaluate, or review the Ambu® aScope™ Gastro. When there are currently available treatment options for a patient population (as is the case for the Ambu® aScope™ Gastro), substantial clinical improvement is demonstrated when the candidate device demonstrates significantly improved clinical outcomes compared to the currently available treatments.[107] In this context, the submitted evidence in support of the Ambu® aScope™ Gastro's substantial clinical improvement must demonstrate that Ambu® aScope™ Gastro results in substantial clinical improvement when compared to available reusable and single-use devices for the treatment of the patient population. Inferences that the device may improve clinical outcomes because it may obviate complications associated with other available treatments are insufficient to demonstrate substantial clinical improvement. Therefore, the inferences derived from submitted evidence, including analysis of adverse event reports and MAUDE reports, do not establish substantial clinical improvement. Specifically, we are concerned that the details provided in the application and the documents submitted as evidence of substantial clinical improvement are background documents that discuss potential adverse events from reusable gastroscope procedures and rely on indirect inferences from other sources of data. In addition, while we acknowledge that we have considered FDA advisories in the evaluation and subsequent CMS approval for single-use endoscopes in the past, we note that the applicant did not submit an FDA safety communication for reusable gastroscope, rather the applicant speculated that FDA will issue a safety communication similar to the safety communications they issued on bronchoscopes, ureteroscope, and duodenoscopes. We are not aware of an FDA safety communication for gastroscope at this time. We do not believe that the documents provided by the applicant and commenters demonstrate any clinical improvements that result from the use of the Ambu® aScope™ Gastro when compared to available reusable or single-use devices that are similar to the Ambu® aScope™ Gastro. As such, we continue to have the concerns articulated in the CY 2025 OPPS/ASC proposed rule and discussed above.

We appreciate the commenters' input but remain concerned that there has not been an adequate comparison of clinical outcomes between the Ambu® aScope™ Gastro and other available reuseable and/or single-use devices used for similar indications. Because of the reasons discussed above, we do not believe that the Ambu® aScope™

[106] Tomlinson L, Halipern N, Alexander M, Townsend S, Zabriskie K, Luper L. Modernizing Medical Device Instructions for Use (IFUs): Infection Preventionists Speak Up for Patient Safety. APIC_Modernizing-Medical-Device-IFUs_5_16_24.pdf (*sdapic.org*).

[107] Device Pass-through Requirements: *https://mearis.cms.gov/public/resources.*

Gastro represents a substantial clinical improvement relative to existing therapies currently available. Therefore, we have determined that the Ambu® aScope™ Gastro does not meet the substantial clinical improvement criterion at § 419.66(c)(2).

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the Ambu® aScope™ Gastro would be reported with HCPCS codes shown in Table 123.

TABLE 123: HCPCS CODES REPORTED WITH THE AMBU® ASCOPE™

GASTRO

HCPCS Code	Long Descriptor	SI	APC
43192	Esophagoscopy, rigid, transoral; with biopsy, single or multiple	J1	5302
43193	Esophagoscopy, flexible, transoral; with biopsy, single or multiple	J1	5302
43194	Esophagoscopy, rigid, transoral; with removal of foreign body(s)	J1	5302
43201	Esophagoscopy, flexible, transoral; with directed submucosal injection(s), any substance	J1	5302
43205	Esophagoscopy, flexible, transoral; with band ligation of esophageal varices	J1	5302
43211	Esophagoscopy, flexible, transoral; with endoscopic mucosal resection	J1	5302
43215	Esophagogastroduodenoscopy, flexible, transoral; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique	J1	5302
43216	Esophagoscopy, flexible, transoral; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps	J1	5302
43217	Esophagoscopy, flexible, transoral; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique	J1	5302
43229	Esophagoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)	J1	5303
43233	Esophagogastroduodenoscopy, flexible, transoral; with dilation of esophagus with balloon (30 mm diameter or larger) (includes fluoroscopic guidance, when performed)	J1	5302
43235	Esophagogastroduodenoscopy, flexible, transoral; diagnostic, including collection of specimens(s) by brushing or washing, when performed	T	5301
43236	Esophagogastroduodenoscopy, flexible, transoral; with directed submucosal injection(s), any substance	T	5301
43237	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic ultrasound examination limited to the esophagus, stomach or duodenum, and adjacent structures	J1	5302
43238	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s), (includes endoscopic ultrasound examination limited to the esophagus, stomach or duodenum, and adjacent structures)	J1	5302
43239	Esophagogastroduodenoscopy, flexible, transoral; with biopsy, single or multiple	T	5301
43240	Esophagogastroduodenoscopy, flexible, transoral; with transmural drainage of pseudocyst (includes placement of transmural drainage catheter[s]/stent[s], when performed, and endoscopic ultrasound, when performed)	J1	5331
43241	Esophagogastroduodenoscopy, flexible, transoral; insertion of intraluminal tube or catheter	J1	5302
43242	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s) (includes endoscopic ultrasound examination of the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis)	J1	5302
43243	Esophagogastroduodenoscopy, flexible, transoral; injection sclerosis of esophageal/gastric	J1	5302
43244	Esophagogastroduodenoscopy, flexible, transoral; with band ligation of esophageal/gastric varices	J1	5302

HCPCS Code	Long Descriptor	SI	APC
43245	Esophagogastroduodenoscopy, flexible, transoral; with dilation of gastric/duodenal stricture(s) (e.g., balloon, bougie)	J1	5302
43246	Esophagogastroduodenoscopy, flexible, transoral; with directed placement of percutaneous gastrostomy tube	J1	5302
43247	Esophagogastroduodenoscopy, flexible, transoral; with removal of foreign body(s)	T	5301
43248	Esophagogastroduodenoscopy, flexible, transoral; with insertion of guide wire followed by passage of dilator(s) through esophagus over guide wire	T	5301
43249	Esophagogastroduodenoscopy, flexible, transoral; transendoscopic balloon dilation of esophagus (<30 mm)	J1	5302
43250	Esophagogastroduodenoscopy, flexible, transoral; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps	J1	5302
43251	Esophagogastroduodenoscopy, flexible, transoral; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique	J1	5302
43254	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic mucosal resection	J1	5302
43255	Esophagogastroduodenoscopy, flexible, transoral; with control of bleeding, any method	J1	5302
43266	Esophagogastroduodenoscopy, flexible, transoral; with placement of endoscopic stent	J1	5331
43270	Esophagogastroduodenoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)	J1	5302

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). We noted that the applicant used the CY 2023 payment rates for the three tests of the cost criterion. For our calculations, we used APC 5301, which had a CY 2023 payment rate of $825.51 at the time the application was received. HCPCS code 43239 in APC 5301 had a CY 2023 device offset amount of $2.64 at the time the application was received.[108] According to the applicant, the cost of the Ambu® aScope™ Gastro is $799.00.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The average reasonable cost of $799.00 for the Ambu® aScope™ Gastro is 96.79 percent of the applicable APC payment amount for the service related to the category of devices of $825.51 (($799.00/$825.51) × 100 = 96.79 percent). Therefore, we stated that we believe the Ambu® aScope™ Gastro meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $799.00 for the Ambu® aScope™ Gastro is 30,265.15 percent of the cost of the device-related portion of the APC payment amount for the related service of $2.64 (($799.00/$2.64) × 100 = 30,265.15 percent). Therefore, we stated that we believe the Ambu® aScope™ Gastro meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $799.00 for the Ambu® aScope™ Gastro and the portion of the APC payment amount for the device of $2.64 is 96.47 percent of the APC payment amount for the related service of $825.51 ((($799.00 − $2.64)/$825.51) × 100 = 96.47 percent). Therefore, we stated that we believe the Ambu® aScope™ Gastro meets the third cost significance requirement.

We invited public comment on whether the Ambu® aScope™ Gastro meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

Comment: With respect to cost significance criteria, the applicant reiterated that the Ambu® aScope™ Gastro meets all three of the cost significance criteria.

Response: We appreciate the applicant's input. After consideration of

[108] We noted that the applicant selected a device offset amount of $21.55 for APC 5301 without selecting a specific HCPCS/CPT code. However, for the HCPCS/CPT codes provided by the applicant, we noted the HCPCS/CPT code level device offset amounts are available in Addendum P to the CY 2023 OPPS/ASC final rule with comment period. For our calculation, we selected the HCPCS/CPT code level device offset amount of $2.64 related to HCPCS 43239 in APC 5301 found in Addendum P to the CY 2023 OPPS/ASC final rule with comment period. Based on our initial assessment for the proposed rule, using the device offset amount of $2.64 would result in Ambu® aScope™ Gastro meeting the cost significance requirement.

the public comment received and our findings from the first, second, and third cost significance tests, we agree that the Ambu® aScope™ Gastro meets the cost significance criteria specified at § 419.66(d).

After consideration of the public comments received and our review of the device pass-through application, we are not approving the Ambu® aScope™ Gastro for transitional pass-through payment status in CY 2024 because the product does not meet the substantial clinical improvement criterion at § 419.66(c)(2).

(b) OMEZA Wound Care Matrix (OCM™)

OMEZA LLC submitted an application for a new device category for transitional pass-through payment status for OCM™ for CY 2025. According to the applicant, OCM™ is an amorphous, solid, malleable sheet comprised of hydrolyzed fish peptides infused with cod liver oil which acts as an anhydrous skin protectant. Per the applicant, OCM™ is indicated for the management of wounds. The applicant asserted that, when applied to a clean wound surface, OCM™ is naturally incorporated into the wound over time. Per the applicant, OCM™'s cold water fish peptides provide building blocks for tissue regeneration and cell signaling molecules stimulate tissue growth. Additionally, OCM™'s matrix-like device also contains active pharmaceutical ingredient(s) (API) and nutrients that continuously reduce biofilm impact, reduce inflammation, increase tissue proliferation, and support remodeling of tissue.

Please refer to the online application posting for the OCM™, available at *https://mearis.cms.gov/public/publications/device-ptp/DEP2403016HWP6*, for additional detail describing the device and the disease treated by the device.

Comment: Several commenters with experience treating patients with OCM™ stated their belief that it meets all the criteria outlined in the rule and should be granted pass-through status so that patients with stalled or non-healing wounds can be treated before the wound increases in size or becomes infected.

Response: As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), on September 1, 2021, the applicant received 510(k) clearance from FDA for OCM™ as a device to be used for the management of wounds including: (1) partial and full-thickness wounds, (2) pressure ulcers, (3) venous ulcers, (4) diabetic ulcers, (5) chronic vascular ulcers, (6) tunneled/undermined wounds, (7) surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), (8) trauma wounds (abrasions, lacerations, superficial partial thickness burns, skin tears), and (9) draining wounds. We received the application for a new device category for transitional pass-through payment status for OCM™ on March 1, 2024, which is within 3 years of the date of the initial FDA marketing authorization.

We invited public comment on whether OCM™ meets the newness criterion at § 419.66(b)(1).

Comment: The applicant thanked CMS for agreeing that OCM™ meets the newness criteria.

Response: We appreciate the applicant's comment. We received the application for a new device category for transitional pass-through payment status for OCM™ on March 1, 2024, which is within 3 years of September 1, 2021, the date of FDA 510(k) clearance. Based on our review of the application, we have determined that OCM™ meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criteria at § 419.66(b)(3), the device must be an integral part of the service furnished, used for one patient only, come in contact with human tissue, and be surgically inserted or implanted, or applied in or on a wound or other skin lesion. The applicant did not indicate whether OCM™ is integral to the service furnished. In the CY 2014 final rule with comment period (78 FR 75005), we stated that we have interpreted the term ''integral'' to mean that the device is necessary to furnish or deliver the primary procedure with which it is used. For example, a pacemaker is integral to the procedure of implantation of a pacemaker. We noted that OCM™ does not appear to be necessary to furnish or deliver the primary procedure with which it is used, specifically debridement. Rather, we noted the use of OCM™ following the debridement procedure, including the duration of treatment and the reapplication frequency, seems to be based entirely on provider discretion. As such, we stated that we do not believe that OCM™ is integral to the service furnished as required by § 419.66(b)(3). The applicant stated that OCM™ is classified for one-time use and is designed for intimate contact with both regular and irregular wound beds, and as such, it is applied in or on a wound.

We invited public comment on whether OCM™ meets the eligibility criterion at § 419.66(b)(3).

Comment: In response to our concern that OCM™ may not meet the eligibility criteria under § 419.66(b)(3), the applicant asserted that OCM™ is integral to services furnished in the outpatient setting for non-healing wounds. Specifically, the applicant stated that OCM™ is integral to both the active wound care management furnished for HCPCS codes 97597, 97598, 97602, and 97605–97608, and surgical debridement services furnished under HCPCS codes 11000–11012 and 11042–11047. The applicant added that for hard-to-heal, non-healing wounds that fail to respond to four weeks of standard wound care (including debridement), adjunctive application of advanced wound therapies, like OCM™, is the next recommended wound management step. The applicant stated that OCM™ is indicated for application following initial standard of care failure and may replace the need for negative-pressure wound therapy, placental membranes, bioengineered skin substitutes, several acellular matrices, autologous fibrin, and leukocyte platelet patches, which are all typically used in the hospital outpatient setting. The applicant further explained that OCM™ is not a skin protectant, but instead, a bioactive matrix that conforms to the wounds allowing for more complete coverage of the wound in a safe and effective manner; thus, it supplements the missing necessary components for the natural healing to occur. The applicant asserted that OCM™ performs a similar function to certain collagen-based implantable devices used in internal surgeries to promote healing by improving the structural integrity of joints, soft tissues, and nerves. Per the applicant, debridement alone is insufficient for managing refractory wounds, necessitating adjunctive advanced wound therapies, such as OCM™. The applicant, therefore, stated that classification of OCM™ as specifically an incident to supply is inconsistent with its necessitated clinical use. Several non-applicant commenters agreed with the applicant that OCM™ does not always require debridement, and therefore, the device is integral to the service performed.

As support for the integral function of OCM™, the applicant quoted the CY 2014 OPPS/ASC final rule [109] (78 FR

[109] Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Hospital Value-Based Purchasing Program; Organ Procurement Organizations; Quality Improvement Organizations; Electronic Health Records (EHR) Incentive Program; Provider Reimbursement Determinations and

75005) statement that skin substitutes are integral to, dependent on, and supportive to the surgical procedures in which they are used. Specifically, the applicant asserted that while OCM™ is not a skin substitute, it has a distinct composition and mechanism, as well as a higher degree of regulatory oversight, exemplified by its FDA 510(k) clearance for wound management. The applicant stated that, like skin substitutes, OCM™ meets the integral to service criterion for wound management, as outlined in the CY 2014 OPPS final rule, given that OCM™ not only matches but also exceeds the clinical utility of skin substitutes as an advanced wound therapy. The applicant concluded by asserting that OCM™'s indicated use, per its FDA 510(k) clearance, supports the device's classification as integral to the services furnished.

Response: We appreciate the applicant's input. Based on the additional information provided in the comments, we agree that OCM™ is integral to advanced wound therapy because it is used for active wound care management after the patient has received standard of care services with or without debridement including in the management of refractory wounds. Specifically, we agree that OCM™ is integral to active wound care management furnished for HCPCS codes 97597, 97598, 97602, and 97605–97608 and surgical debridement services furnished under HCPCS codes 11000–11012 and 11042–11047. Additionally, we agree with the applicant that OCM™ is used for one patient only, comes in contact with human tissue, and is applied in or on a wound. After consideration of the public comments received and our review of the application, we have determined that OCM™ meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criteria at § 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker). The applicant did not indicate whether OCM™ is equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered, or if OCM™ is a supply or material furnished incident to a service. However, in the CY 2014 final rule, we described skin substitutes as a type of supply used in a surgical procedure (78 FR 74929 through 74930). As explained in the CY 2014 final rule, supplies are a large category of items that typically are either for single-patient use or have a shorter life span in use than equipment. Supplies can be anything that is not equipment and include not only minor, inexpensive, or commodity-type items but also include a wide range of products used in the hospital outpatient setting, including certain implantable medical devices, which we have considered supplies since the inception of the OPPS (78 FR 74929 through 74930). We clarified that we believe skin substitutes are supplies used in a surgical procedure because, as a part of a surgical repair procedure, they reinforce and aid the healing of tissue like implantable biologicals, but with skin substitutes, the tissue is skin instead of internal connective tissues (78 FR 74931). As such, we questioned whether OCM™ would be considered a supply, and as such it would be excluded from device pass-through payments under § 419.66(b)(4).

We invited public comment on whether OCM™ meets the exclusion criterion at § 419.66(b)(4).

Comment: In response to our concern that OCM™ would be excluded under § 419.66(b)(4), the applicant asserted that OCM™ is not an item for which depreciation and financing expenses are recovered and that, like an implantable biologic or medical device, is used as an integral and necessary supply in a surgical procedure. The applicant stated that OCM™ does not fit the classification of an incident to supply, defined as a material or supply furnished incident to a service because it aids in the management of wounds by supplementing the missing necessary components for the natural function of healing to occur; and is necessary to the wound care procedure itself when debridement alone is insufficient. The applicant asserted that classification of OCM™ as an incident to supply is not consistent with its necessitated clinical use. The applicant asserted that given that OCM™ exceeds the clinical utility of skin substitutes as an advanced wound therapy and that skin substitutes as outlined in the CY 2014 OPPS final rule meet the integral to service criteria for wound management, the applicant believes that OCM™ does not meet the disqualifying criteria of being an incidental supply under § 419.66(b)(4).

Response: We appreciate the clarification from the applicant. Based on the additional information provided in the comments, we agree with the applicant that OCM™ is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets, or are a material or supply furnished incident to a service. Specifically, we believe that OCM™ is necessary to the wound care procedure itself when debridement alone is insufficient and is, therefore, not a material or supply furnished incident to a service. We note that while the applicant did not furnish further detail to explain why OCM™ is not a depreciable asset, we believe that the applicant provided enough additional information about OCM™ to conclude that it is like other cellular and tissue-based products for wound management, and therefore, OCM™ is not an asset subject to depreciation or used in a normal or standby capacity by the provider per the Medicare Reimbursement Manual (CMS Pub. 15–1). After consideration of the public comment received and our review of the application, we have determined that OCM™ meets the eligibility criterion at § 419.66(b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), the criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. The applicant asserted that OCM™ is indicated for the comprehensive treatment of advanced wounds and provides continuous delivery of pharmaceutical grade products through an amorphous, anhydrous solid, which reduces biofilm while simultaneously promoting tissue proliferation and remodeling. According to the applicant, no previous or existing device categories for pass-through payment appropriately describe OCM™.

We did not identify an existing pass-through payment category that describes OCM™. We invited public comment on whether OCM™ meets the device category criterion at § 419.66(c)(1).

We did not receive any comments regarding whether OCM™ meets the eligibility requirements at § 419.66(c)(1). Based on our review of the application, we continue to believe there is no

Appeals (CMS–1601–FC), 78 FR 74826 (Dec. 10, 2013) (amending 42 CFR parts 405, 410, 412, 419, 475, 476, 486, and 495).

existing category or category previously in effect that appropriately describes OCM™. Therefore, we have determined that OCM™ meets the device category eligibility criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The applicant claimed that OCM™ represents a substantial clinical improvement over existing technologies in the treatment of hard to heal or chronic wounds which require advanced wound care procedures such as venous leg ulcers, diabetic foot ulcers, pressure ulcers, and wound dehiscence where proper wound preparation, product application, and proper secondary dressings are a requirement. Specifically, the applicant claimed that OCM™ demonstrates: (1) superior clinical outcomes and healing for Diabetic Foot Ulcers (DFU) compared to standard of care; (2) faster healing rates than standard of care for Venous Leg Ulcers (VLUs); (3) superior clinical outcomes for patients who could not qualify for clinical trials due to comorbidities; (4) improved results when compared to results with standard of care for patients who failed prior treatment; (5) in vitro/in vivo antimicrobial properties and patient safety; and (6) improved patient safety.

The applicant provided the following clinical trial data and case studies to support these claims: (1) two randomized controlled trials (a single-site trial of patients with DFUs to evaluate percent area reduction, and a randomized, multicenter, open label study for a patient group with VLUs); (2) two real-world trials comprised of two separate case studies of patients receiving follow-up care at two different wound treatment centers; (3) one in vitro study; (4) one in vivo porcine study; and (5) one consumer research study assessing the safety of OCM™ using the skin prick method. Table 124 summarizes the applicant's assertions regarding the substantial clinical improvement criterion. We noted that there are multiple variations in poster presentations for the same study; these posters are identified by study number and presentation number in parentheses. Please see the online posting for OCM™ for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

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TABLE 124: SUBSTANTIAL CLINICAL IMPROVEMENT ASSERTIONS

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments		
Applicant statements in support	**Supporting Evidence Provided by the Applicant**	**Reference Title**
Superior clinical outcomes and healing for DFU compared to standard of care	OCM™ arm shows 55 percent improvement in wound size over standard of care after 12 weeks of treatment. 68 percent of patients treated with OCM™ had wounds present for over 3 months. 5 wounds were unhealed for over a year with 1 wound present more than 3 years. OCM™ healed 3 of these wounds in less than 12 weeks. One year-old wound reduced by 85 percent in size and a 72-month-old wound reduced by 73 percent in 12 weeks. Every wound treated with OCM™ reduced by more than 70 percent in 12 weeks. All wounds previously failed treatments.	Simman, R., MD, FACS, FACCWS, Cheney, M., APRN, CNP, CWS, COCN, Shuman, S, BSN, RN, Bakewell, S., PhD, Bell, D.P., DPM, CWS, FFPM RCPS. (submitted 2023). A Clinical Study Using Combination Therapy with Standard of Care for the Treatment of Diabetic Foot Ulcers: Final Analysis. ProMedica Jobst Wound Care.
	These results show encouraging healing rates (60 percent 4-week PAR and 93 percent 12-week PAR) of DFUs managed with the combination therapy and SOC. Clinical trials evaluating the combination therapy in VLUs (NCT05291169) and multiple wound types (NCT05921292) are underway.	Bell, D.P. DPM, CWS, FFPM RCPS, Shuman, S., BSN, RN, Cheney, M., APRN, CNP, CWS, COCN, Richard Simman, R., MD, FACS, FACCWS. (submitted 2023). A Clinical Study Using Combination Therapy with Standard of Care for the Treatment of Diabetic Foot Ulcers: Interim Analysis. ProMedica Jobst Wound Care.
	OCM™ arm shows 55 percent improvement in wound size over standard of care after 12 weeks of treatment. 68 percent of patients treated with OCM™ had wounds present for over 3 months. 5 wounds were unhealed for over a year with 1 wound present more than 3 years. OCM™ healed 3 of these wounds in less than 12 weeks. One year-old wound reduced by 85 percent in size and a 72-month-old wound reduced by 73 percent in 12 weeks. Every wound treated with OCM™ reduced by more than 70 percent in 12 weeks. All wounds previously failed treatments.	Black, G., DPM, Bakewell, S., PhD., Bell, D.P., DPM, CWS, FFPM RCPS A (presented 2023). Novel Combination Therapy Technology: Case Studies of Complete Closure of a Diabetic Foot Ulcer and a Charcot Foot Ulcer.

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments		
Applicant statements in support	**Supporting Evidence Provided by the Applicant**	**Reference Title**
	OCM™ arm shows 55 percent improvement in wound size over standard of care after 12 weeks of treatment. 68 percent of patients treated with OCM™ had wounds present for over 3 months. 5 wounds were unhealed for over a year with 1 wound present more than 3 years. OCM™ healed 3 of these wounds in less than 12 weeks. One year-old wound reduced by 85 percent in size and a 72-month-old wound reduced by 73 percent in 12 weeks. Every wound treated with OCM reduced by more than 70 percent in 12 weeks. All wounds previously failed treatments.	Barrett, C.L., DPM, CWS, Bakewell, S.J., PhD, Bell, D.P., DPM, CWS, FFPM RCPS. (presented 2023). A Novel Combination Therapy Technology: Case Studies of Complete Closure of Diabetic Foot Ulcers.
Faster healing rates than standard of care for VLU	OCM™ was compared to a standard of care treated group with Venous Leg Ulcers (NCT05291169). The average percent area reduction at 12 weeks was 66 percent. The same percent of patients (77 percent) responded in both cohorts, but OCM™ treatment increased the rate of healing by 22 percent.	Randomized Controlled Trial in Venous Leg Ulcers (NCT05291169) (no author or publication date given).
		Demographics for RCT in VLU (no author or publication date given).
Superior clinical outcomes for patients who could not qualify for clinical trials, due to comorbidities	OCM™ treatment of Multiple Etiologies (NCT05921292) enrolled 78 patients who would not have qualified for clinical trials, because of comorbidities, wound size, tobacco use, BMI, etc. Results show average reduction in wound size at 12 weeks by 73 percent, with 45 percent seeing full closure by 12 weeks. Pain score, exudate, demographics, comorbidities, and medications were collected. Wounds treated include diabetic foot, venous leg ulcers, pressure injuries, arterial, pyoderma, hematomas, surgical, and trauma.	Bettle III, G., Bell, D.P., Bakewell, S.J. (submitted 2023). A Novel Comprehensive Therapeutic Approach to the Challenges of Chronic Wounds: A Brief Review and Clinical Experience.
		OCM treating Multiple Etiologies Final Trial Data (no author or publication date given).

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments		
Applicant statements in support	**Supporting Evidence Provided by the Applicant**	**Reference Title**
Improved results when compared to results with standard of care for patients who failed prior treatment	OCM™ was used by 16 independent investigators treating 65 patients who failed prior treatment. These case studies showed 77 percent of wounds were closed by 12 weeks and average area reduction was 90 percent. Patients were not subjected to inclusion or exclusion criteria. Six patients failed cellular tissue product therapies. The age of wounds healed ranged from 12 weeks to 15 years. Wounds treated include diabetic foot, venous leg ulcers, pressure injuries, arterial, pyoderma, hematomas, surgical, and trauma.	Bettle III, G., Bell, D.P., Bakewell, S.J. (submitted 2023). A Novel Comprehensive Therapeutic Approach to the Challenges of Chronic Wounds: A Brief Review and Clinical Experience
		OCM treating Multiple Etiologies Final Trial Data (no author or publication date given.
Demonstrated antimicrobial properties and patient safety for in vitro/in vivo studies	In vitro study showed OCM™ significantly inhibiting Methicillin-resistant Staphylococcus aureus (MRSA) and Pseudomonas aeruginosa compared to negative controls. OCM™ addresses an unmet medical need; no other product demonstrates antimicrobial properties and leads to complete wound healing.	Davis, S.C., Gil, J., Solis, M. MBA, Bell, D.P., DPM, CWS, FFPM RCPS, Bakewell, S.J., PhD., Frost, P. (2023). University of Miami Miller School of Medicine Department of Dermatology & Cutaneous Surgery. In Vitro Study Evaluating Antimicrobial Effects of a Novel Combination Therapy Technology Against Methicillin-Resistant Staphylococcus aureus and Pseudomonas aeruginosa.
	In vivo porcine study showed OCM™ significantly reducing MRSA and Pseudomonas counts in infected wound, with significant reductions over positive (Silver dressing treatment) and negative results (untreated wounds). OCM™ addresses an unmet medical need; no other product demonstrates antimicrobial properties and leads to complete wound healing.	Stephen C. Davis. S.C., Jozic, I., PhD., Gil, J., Solis, M., Abdo Abujamra, B. (2023). University of Miami Miller School of Medicine Department of Dermatology & Cutaneous Surgery. Antimicrobial Effects of a Novel Combination Therapy Against Methicillin-Resistant Staphylococcus aureus and Pseudomonas aeruginosa in a Porcine Wound Model.
Demonstrated patient safety	Data show patient safety	Princeton Consumer Research Corp. (2019). Final Report. A safety study to assess the allergy potential of OMEZA collagen matrix in human subjects using the skin prick method.

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After review of the information provided by the applicant, we stated we had the following concerns regarding whether the applicant presents clinical data to suggest that OCM™ provides a substantial clinical improvement over other similar skin protectant and wound healing products to meet the criterion at § 419.66(c)(2)(i). Based on the evidence submitted in the application, we noted the following concerns: (1) lack of direct comparison between the nominated device and the predicate or reference devices for skin substitutes, particularly with respect to treatment of deep or persistent chronic wounds in people with DFU and VLU; (2) reliance on non-peer-reviewed studies, such as unpublished abstracts or conference posters, the results of which are only presented in a final data table; and (3) reliance on studies which were sponsored by the device manufacturer rather than independent research. We noted that the unpublished abstract for OCM™ lacked a detailed discussion of study limitations, patient population, and assurances that studies have been thoroughly peer-reviewed and free from implicit bias. Furthermore, the abstract does not state if or how standard of care treatment was administered within the same time period to control groups, and therefore, we stated we were unsure if there was a direct comparison between OCM™ and its predicate or reference

devices. Furthermore, we noted that the two randomized controlled trials [110] [111] and two real world studies [112] [113] submitted by the applicant to support its claims had relatively small sample sizes, some investigating only two patients total, which potentially limits the statistical significance of the results.

We noted that the applicant did not provide a comparison of OCM™ to other devices it identified are closely related or similar to OCM™. Specifically, in the FDA authorization letter dated September 1, 2021, FDA identified one predicate device, SweetBio Apis (K182725), and three reference devices, INTEGRA™ Flowable Wound Matrix (K072113), Kerecis MariGen Wound Dressing (K132343), and Southwest Technologies Stimulen Collagen (K030774) to which OCM™ may be compared. We noted that we did not approve transitional device pass-through payment for Kerecis MariGen Wound Dressing (K132343) for CY 2018 after determining that the clinical data provided by the applicant did not support the claim that Kerecis Omega3 Wound Dressing provides a substantial clinical improvement over other similar skin substitute products (82 FR 59330 through 59332). The FDA authorization letter noted that OCM™ and the predicate device SweetBio Apis have similar indications and the same intended use, namely, to manage wounds by providing an animal-derived collagen product that is biodegradable and incorporates into the surrounding tissue during the body's natural wound healing processes. Both products supplement the collagen constituent with additional biocompatible materials to achieve a final product that covers and protects the wound, assists in managing wound exudate, and maintains a moist wound environment. Further, the substantial equivalence table included in the FDA authorization letter indicated that OCM™ raised no new questions of safety or effectiveness when compared to the predicate and reference devices.

In the first claim, the applicant asserted OCM™ has superior clinical outcomes and healing for DFU compared to the standard of care. Based on the evidence submitted by the applicant, we noted the following concerns: (1) lack of a direct comparison to the predicate or reference devices in the two randomized controlled trials and the two real world clinical studies; (2) reliance on unpublished studies; (3) reliance on manufacturer sponsored studies; and (4) small sample sizes. First, Simman, et al. (2023) describes the results of a single-site trial in patients with DFUs to evaluate percent area reduction in wound healing. The stated goal of this study was to demonstrate that a combination therapy, using OCM™ plus standard of care treatment, moves chronic DFUs from a stalled state to a healing state in a 4-week period. The study enrolled 25 patients, five of whom did not complete the study, and one of whom died during the study from comorbidities related to their underlying condition. Study group DFUs were managed with combination therapy from 4–12 weeks, and control group DFUs (comprised of six total study participants) were managed with standard of care treatment involving cleaning and debridement only.

Interim analyses presented as a poster (Bell, et al., 2023) as evidence to support the first claim was limited to 12 total study participants. The interim analysis concluded that healing rates showed an average of 63 percent area reduction for the remaining participants at 4 weeks following standard of care treatment, and an average of 91 percent area reduction at 12 weeks following the treatment in patients with DFUs managed with the combination therapy. The interim analysis study further showed that one patient with a 12-week percent area reduction of 73 percent continued to improve through week 14 while three patients' wounds had not healed at the time of analysis for those receiving combination therapy.

In the final results presented in Simman, et al. (2023), the average 4-week percent area reduction was 60 percent, with three patients experiencing 100 percent closure with combination therapy. At 12 weeks, the median wound size was 0.0 cm^2 (range, 0–2.59), and the average percent area reduction was 93 percent, with five additional patients experiencing 100 percent closure with combination therapy. The average 4- and 12-week percent area reductions with standard of care alone were 42 percent and 45 percent, respectively. According to the final analysis study abstract, every wound treated with OCM™ combination therapy was reduced by more than 70 percent in 12 weeks; and all wounds previously failed treatments.

We noted that the Simman, et al. (2023) study abstract and the interim analysis do not provide any direct comparison to standard of care treatment with another collagen-based wound matrix or device that is otherwise similar to the indications for use of OCM™ in nonhealing wounds. In addition, we noted that it is unclear if any of the control group patients received collagen-based treatments including the predicate or reference devices to draw comparisons to collagen-based skin products that perform similarly to OCM™. While we recognized, given the number of skin substitute products on the U.S. market, it is not possible to compare OCM™ to each product, we stated that we believe studies comparing the product against other powder, liquid, or gel skin substitute products could provide more evidence demonstrating the clinical superiority of OCM™. In addition to the lack of comparison to other collagen-based wound matrix devices, we noted that the standard of care treatment in this study was limited to cleaning and debridement, which, based on the applicant's description for methods for administering OCM™, is a step prior to administering OCM™.

In reference to the applicant's statements that debridement combined with application of OCM™ is more effective in the removal of biofilm compared to the standard of care of debridement alone, we noted that neither the abstract nor the interim analysis for this study analyzed results on removal or prevention of biofilm in isolation from the overall metric on wound percent area reduction. We noted that FDA recommends sharp debridement alone as an effective method to remove the biofilm and necrotic tissue in a chronic wound (Bettle, et al., 2023). We questioned whether the results describing the average percent area reduction in wounds transitioning from a nonhealing state to a healing state are sufficient to show substantial clinical improvement in removal or prevention of biofilm. We further questioned whether the results in percent area reduction can be attributed to debridement combined with application of OCM™ as opposed to debridement alone because it is unclear if debridement was performed on all participants in the retrospective control group.

[110] Bell, D.P., et al. (2023). A Clinical Study Using Combination Therapy with Standard of Care for the Treatment of Diabetic Foot Ulcers: Interim Analysis. (poster presented at the 20th Annual Desert Foot Conference, December 6–9, 2023, Phoenix, AZ, USA).

[111] Randomized Controlled Trial in Venous Leg Ulcers (NCT05291169) (no author or publication date given).

[112] Black, G., Bakewell, S., & Bell, D. (2023). A Novel Combination Therapy Technology: Case Studies of Complete Closure of a Diabetic Foot Ulcer and a Charcot Foot Ulcer. (poster presented at the 2023 Diabetic Foot Conference, September 28–30, 2023, Anaheim, CA).

[113] Barrett, C.L., Bakewell, S.J., & Bell, D. (2023). A Novel Combination Therapy Technology: Case Studies of Complete Closure of Diabetic Foot Ulcers. Presented at the 2023 Diabetic Foot Conference, September 28–30, 2023, Anaheim, CA.

Furthermore, we noted that only the effects of historic standard of care treatments administered prior to the start of the study to patients in the control group were included for analysis. While one of the selection criteria for study participants was having failed prior treatment, neither the abstract nor interim analysis discussed how other variables, such as age and comorbidities, may have contributed to treatment failure, or which specific treatments failed in each of the six control group participants. We noted that not all patients in the control group received, or were eligible to receive, the same standard of care treatments prior to the study and did not receive any skin substitute or wound dressing treatments during the study as a comparison to the test group patients that were treated with OCM™. Due to the stated limitations in the study as previously described, we stated that we do not believe that the applicant has demonstrated that OCM™ offers a substantial clinical improvement over existing treatments.

Finally, we noted that the sample size of 19 individuals (six of whom were assigned to the control group) in the Simman, et al. (2023) study limits the generalizability of the findings. Therefore, we questioned whether OCM™ has superior clinical outcomes and healing for DFUs compared to the standard of care or the predicate or reference devices. Additionally, we noted that the Simman, et al. (2023) study abstract and interim analysis were sponsored by the manufacturer and have not been published, and therefore are not based on independent and peer-reviewed findings.

In addition to the Simman, et al. (2023) study (including the abstract and interim results), in support of its first claim, the applicant submitted two posters presenting results from limited case studies investigating two patients who received treatment using OCM™ combination therapy at the point of care. The first poster (Black, et al., 2023) discussed the treatment of two patients seeking treatment for DFUs at a wound care clinic: (1) a 75-year-old female patient who developed a DFU on her right third toe whose DFU wound progressed from nonhealing to healing after one application of the combination OCM™ therapy; and (2) a 65-year-old female patient with a history of diabetes and a blister of 3-month duration that progressed from nonhealing (after treatment with collagen powder, a gauze covering, an absorbent dressing, and a protective bandage) to completely closed after nine applications of the combination OCM™ therapy over 63 days. The study authors concluded that these case studies demonstrated: (1) rapid and durable healing of chronic/nonhealing wounds in two patients with diabetes who received the combination therapy for their chronic wounds; (2) significantly faster closure of a DFU within 1 week using OCM™ combination therapy than the average healing rate of 84 days for a 1–3 cm^2 plantar ulcer managed using standard care practices; and (3) that early treatment of chronic/nonhealing wounds with OCM™ combination therapy improves outcomes and can lead to complete closure.

Similarly, the second poster (Barrett, et al., 2023) presented results from a case study of two patients who received follow-up care at an outpatient wound center: (1) a 58-year-old male patient with a distal plantar lateral ulceration with infection, which required hospitalization; and (2) a 56-year-old male patient with leg trauma that had obliterated the patient's anterior tibial and peroneal arteries, leaving him with single vessel runoff to the left foot via the posterior tibial artery. In the first patient, after 5 weeks of initial negative pressure wound therapy following surgery, the percentage area reduction of the wound was 19 percent. In comparison, after three weekly follow-up applications of OCM™ combination therapy, the patient's percentage area reduction was 95 percent. In the second patient, the amputation site was noted as completely necrotic, and therefore not a candidate for standard of care negative pressure wound therapy due to poor skin condition, ischemia, and hyperalgesia. It was noted that after three applications of OCM™ combination therapy, there was a significant improvement in the wound depth and tissue color, with visible epithelialization at the wound edges despite the patient's obvious ischemia. It was noted that the wound size improved and completely healed between the fourth and fifth application of OCM™ combination therapy and after the seventh application of OCM™ combination therapy. The researchers concluded that the case studies demonstrate complete and rapid healing of refractory DFUs in two patients with diabetes who had previously undergone lower extremity amputations and that early use of OCM™ combination therapy has the potential to reduce the rate of amputations and improve patients' quality of life.

We noted that both case studies (Barrett, et al., 2023, and Black, et al., 2023) were sponsored by the manufacturer and only had two study participants treated with OCM™ combination therapy, which limits the generalizability of the findings. Although the studies suggest that the two participants treated with OCM™ combination therapy showed transition to a healing state subsequent to the application of OCM™, the results varied widely in terms of number of applications needed to achieve positive results and treatment duration. Further, we noted that these case studies provide no direct comparison to the standard of care treatment or the predicate or reference devices. We noted that eligibility for standard of care treatments also varied across patients and resulted in varying degrees of percent area reduction or wound closure from prior treatments before application of OCM™ combination therapy. While in one patient, the study showed an improved clinical outcome in percentage area reduction (19 percent to 95 percent) with treatment utilizing OCM™ combination therapy, we noted that the treatment including OCM™ was not only completed subsequent to standard of care treatment with a collagen wound protectant, but also delivered to the same individual rather than as a comparison to standard of care treatments in a control group.

We questioned whether the submitted evidence adequately supports the claim that OCM™ has superior clinical outcomes and healing for DFU compared to the standard of care. We stated our interest in additional information to demonstrate whether the nominated device demonstrates a substantial clinical improvement in comparison to similar collagen-based matrix devices.

In the second claim, the applicant asserted that OCM™ provides faster healing rates than standard of care for VLUs. However, based on the evidence submitted, we noted the following concerns: (1) reliance on unpublished studies; and (2) a lack of any documentation indicating the study authors, study description, methods, limitations, information on standard of care treatment for the comparison of control groups, analysis, or discussion. The only data provided were in the form of two tables. One table [114] provided demographic information for the study participants, such as race, age, gender, presence of VLUs, comorbidities, wound area, and wound age; however, there is no indication of how many initial study participants were included in the final results or how many were assigned to either the treatment or control group receiving the standard of

[114] Demographics for RCT in VLU (no author or publication date given).

care. The other table [115] presented one row of data from the final results of a randomized controlled trial on VLUs showing an average percent area reduction of 66 percent at 12 weeks in OCM™ treatment group (there was no comparison to the standard of care treatment group) and an average percent area reduction of 34 percent at four weeks in the OCM™ treatment group compared to an average percent area reduction of 31 percent at four weeks in the standard of care group. Due to the lack of a study report, we stated that we have insufficient information to adequately assess this study or make a determination as to whether the study supports the claim that OCM™ provides faster healing rates than standard of care for VLU.

In order to demonstrate substantial clinical improvement over currently available treatments, we noted that we consider supporting evidence, preferably published peer-reviewed clinical trials, that shows improved clinical outcomes, such as reduction in mortality, complications, subsequent interventions, future hospitalizations, recovery time, pain, or a more rapid beneficial resolution of the disease process compared to the standard of care. We noted that additional supporting evidence, preferably published peer-reviewed clinical trials, that shows these improved clinical outcomes would help inform our assessment of whether OCM™ demonstrates substantial clinical improvement over existing technologies.

In the third claim, the applicant asserted that OCM™ provides superior clinical outcomes for patients who could not qualify for clinical trials due to comorbidities, and in the fourth claim, the applicant stated that OCM™ improved results when compared to results with standard of care for patients who failed prior treatment. The applicant used the same pair of documents as supporting evidence for both the third and fourth claims: (1) a case study by 16 independent investigators (Bettle, et al., 2023), and (2) a final summary table [116] of the results of that case study. In the case study by the 16 independent investigators, OCM™ combination therapy was administered to 65 patients with wound ages ranging from 12 weeks to 15 years who failed prior treatment, including six patients with prior failed cellular tissue product therapies. Patients were not otherwise subjected to inclusion or exclusion criteria. According to the applicant, the findings by the 16 independent investigators showed 77 percent of wounds were closed by 12 weeks and the average area reduction was 90 percent. Wounds treated included DFUs, VLUs, pressure injuries, arterial, pyoderma, hematomas, surgical, and trauma. We noted that the study lacked direct comparison to a standard of care treatment. Rather, the study compared patient data to standardized data on wound closure and mean time to total wound closure by wound type based on standardized data from the U.S. Wound Registry.

We questioned whether the submitted evidence adequately supports the claims that OCM™ provides superior clinical outcomes for patients who could not qualify for clinical trials, due to comorbidities, or that OCM™ improved results when compared to results with standard of care for patients who failed prior treatment. We welcomed further investigation with comparators to help determine whether the device demonstrates substantial clinical improvement over currently available treatments in the clinical setting where it is most likely to be used.

In its fifth claim, the applicant asserted that in vitro (Davis, et al., 2023) and in vivo (Davis, Jozic, et al., 2023) study results demonstrate antimicrobial properties and patient safety. The applicant further asserted that OCM™ addresses an unmet medical need, stating that no other product demonstrates antimicrobial properties and leads to complete wound healing. In the in vivo study (Davis, Jozic, et al., 2023), researchers made 31 deep reticular wounds across the paravertebral and thoracic areas on each of specific pathogen-free pigs. Pathogenic strains of Methicillin-Resistant Staphylococcus Aureus (USA300) or Pseudomonas Aeruginosa (ATCC 27312), prepared as 106 CFU/ml inoculum suspensions, were used to inoculate all wounds within 20 minutes after wounding followed by application of polyurethane dressings (Tegaderm, 3M, USA) for 72 hours before being treated. Subsequent treatment consisted of OCM™ alone in one test group, OCM™ plus a skin protectant in another test group, Aquacel Ag Advantage in the positive control group, or the wounds were left untreated in the negative control group. We noted that the only in vivo study (Davis, Jozic, et al., 2023) with direct comparison to a skin protectant was conducted on non-human subjects (pigs). We questioned whether these data can be extrapolated to demonstrate significant clinical improvement in humans. In addition, according to the applicant, the in vitro study (Davis, et al., 2023) showed OCM™ significantly inhibiting Methicillin-resistant *Staphylococcus aureus* and *Pseudomonas aeruginosa* compared to negative controls. We noted that the in vitro study (Davis, Jozic, et al., 2023) lacked a direct comparison to performance of other similar skin protectant products or wound therapies besides infection control methods such as silver sulfadiazine or Mupirocin antibiotic. We further noted that both the in vitro and in vivo studies were submitted as poster presentations and that the studies had not been published and peer-reviewed in full.

We questioned whether the submitted evidence adequately supports the claims that OCM™ demonstrates antimicrobial properties and patient safety. We noted that additional supporting evidence, preferably published peer-reviewed clinical trials, that demonstrates improved clinical outcomes, such as reduction in mortality, complications, subsequent interventions, future hospitalizations, recovery time, pain, or a more rapid beneficial resolution of the disease process, would help inform our assessment of whether OCM™ demonstrates substantial clinical improvement over the standard of care and existing technologies.

For its sixth claim, the applicant asserted that study results demonstrated patient safety of OCM™. In support of this claim, the applicant provided one consumer research study (Princeton Consumer Research Corp., 2019) [117] of 25 subjects showing no immediate allergic reaction to OCM™. We noted that, similar to our previously stated concerns, the study did not include a direct comparison to predicate or reference devices despite claiming an improvement over standard of care treatment. We noted that the submitted evidence does not adequately support the claims that OCM™ demonstrates substantial clinical improvement in product safety in comparison to similar products.

Finally, we noted that OCM™ may not demonstrate that it substantially improves the diagnosis or treatment of an illness when compared to the benefits of other available treatments. OCM™ was determined to be substantially equivalent to a legally marketed device, the SweetBio Apis, which received 510(k) clearance on

[115] Randomized Controlled Trial in Venous Leg Ulcers (NCT05291169) (no author or publication date given).

[116] OCM treating Multiple Etiologies Final Trial Data (no author or publication date given).

[117] Princeton Consumer Research Corp. (2019). Final Report. A safety study to assess the allergy potential of OMEZA collagen matrix in human subjects using the skin prick method.

April 29, 2019. The FDA 510(k) summary for OCM™ indicated that both devices share similar technological characteristics. Per FDA, the main differences between OCM™ and the predicate are the specific collagen source (OCM™ uses whitefish skin-derived collagen, while the SweetBio Apis uses porcine skin-derived collagen) and the specific identity of the supplemental components, which serve the same fundamental purpose in enabling each wound dressing to achieve the shared intended use.[118]

We invited public comment on whether OCM™ meets the substantial clinical improvement criterion at § 419.66(c)(2)(i).

Comment: With respect to our concern about the lack of independent peer-reviewed or published clinical evidence, the applicant commented that they recognize the importance of peer-reviewed research. Further, the applicant noted that while at the time of the initial application, none of the studies had been submitted for peer-review or published in indexed journals, the clinical evidence previously referenced has now been published, is in press for an indexed journal, or has been submitted for review at an indexed journal and is publicly available on a preprint server. The applicant submitted these as part of its comment.[119] [120] [121] The applicant also acknowledged that it sponsored the provided studies but asserted that, due to the newness of the product, cost, and unclear coverage status, the lack of investigator-sponsored trials is not unexpected.

Response: We thank the applicant for their response to our concerns regarding the lack of independent and peer-reviewed studies. After consideration of the applicant's comments, we believe the applicant has addressed our concern about the lack of peer-reviewed and published studies by submitting two studies (Bettle III, et al., 2024, and Simman, et al., 2024) that appear to support the applicant's claims of substantial clinical improvement that have been accepted for publication in peer-reviewed medical journals.

Comment: In response to our concerns that the applicant did not provide a comparison of OCM™ to similar wound closure products, the applicant reiterated that OCM™ catalyzes wound closure in patients with nonhealing wounds treated with other advanced wound therapies. The applicant also asserted that OCM™ offers a more rapid beneficial resolution over the best available therapies, including the predicate and reference devices. Specifically, the applicant asserted that in comparison to the protective dressing application, OCM™ application in conjunction with debridement qualifies as an active wound procedure within the scope of active wound care management services. The applicant also noted that OCM™ application following initial standard of care failure may replace the need for negative-pressure wound therapy, placental membranes, bioengineered skin substitutes, several acellular matrices, autologous fibrin, and leukocyte platelet patches, all of which are currently used in the hospital outpatient setting.

The applicant clarified that it has not advocated for OCM™ to be used in routine management of wounds as it believes the current standard of care, which includes four weeks of routine therapy, should be utilized prior to the application of OCM™. Specifically, the applicant asserted that once wounds become refractory, then OCM™ can be applied to re-initiate the healing process, as demonstrated in the submitted studies.

The applicant further stated that FDA has specifically acknowledged the lack of innovative products aimed at the treatment of non-healing chronic wounds. The applicant noted that patients with significant medical comorbidities presenting with non-healing wounds of any size have not been enrolled in advanced wound therapy randomized controlled trials, even though these patients represent a high-risk group that most clinicians believe need active treatment beyond the routine standard of care to prevent infection, amputation, and even death. The applicant asserted that OCM™ addresses an unmet need for patients with multiple comorbidities who have refractory wounds of at least four weeks duration, including at least two weeks of care by a wound specialist, who would have likely been excluded from the few randomized control trials in this field.

Response: We thank the applicant for its input and clarification. While we appreciate that FDA has specifically acknowledged the lack of innovative products aimed at the treatment of non-healing chronic wounds, we remain concerned with the lack of clinical studies and comparative studies demonstrating whether the use of OCM™, when applied following initial standard of care failure as an active wound procedure, results in substantial clinical improvement over other available active wound care management services. With respect to replacing the need for negative pressure wound therapy, placental membranes, bioengineered skin substitutes, several acellular matrices, autologous fibrin and leukocyte platelet patches, we address specific substantial clinical improvement claims and responses to our concerns below.

Comment: Several commenters stated that they believed for wound infections that could progress to sepsis or necessitate an amputation, OCM™ could prevent patient complications, including disability secondary to the complications of a non-healing wound, or death. The commenters stated that for chronic non-healing and hard-to-heal wounds OCM™ offers several advantages including that its effects can be seen quickly, even though other products used prior to OCM™ failed, and its amorphous property enables optimal use of the product, even in wounds with non-perfect, irregular wound beds. The commenters stated that this amorphous structure allows the product to fill unique areas within wounds, such as tunneling and undermining, that would otherwise be unmanageable using a standard advanced wound graft product.

Response: We thank the commenters for their input. We maintain our concerns that the submitted evidence does not adequately support the applicant's claims that OCM™ demonstrates substantial clinical improvement compared to other available treatments. We appreciate that commenters provided information about the unique uses for OCM™'s amorphous structure; however, we note that the commenters did not supply additional data in support of these claims. Furthermore, we note that the applicant did not make any specific claims about the consequential benefits directly attributable to any specific or isolated mechanism of OCM™.

Comment: With respect to our concerns about the lack of direct comparison to the predicate or reference devices in the studies used to support its first three claims, the applicant noted

[118] The SweetBio Apis is FDA cleared and marketed under 510(k) since 2019 (FDA 510(k)) letter: *https://www.accessdata.fda.gov/cdrh_docs/pdf21/K211972.pdf.*

[119] Bettle III, G., Bell, D.P., & Bakewell, S.J. (2024). A Novel Comprehensive Therapeutic Approach to the Challenges of Chronic Wounds: A Brief Review and Clinical Experience Report. *Advances in Therapy, 41:* 492–508. *https://doi.org/10.1007/s12325-023-02742-4.*

[120] Simman, R., Bakewell, S.J., Bell, D., Shuman, S., & Cheney, M. (2024). A novel approach for the treatment of diabetic foot ulcers using a multimodal wound matrix: a clinical study. Journal of Wound Care. *https://doi.org/10.12968/jowc.2024.0085.*

[121] Cole, W. (2024). Treatment of bacterially contaminated lower extremity ulcers with a fatty acid-containing wound matrix: a case series. Journal of Wound Care, *33*(8):554–559. *https://doi.org/10.12968/jowc.2024.0101.*

that while OCM™ and the predicate device SweetBio Apis have similar indications and the same intended use, they differ in the chemical and physical properties of the derived collagen product as well as the additional biocompatible materials that supplement the product. The applicant also asserted that SweetBio Apis does not have any published data on its effectiveness in healing wounds in a similar population, as in OCM™'s most recently completed study. The applicant stated that SweetBio Apis's study of real-world evidence featured a small sample size (n = 12) with likely singular etiology (implied to be DFU given diabetic population) and limited transparency into the selection of study participants. The applicant asserted that, in comparison, OCM™ has been investigated in a patient group that is significantly larger, has more variability in ulcer etiology, and has more comorbidities, which is representative of the overall patient population for whom OCM™ is indicated. Additionally, the applicant highlighted that SweetBio Apis has published only one randomized controlled trial involving participants with Mohs Surgical Defects, which demonstrated no significant difference in re-epithelization.

The applicant asserted that, as such, a direct comparison of OCM™'s and SweetBio Apis's published evidence indicates that OCM™ has more substantially proven capability to deliver clinical improvement for these hard-to-treat wounds. In addition, the applicant stated that while OCM™ and SweetBio Apis have similar indications and the same intended use, their derived collagen products differ in the chemical and physical properties. The applicant further stated that OCM™ differs from SweetBio Apis in terms of additional biocompatible materials that supplement the product. The applicant asserted that this supplement material (*i.e.,* the additional biocompatible materials) raises no new questions of safety or effectiveness when OCM™ is compared to the predicate and reference devices but does confer additional benefits to OCM™. The applicant asserted that OCM™'s additional benefits warrant the product's consideration for transitional device pass-through payment. The applicant stated they are planning to work with the HCPCS workgroup to define a more accurate description of OCM™ since it is unlike other collagen products on the market.

The applicant also clarified that their most recent clinical studies demonstrate the multi-faceted impact of OCM™'s multiple components on wound healing. Specifically, the applicant asserted that other collagen wound matrix devices' similar compositions confer some, but not all, of the wound healing properties characteristic of OCM™. The applicant further asserted that a head-to-head comparison of OCM™ to any of these other products would only represent the marginal benefits of OCM™'s supplemental biomaterials. In addition, the applicant stated that their clinical study relies on the metric of wound percent area reduction in hard-to-heal wounds in order to demonstrate OCM™'s total clinical benefit, rather than the consequential benefits directly attributable to any specific mechanism in isolation. The applicant asserted it has not made individual claims about OCM™'s clinical superiority over similar wound healing products in regards to any specific mechanisms that contribute to the totality of OCM™'s clinical benefits conferred to patients with hard-to-heal wounds as it has not performed such independent or multi-factorial statistical analyses.

Response: We thank the applicant for the additional information. After reviewing the provided information, we note that the applicant's points regarding the differences between OCM™ and SweetBio Apis are comparisons of volume of data, study design, and test results between studies that each evaluate OCM™ and SweetBio Apis separately and without a direct comparison. Therefore, we remain concerned about the lack of direct comparison of OCM™ to other similar devices, particularly those that are animal-derived collagen-based products in test arms or cohorts within the same study. We note that we were not able to verify the applicant's claims that there is more scientific data supporting the clinical effectiveness of OCM™ while there is none supporting the clinical effectiveness of SweetBio Apis, especially since there appears to be a high volume of data showing clinical effectiveness of SweetBio Apis available on the manufacturer's website.[122] We also note that even if the applicant could demonstrate that there is comparatively more data on effectiveness in wound healing from treatment with OCM™ than for SweetBio Apis, clinical effectiveness is not an equivalent standard to substantial clinical improvement over existing technologies. With respect to the applicant's argument that SweetBio Apis may not be a suitable comparator because OCM™'s derived collagen products differ in chemical and physical properties as well as the additional biocompatible materials that supplement the products, as we noted previously, the FDA made no distinction between porcine or fish-derived collagen in wound dressings,[123] or the chemical and physical properties of any additives used to anchor this collagen to the wound.[124] We do not believe that the applicant has demonstrated that the physical and chemical properties result in substantial clinical improvement because of the lack of direct comparison of OCM™ to these similar products.

In response to the applicant's assertion that a head-to-head comparison of OCM™ to any other products would only represent the marginal benefits of OCM™'s supplemental biomaterials, we believe that this suggests that other products would perform similarly to OCM™ in the metric of percent area reduction across different test arms in patients with the same or similar hard-to-heal wounds. While we appreciate the need to study OCM™'s effect on the total clinical benefits in hard-to-heal wounds in isolation, we continue to believe evaluation of the applicant's first three claims of substantial clinical improvement (*i.e.,* OCM™'s superior outcomes and faster healing rates in comparison to the standard of care) requires a direct comparison of OCM™'s clinical outcomes to those similar products. For the reasons discussed, we do not believe that OCM™ represents a substantial clinical improvement relative to similar currently available therapies.

Comment: In regard to the applicant's claim that OCM™ provides a treatment option for a patient population unresponsive to, or ineligible for currently available treatments, the applicant submitted additional information to clarify that OCM™ not

[122] Sweetbio®. Citations. *https://www.sweetbio.com/apis.*

[123] Note that while CMS refers to these materials as ''skin substitutes'' in its 2024 guidance Billing and Coding: Skin Substitutes Grafts/Cellular Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers, *https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=59625*, the FDA collectively refers to this class of products as Dressings, Wound/Dressings, Wound, Collagen. see *e.g.* FDA (2022). Traditional 510(k), Kerecis, pg. 6. *https://www.accessdata.fda.gov/cdrh_docs/pdf21/K213231.pdf.*

[124] The SweetBio Apis is FDA cleared and marketed under 510(k) since 2019 (FDA 510(k)) letter: *https://www.accessdata.fda.gov/cdrh_docs/pdf21/K211972.pdf.* Note that the FDA collectively refers to this class of products as Dressings, Wound or Dressings, Wound, Collagen. See *e.g.* FDA (2022). Traditional 510(k), Kerecis, pg. 6. *https://www.accessdata.fda.gov/cdrh_docs/pdf21/K213231.pdf.*

only matches but exceeds the clinical utility of skin substitutes as advanced wound therapy for patients with hard-to-heal wounds. Specifically, the applicant asserted that OCM™'s superiority over other forms of wound management is evident in its ability to reduce wound size in patients with non-healing wounds that were failed by alternative wound products, such as gentian violet/methylene blue foam, manuka honey, cellular tissue products (CTPs), Negative Pressure Wound Therapy (NPWT), and dressings consisting of alginate, collagen, or silver. The applicant stated that the study protocol in Dhillon, et al. (2024) [125] ensured that patients had wounds that had not responded to therapy for at least eight weeks and had undergone high-quality wound care for a minimum of two weeks that included the use of advanced therapies, such as the predicate and reference devices. Furthermore, the applicant asserted that the OCM™ clinical trial design was intentional in evaluating the device's clinical utility in a patient population that was not served by other alternative wound products.

Response: We appreciate the applicant's clarification. We agree with the applicant that the Dhillon, et al. (2024) study demonstrated OCM™'s effectiveness in treating a group of 53 patients who did not improve after receiving alternative wound products prior to the study. However, we note that, of the 111 patients that entered the study's screening phase, only 53 patients and 54 wounds (which included 18 DFUs, 19 VLUs, two pressure injuries, one surgical, one lower extremity wound, and 12 unclassified etiology) received treatment and were eligible for the data set. We also note that the study's final analysis excluded the 58 patients who responded to the standard of care (*i.e.,* cleaning and debridement) with wound reduction of more than 30 percent. We are concerned that Dhillon, et al. (2024) fails to provide details about the specific previous wound management treatments that the study participants received to demonstrate that it exceeds the clinical utility of skin substitutes as advanced wound therapy for hard-to-heal wounds as the applicant claims above. Absent this data, we are unable to verify that OCM™ treats a patient population unresponsive to currently available multimodal wound management treatments.

Comment: In response to our concerns that the studies provided on OCM™'s antimicrobial properties do not demonstrate results in live human subjects, the applicant commented that OCM™ can play a preventative role in wound management through the inherent antimicrobial properties of its anhydrous matrix. The applicant asserted that a small-scale clinical study signaled OCM™'s antimicrobial capacity and that its antimicrobial properties could enable preventative care of hard-to-heal wounds. Specifically, the applicant stated that OCM™'s non-antibiotic composition may reduce the probability of bacterial colonization progressing to wound infection, which could result in antibiotic resistance or even sepsis and limb amputation. In addition, the applicant asserted that OCM™ has clinical utility as a non-antibiotic decolonization agent in clinically uninfected wounds for which antibiotic prophylaxis is deemed inappropriate, per International Working Group on the Diabetic Foot/Infectious Diseases Society of America (IWGDF/IDSA) Guidelines. The applicant also commented that it is committed to working with FDA to evaluate the extent to which the OCM™'s antimicrobial properties confer substantial clinical benefit over the standard of care treatment.

Furthermore, the applicant suggested that transitional device pass-through payments would enable it to continue developing evidence that OCM™'s decolonization function provides substantial clinical benefit over the standard of care. The applicant compared OCM™'s decolonization function to topical prophylactic decolonization methods, for which clinical significance has historically been difficult to substantiate. The applicant asserted that this mechanism of infection prevention and control has been widely practiced for decades in accordance with CDC guidance, as exemplified by chlorhexidine bathing and administration of intranasal mupirocin or Iodophor. Similarly, several non-applicant commenters stated that OCM™ has some unique and validated anti-microbial properties that can potentially reduce the risk of infection, as many hard-to-heal wounds are colonized by bacteria but not yet infected. These commenters also asserted that this may lead to a further reduction in antibiotic prescriptions during treatment of hard-to-heal wounds.

Response: We thank the applicant and commenters for their input. After consideration of the comments received, we remain concerned that the applicant has not provided sufficient clinical evidence to demonstrate OCM™'s antimicrobial properties in human subjects. The provided case study of OCM™'s decolonization effects includes only three patients with hard-to-heal wound etiologies and compares OCM™ to non-treatment of periwound skin, rather than wound beds of similar etiology treated with the standard of care.[126] Therefore, we do not believe this demonstrates that OCM™ application to the wound bed results in fewer bacterial infections.

Concerning the applicant and other commenters' statements about the claim about antimicrobial properties, we note that these claims appear to be conditional. While the applicant compared OCM™'s decolonization function to topical prophylactic decolonization methods, its claims that OCM™ has the potential to reduce the probability of bacterial colonization, play a preventative role in wound management, and reduce the risk of infection are not proven. In addition, we note that the applicant did not provide the referenced joint CDC/FDA workshop materials describing this study's methods, so we are unable to verify whether topical prophylactic decolonization methods are analogous to OCM™. Therefore, we remain concerned about the lack of evidence demonstrating that OCM™ antimicrobial properties improve outcomes by reducing the risk of infection.

In regard to the applicant's plan to pursue further studies to demonstrate substantial clinical improvement in this area, we are unable to consider future evidence for OCM™'s current transitional pass-through payment application.

Comment: In response to our concerns that the submitted evidence does not adequately support the applicant's claim that OCM™ demonstrates substantial clinical improvement in product safety in comparison to similar products, the applicant stated that FDA's clearance of OCM™ through the 510(k) application process involves a comprehensive review of the device's safety and performance data. Specifically, the applicant asserted that

[125] Dhillon, Y., Mulder, G., Patel, K., Moya, L., Boghossian, G., Swain, D., McLafferty, R., Perez, K., Nguyen, J., Wilkinson, N., Arragon, J., Contreras, L., Geiger, D., Cummings, R., LaVigne, B., Bell, D., Bakewell, S. (2024). An open-label, interventional, prospective, real-world evidence study to evaluate a multimodal wound matrix in patients with refractory wounds. *Advances in Wound Care, Ed* (pre-print).

[126] Cole, W. (2024). Treatment of bacterially contaminated lower extremity ulcers with a fatty acid-containing wound matrix: a case series. *Journal of Wound Care, 33*(8):554–559. *https://doi.org/10.12968/jowc.2024.0101.*

OCM™ is among the minority of advanced wound therapies that have passed rigorous FDA review of safety and effectiveness. In addition, the applicant stated that Bettle, et. al. (2024) demonstrates that OCM™ has no potential allergenicity, no potential sensitization, and resulted in no known product-related adverse events. The applicant asserted that this was further corroborated by OCM™'s most recent, real-world evidence dataset presented in Dhillon, et. al. (2024), which showed that treatment with OCM™ resulted in only eight potential product-related adverse events and no serious adverse events.

Response: We appreciate the applicant's input. However, we maintain our concern that the submitted evidence does not demonstrate OCM™'s substantial clinical improvement in product safety in comparison to similar products. We acknowledge that FDA's 510(k) clearance process includes a comprehensive review to evaluate the safety and effectiveness of a new product, however, demonstrating substantial clinical improvement for device pass-through payment is different from FDA's 510(k) process. While the applicant has shown that OCM™ is safe, we continue to believe that the applicant has not shown that OCM™ demonstrates substantial clinical improvement in product safety in comparison to currently available therapies. For the reasons discussed, we do not believe that OCM™ represents a substantial clinical improvement relative to existing therapies currently available as discussed in the summary above. Therefore, we have determined that OCM™ does not meet the substantial clinical improvement criterion at § 419.66(c)(2).

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that OCM™ would be reported with HCPCS codes as shown in Table 125.

TABLE 125: HCPCS CODES REPORTED WITH OCM™

HCPCS Code	Long Descriptor	SI	APC
A2014**	Amorphous solid malleable sheet for hard to treat or chronic wounds	N	
11042	Debridement, subcutaneous tissue (includes epidermis and dermis, if performed); first 20 sq cm or less	T	5052
11043	Debridement, muscle and/or fascia (includes epidermis, dermis, and subcutaneous tissue, if performed); first 20 sq cm or less	T	5053
11044	Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed); first 20 sq cm or less	J1	5072
97597	Debridement (*e.g.*, high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (*e.g.*, fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; first 20 sq cm or less	T	5051
97598**	Debridement (*e.g.*, high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (*e.g.*, fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; each additional 20 sq cm, or part thereof (list separately in addition to code for primary procedure	N	

**Denotes a HCPCS code that was not included in the corrected Addendum P to the CY 2024 OPPS/ASC final rule with comment period, with no CY 2024 HCPCS/CPT code level device offset amount available. We noted the applicant used the CY 2024 payment rates for the three tests of the cost criterion. We used the CY 2024 HCPCS/CPT code level device offset amounts for the HCPCS/CPT codes included in the corrected Addendum P to assess whether the device meets the cost significance criterion.

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). We noted that the applicant utilized the CY 2024 payment rates for the three tests of the cost criterion. For our calculations, we used APC 5052, which had a CY 2024 payment rate of $379.92 at the time the application was received. HCPCS code 11042 in APC 5052 had a device offset amount of $0.04 at the time the application was received. According to the applicant, the cost of OCM™ is $1,320.00.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25

percent of the applicable APC payment amount for the service related to the category of devices. The average reasonable cost of $1,320.00 of OCM™ is 347.44 percent of the applicable APC payment amount for the service related to the category of devices of $379.92 (($1,320.00/$379.92) × 100 = 347.44 percent). Therefore, we stated that we believe OCM™ meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $1,320.00 for OCM™ is 3,300,000.00 percent of the cost of the device-related portion of the APC payment amount for the related service of $0.04 (($1,320.00/$0.04) × 100 = 3,300,000.00 percent). Therefore, we stated that we believe OCM™ meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $1,320.00 for OCM™ and the portion of the APC payment amount for the device of $0.04 is 347.43 percent of the APC payment amount for the related service of $379.92 ((($1,320.00 − $0.04)/$379.92) × 100 = 347.43 percent). Therefore, we stated that we believe OCM™ meets the third cost significance requirement.

We invited public comment on whether OCM™ meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

Comment: Several non-applicant commenters asserted that OCM™ warrants transitional pass-through payments because the current construction of the APC bundle includes the services for hard-to-heal wounds but its associated payment rate (*i.e.,* the reimbursement amount for the services assigned to the APC) is not sufficient to cover the cost of more advanced treatments, such as the OCM™, which are needed to manage complex wounds. The commenters stated that they strongly support the use of OCM™ in the outpatient hospital setting; however, they asserted that the costs are too high given the current APC assignment and its payment rate. The commenters stated that without access to OCM in the hospital outpatient setting patients may be treated in other settings, which can be costlier since these other settings bill separately for advanced wound therapy. The commenters stated that OCM™ represents a clinically effective solution for hard-to-heal wounds that, at present, cannot be used in the outpatient hospital setting given that the cost of using OCM™ is not adequately reflected in the payment rate for the APC to which the product is assigned under the OPPS.

Response: We thank the commenters for their additional input. We acknowledge the commenters' concerns about the cost of OCM™ as a treatment option in the hospital outpatient department; however, we note that in order to be eligible for device pass-through, a device must meet all requirements for pass-through payment status in our regulation at § 419.66, in addition to determining that the cost of the device is not insignificant, as described in § 419.66(d).

Comment: The applicant thanked CMS for agreeing that it met the cost criterion.

Response: We appreciate the applicant's comment. After consideration of the public comment received and our findings from the first, second, and third cost significance tests, we agree that OCM™ meets the cost significance criteria specified at § 419.66(d).

After consideration of the public comments received and our review of the device pass-through application, we are not approving OCM™ for transitional pass-through payment status in CY 2025 because the product does not meet the substantial clinical improvement criterion at § 419.66(c)(2).

(c) OPN NC

SIS Medical AG submitted an application for a new device category for transitional pass-through payment status for OPN NC for CY 2025. Per the applicant, OPN NC percutaneous transluminal coronary angioplasty (PTCA) dilatation catheter is a sterile, single-use, rapid exchange catheter with a distal non-compliant double layer balloon attached to a flexible distal polymer shaft. The applicant explained that OPN NC is intended for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion. Per the applicant, the balloon dilatation catheter is also indicated for post deployment expansion of balloon expandable coronary stents. The applicant asserted that the device is inserted to position a balloon in a calcified coronary lesion where super-high pressure is used with the intention of achieving acceptable expansion of the lesion. Per the applicant, radiopaque balloon marker bands enable accurate positioning of the device, and shaft markers for brachial and femoral techniques are also in place. According to the applicant, OPN NC is intended for all patient populations.

Please refer to the online application posting for OPN NC, available at *https://mearis.cms.gov/public/publications/device-ptp/DEP231214L8XQC*, for additional detail describing the device and the disease treated by the device.

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), on March 14, 2022, the applicant received 510(k) clearance from FDA for OPN NC as a device intended for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion. The balloon dilatation catheter is also indicated for post deployment expansion of balloon expandable coronary stents. We received the application for a new device category for transitional pass-through payment status for OPN NC on December 14, 2023, which is within 3 years of the date of the initial FDA marketing authorization.

We invited public comment on whether OPN NC meets the newness criterion at § 419.66(b)(1).

Comment: With respect to the newness criterion at § 419.66(b)(1), one commenter stated that they believe OPN NC meets the newness criterion at § 419.66(b)(1) because unlike prior balloons including noncompliant balloons, it is specially designed to achieve 35–55 atmospheres (atm) of pressure, which is far beyond the 20 atm of conventional balloons. The commenter further noted that this can be particularly and uniquely useful for under-expanded stents from fibrotic or calcified vessels, which even new technologies such as lithotripsy and older technologies such as laser are unable to expand.

Response: We appreciate the commenter's input; however, the comment relates to an assessment of whether the technology meets the substantial clinical improvement criterion rather than the newness criterion. As such, we have addressed

this comment in the substantial clinical improvement criterion discussion below.

We received the application for a new device category for transitional pass-through payment status for OPN NC on December 14, 2023, which is within 3 years of March 14, 2022, the date of FDA 510(k) clearance. Based on our review of the application, we have determined that OPN NC meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criteria at § 419.66(b)(3), the device must be an integral part of the service furnished, used for one patient only, comes in contact with human tissue, and be surgically inserted or implanted, or applied in or on a wound or other skin lesion. Per the applicant, OPN NC is integral to the service provided and is used for one patient only. While the applicant did not explicitly state whether the device is surgically inserted or comes in contact with human tissue, per the device description, OPN NC is inserted into the patient for balloon dilation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.

We invited public comment on whether OPN NC meets the eligibility criterion at § 419.66(b)(3).

Comment: One commenter submitted a comment stating that they believe that OPN NC meets the § 419.66(b)(3) criterion because it is integral to the service provided and used for one patient only, that is, it is disposable.

Response: We appreciate the commenter's input. With respect to the eligibility criterion at § 419.66(b)(3), as noted in the proposed rule, the applicant did not indicate that OPN NC is surgically inserted or comes in contact with human tissue; however, because the device is inserted into the patient for balloon dilation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion, we believe that OPN NC is surgically inserted and comes in contact with human tissue. In addition, we agree with the applicant that OPN NC is an integral part of the service furnished and used for one patient only. After consideration of the public comment we received and our review of the application, we have determined that OPN NC meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker). The applicant did not address whether OPN NC is equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered, or if OPN NC is a supply or material furnished incident to a service.

We invited public comments on whether OPN NC meets the exclusion criterion at § 419.66(b)(4).

Comment: With regards to criterion § 419.66(b)(4), one commenter stated that OPN NC is not equipment.

Response: We appreciate the commenter's input. With respect to the eligibility criterion at § 419.66(b)(4), as noted in the proposed rule, the applicant did not indicate that OPN NC is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered, or if OPN NC is a supply or material furnished incident to a service; however, because the device is inserted into a calcified coronary lesion where super-high pressure is used for the purpose of improving myocardial perfusion, we believe that OPN NC is not a supply or material furnished incident to a service. In addition, OPN NC is a single-use PTCA dilatation catheter with a distal non-compliant double layer balloon attached to a flexible distal polymer shaft, and therefore does not appear to be equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets. After consideration of the public comment we received and our review of the application, we have determined that OPN NC meets the eligibility criterion at § 419.66(b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), the criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. The applicant described OPN NC as a PTCA dilatation catheter with a distal non-compliant double layer balloon attached to a flexible distal polymer shaft. According to the applicant, no previous or existing device categories for pass-through payment appropriately describe OPN NC. Per the applicant, the device category, C1725 (Catheter, transluminal angioplasty, non-laser (may include guidance, infusion/perfusion capability)) does not appropriately describe OPN NC, because OPN NC is a super high pressure, non-compliant double (twin) layer balloon. Based on the description the applicant provided, OPN NC is a transluminal vascular dilatation catheter with a balloon intended for dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion, which is consistent with the devices described by C1725. In this context, we stated that we believe OPN NC may be similar to the devices described by C1725, and therefore, OPN NC may also be appropriately described by C1725.

We invited public comment on whether OPN NC meets the device category criterion at § 419.66(c)(1).

Comment: In response to our concerns that OPN NC may be appropriately described by C1725, one commenter commented that OPN NC is similar in purpose and function to other devices under C1725; however, the double-layer construction is unique in the coronary space, and enables the high-pressure inflation needed for angioplasty of resistant lesions. The commenter further commented that while this is similar in mechanism to conventional angioplasty balloons (dilatation through pressure, rather than through intravascular lithotripsy (IVL)), it creates a unique functionality of using pressure to dilate lesions and stents that would otherwise be resistant to dilatation. Another commenter stated that it thinks OPN NC should be reimbursed and assigned the same codes as coronary IVL (C1761) as it is used for similar patients/treatments.

Response: We appreciate the commenters' input. We do not agree that OPN NC is described by the C1761 (Catheter, transluminal intravascular lithotripsy, coronary) device category as suggested. We note that C1761 is used to describe coronary IVL devices that are used to perform IVL, a methodology that delivers sonic pressure waves to break calcium deposits in a coronary vessel, which is inconsistent with the function and purpose of OPN NC. As such, we do not believe that C1761 describes OPN NC. However, we continue to believe OPN NC is similar to the devices described by C1725. Specifically, C1725 (Catheter, transluminal angioplasty, non-laser (may include guidance, infusion/

perfusion capability)) is used to describe devices that rely on inflation of a balloon to directly apply pressure to plaque in a vessel during an angioplasty procedure. The applicant stated that OPN NC is a transluminal vascular dilatation catheter with a balloon intended for dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion, which is consistent with the devices described by C1725. While we recognize that OPN NC may vary in construction from other devices described by C1725, we nevertheless continue to believe that OPN NC is appropriately described by C1725. Therefore, we have determined that OPN NC does not meet the device category eligibility criterion at § 419.66(c)(1) because it is appropriately described by an existing category or a category previously in effect.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. According to the applicant, OPN NC represents a substantial clinical improvement over existing technologies in the management of patients with highly calcified coronary lesions by providing optimal lumen expansion and demonstrating better outcomes in lesion treatment compared to other devices.

The applicant provided the following evidence to support its claim: three peer-reviewed studies; a PowerPoint presenting an indirect comparison of OPN NC versus another device, Shockwave Intravascular Lithotripsy (IVL) System with Shockwave C2 Coronary Intravascular Lithotripsy (IVL) Catheter (Shockwave),[127] that uses IVL to treat calcium lesions; a spreadsheet summarizing the data presented in the PowerPoint document comparing OPN NC and Shockwave; and a background article providing an expert consensus statement from the Society for Cardiovascular Angiography & Interventions on management of in-stent restenosis and stent thrombosis.[128] Table 126 summarizes the applicant's assertion regarding the substantial clinical improvement criterion. Please see the online posting for OPN NC for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

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[127] CMS approved an application for the Shockwave IVL System with Shockwave C2 Coronary IVL Catheter as a new device category for transitional pass-through payment status and established HCPCS code C1761 as a new device category effective July 1, 2021. We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63577 through 63583) for a full discussion the Shockwave IVL System with Shockwave C2 Coronary IVL Catheter application and decision.

[128] Background articles are not included in the following table but can be accessed via the online posting for the technology.

TABLE 126: SUBSTANTIAL CLINICAL IMPROVEMENT ASSERTIONS

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments		
Applicant statements in support	**Supporting evidence provided by the applicant**	**Reference title**
Highly calcified unresponsive lumen expansion. OPN NC provides optimal lumen expansion.	Expansion of ≥80 percent was achieved in 40 out of 50 cases (80 percent) with a mean final expansion post intervention of 85.7 percent ± 8.9. Calcium fractures were documented in 49 (98 percent) cases; multiple in 37 (74 percent). There was 1 flow limiting dissection requiring stent deployment and 3 non-cardiovascular related deaths in 6 months follow-up. No records of perforation, no-reflow or other major adverse events. Among patients with heavy calcified lesions undergoing optical coherence tomography (OCT) guided intervention with OPN NC, acceptable expansion was achieved in most cases without procedure related complications.	Natalia Pinilla-Echeverri, Matthias Bossard, Ali Hillani, Jorge A Chavarria, Giacomo M Cioffi, Gustavo Dutra, Fernando Guerrero, Mehdi Madanchi, Adrian Attinger, Ellen Kossmann, Matthew Sibbald, Florim Cuculi, Tej Sheth. Treatment of Calcified Lesions Using a Dedicated Super-High Pressure Balloon: Multicenter Optical Coherence Tomography Registry. Cardiovasc Revasc Med. 2023; 52:49-58. doi: 10.1016/j.carrev.2023.02.020.
	The unique possibility offered by the OPN super-high pressure dedicated balloon provides an effective and easy strategy for treatment of resistant coronary lesions non-responsive to conventional NC balloon dilatation. Moreover, our data suggest that the unique twin-layer technology offered by the OPN balloon achieves uniform balloon expansion reducing the use of additional debulking devices. Angiographic success was achieved in 97.5 percent, procedural success in 96.6 percent; 53 percent of the lesions were responsive to a slower inflation pressure (Group I) while in the remaining 47 percent, the optimal expansion required a pressure> 40 atmosphere (Group II). The OPN alone was able to achieve adequate expansion in> 90 percent. 0.9 percent days major adverse cardiovascular events (MACE) were reported. The OPN-dedicated high-pressure balloon provides an effective and safe strategy for treatment of severe resistant coronary lesions.	Gioel Gabrio Secco, Achim Buettner, Rosario Parisi, Gianfranco Pistis, Matteo Vercellino, Andrea Audo, Mashayekhi Kambis, Roberto Garbo, Italo Porto, Giuseppe Tarantini, Carlo Di Mario. Clinical Experience with Very High-Pressure Dilatation for Resistant Coronary Lesions. Cardiovasc Revasc Med. 2019; 20(12):1083-1087. doi: 10.1016/j.carrev.2019.02.026
	Systematic report focusing on the super-high-pressure OPN NC for treatment of In-stent restenosis (ISR). Using this dedicated NC ballon at very high pressures is safe. Moreover, its use not only appears to be efficient in tackling moderately to severely calcified ISR lesions, but also seems to lead to a low rate of TLF/TVF in complex ISR lesions during long-term follow-up. OPN NC might therefore represent an efficient and less expensive alternative for ISR management compared to other commonly used tools.	Thomas Seiler, Adrian Attinger-Toller, Giacomo Maria Cioffi, Mehdi Madanchi, Mario Teufer, Mathias Wolfrum, Federico Moccetti, Stefan Toggweiler, Richard Kobza, Matthias Bossard, Florim Cuculi. Treatment of In-Stent Restenosis Using a Dedicated Super High-Pressure Balloon. Cardiovasc Revasc Med. 2023; 46:29-35. doi: 10.1016/j.carrev.2022.08.018

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments		
Applicant statements in support	**Supporting evidence provided by the applicant**	**Reference title**
	Double layer, noncompliant coronary balloons (OPN NC, SIS Medical) capable of inflation pressures ranging from 35 to 55 atm have recently become available in the United States. This class of percutaneous transluminal coronary angioplasty balloon has performed favorably in severely calcified de novo lesions and may be a consideration in ISR secondary to an under expanded stent.	Lloyd W. Klein, Sandeep Nathan, Akiko Maehara, John Messenger, Gary S. Mintz, Ziad A. Ali, Jennifer Rymer, Yader Sandoval, Karim Al-Azizi, Roxana Mehran, Sunil V. Rao, Amir Lotfi. SCAI Expert Consensus Statement on Management of In-Stent Restenosis and Stent Thrombosis. JSCAI. 2023; 2(23):100971. doi: 10.1016/j.jscai.2023.100971*

*We noted this source does not assess, evaluate, or review the nominated device and only provides background information in support of the applicant's claims of substantial clinical improvement.

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After review of the information provided by the applicant, we stated that we have the following concerns regarding whether OPN NC meets the substantial clinical improvement criterion. The applicant presented the published results of one study of 50 patients undergoing optical coherence tomography (OCT)-guided percutaneous coronary interventions, including OPN NC, to treat calcified lesions (Natalia Pinilla-Echeverri, et al., 2023). The retrospective study aimed to gain a better understanding of OPN NC calcium modification mechanisms, such as creating deep and wide calcium fractures during percutaneous coronary interventions with the intended clinical outcome of improving myocardial perfusion. Per the applicant, the study showed a primary efficacy endpoint of ≥ 80 percent expansion of the mean reference lumen area achieved in 80 percent of the patients treated. The applicant also presented a retrospective study evaluating 326 highly resistant coronary lesions that had failed to achieve adequate post-dilatation luminal gain with conventional NC-balloons (Secco, et al., 2019). Per the study authors, an OPN NC balloon was inflated to achieve a uniform balloon expansion after the failed attempts with conventional NC-balloons. According to the authors, 413 OPN NC balloons were used (1.26 per lesion), and angiographic success was achieved in 318 lesions (97.5 percent), procedural success was achieved in 315 lesions (96.6 percent), and technical success was achieved in 288 patients (90.5 percent). The study authors also reported that the OPN NC balloon alone was able to achieve adequate expansion in 288 cases (90.5 percent), while in 30 patients, rotational atherectomy was needed and performed because of the impossibility to cross the lesion with a proper sized OPN NC balloon. The applicant presented a third study focused on patients needing treatment of in-stent restenosis (ISR) (Seiler, et at., 2023). According to the authors, 208 ISR lesions were treated in 188 patients. The study authors concluded that the use of OPN NC for treatment of ISR lesions was safe (primary endpoint of the study) and may lead to a low rate of target lesion/vessel failure (TLF/TVF) during long-term follow-up. We noted that these studies were not randomized clinical trials with a comparator to demonstrate clinical improvement. Instead, the applicant presented results from registries using non-randomized, retrospective study designs without a control group, which we stated that we believe may reduce the strength of the evidence presented to support the claim. The authors noted in all three studies that randomized trials may be needed to compare OPN NC to other similar devices.

Further, we also noted that in one of the studies (Natalia Pinilla-Echeverri, et al., 2023), the study authors indicated that use of other calcium lesion modification devices prior to applying OPN NC to the patients in that study is a potential confounder that could result in overestimation of OPN NC's effectiveness. The study authors stated that this was controlled by having an exclusive OCT pullback pre-OPN NC but indicated that calcium plaque modification caused by other devices may not be evident on OCT. The study authors further noted that since other devices were used before OPN NC, they could not comment on calcium modification from OPN NC use upfront or an OPN NC-only strategy. We welcomed any additional evidence supporting the claim that that OPN NC provides optimal lumen expansion and the impact of using other calcium lesion modification devices prior to applying OPN NC to a patient.

With regard to safety, in the Natalia Pinilla-Echeverri, et al. (2023) study, one patient was found to have had a flow limiting dissection requiring stent deployment; however, no coronary perforations or no-reflow were reported. In the Secco, et al. (2019) study, three patients (0.9 percent) were reported to have experienced coronary rupture after balloon inflation and were successfully treated with stent implantation. In the Seiler, et al. (2023) study, coronary perforation was reported to have occurred twice (0.96 percent) with both successfully treated by balloon inflation and implantation of a covered stent; a total of nine (4.3 percent) locally limited, but flow limiting dissections were reported to have occurred and were successfully treated with implantation of a drug-eluting stent; 4 (1.9 percent) cases of flow deterioration due to embolization of thrombotic material (no-reflow) were found; and one patient (0.5 percent) was reported to have suffered from immediate vessel closure after stent implantation. The application did not address whether the use of the device is safe beyond the data on safety endpoints presented in the studies provided. We welcomed additional studies or evidence discussing the risk of adverse events with the use of these types of non-compliant balloons.

Finally, we expressed concern that the evidence may not demonstrate that

OPN NC substantially improves the treatment of an illness when compared to the benefits of other available treatments. The applicant asserted in a supporting document included in the application, that OPN NC is not the only FDA-authorized device with an indication for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion and also an indication for post deployment expansion of balloon expandable coronary stents. OPN NC was determined to be substantially equivalent to a legally marketed device, the NC Euphora Rapid Exchange Balloon Dilatation Catheter (Medtronic Inc; K141090), which received 510(k) clearance on August 15, 2014. The FDA 510(k) summary for OPN NC indicated that the devices share similar technological characteristics. In fact, the FDA 510(k) summary indicated that OPN NC differs only in the rated burst pressure of the balloon. We noted that the applicant did not compare the nominated device with the NC Euphora Rapid Exchange Balloon Dilatation Catheter, which we believe may be similar. While the applicant asserted that OPN NC is the only super-high pressure, non-compliant twin layer balloon dilatation catheter available in the U.S. and the only device on the market of this nature and capability, we stated we would be interested in additional information to demonstrate whether the nominated device demonstrates a substantial clinical benefit in comparison to other similar NC balloon devices.

We invited public comment on whether OPN NC meets the substantial clinical improvement criterion at § 419.66(c)(2).

Comment: We received multiple comments supporting the approval of OPN NC based on personal experience with the product and opinions on the clinical benefit of utilizing OPN NC. The commenters described their experiences using OPN NC and asserted that it works where other interventional strategies, such as traditional non-compliant balloons, atherectomy or intravascular lithotripsy have failed. The commenters added that they believe OPN NC is unique in allowing full expansion of extremely resistant lesions, particularly in the treatment of previous stents with restenosis due to under-expansion of underlying calcium and where the presence of the stent limits the use of technology such as atherectomy to modify the calcium. In addition, the commenters stated that in some cases OPN NC may be used as a stand-alone treatment, particularly in cases involving previously under-expanded stents. Further, the commenters asserted that they believe OPN NC is unique in achieving these results because it is a super high-pressure noncompliant balloon consisting of a double balloon layer and therefore, the rated burst pressure is substantially higher than that of a traditional non-compliant balloon. One commenter stated that the rated burst pressure for OPN NC is 35 atms of pressure, which is significantly higher than traditional non-compliant angioplasty balloons that have rated burst pressures of 20–24 atms of pressure. One commenter stated that OPN NC is specially designed to achieve 35–55 atms of pressure.[129] While this commenter addressed this device feature in reference to the § 419.66(b)(1) in their comment, we believe the comment was intended to address to address the substantial clinical improvement criterion, and therefore is included in the substantial clinical improvement discussion.

One commenter acknowledged that while the OPN NC device has not been tested in randomized trials, the commenter believes the device has demonstrated utility in cases of prior device failure, *i.e.,* where conventional balloons have failed to dilate a lesion and effectively demonstrates its use case in selected circumstances. The commenter further commented that, as a result, they believe that the OPN NC balloon is substantially different from the predicate NC Euphora Rapid Exchange Balloon Dilatation Catheter.

Response: While we appreciate the commenters input regarding their experiences with OPN NC, we did not receive any additional data to address our concerns related to the applicant's claims of substantial clinical improvement. As such, we maintain our concerns listed in the CY 2025 OPPS/ASC proposed rule regarding the lack of randomized trials data, the lack of information about comparators, potential confounders not being accounted for, potential risk of adverse events, limited data supporting substantial improvement in the treatment of an illness, and insufficient evidence comparing OPN NC to its predicate. Several commenters asserted that OPN NC as an intervention yields results where other interventions failed. These commenters stated that OPN NC is unique in allowing full expansion of extremely resistant lesions. Commenters further stated that OPN NC is unique in treatment compared to previous stents with restenosis due to under-expansion of underlying calcium where the presence of the stent limits the use of technology such as atherectomy to modify the calcium. We note that we did not receive comments from the applicant. While we appreciate the information provided by the commenters, we note that no additional evidence was submitted to support the applicant's claims and we continue to have the same concerns discussed in the proposed rule.

After consideration of the public comments we received and our review of the application, we do not believe that OPN NC represents a substantial clinical improvement relative to existing therapies currently available and have determined that OPN NC does not meet the device eligibility criterion at § 419.66(c)(2).

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that OPN NC would be reported with HCPCS codes shown in Table 127.

[129] The applicant indicated 35 atms of pressure as the rated burst pressure in the information included in the application.

TABLE 127: HCPCS CODES REPORTED WITH OPN NC

HCPCS Code	Long Descriptor	SI	APC
92920	Percutaneous transluminal coronary angioplasty; single major coronary artery or branch.	J1	5192
C1725**	Catheter, transluminal angioplasty, non-laser (may include guidance, infusion/perfusion capability)	N	

**Denotes a HCPCS code that was not included in Addendum P to the CY 2023 OPPS/ASC final rule with comment period, with no CY 2023 HCPCS/CPT code level device offset amount available. We noted the applicant used the CY 2023 payment rates for the three tests of the cost criterion. We used the CY 2023 HCPCS/CPT code level device offset amount for the HCPCS/CPT code included in Addendum P to assess whether the device meets the cost significance criterion.

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). We noted that the applicant did not provide details regarding the payment rates it applied for the three tests of the cost criterion. For our calculations, we used APC 5192, which had a CY 2023 payment rate of $5,215.40 at the time the application was received. HCPCS code 92920 in APC 5192 had a CY 2023 device offset amount of $1609.99 at the time the application was received.

We noted that the applicant provided two cost amounts for OPN NC: (1) a price list showing the cost of OPN NC as $2,200.00; and (2) a product list that lists the cost of OPN NC as $1,200.00. We further noted that the cost included on the product list provided by the applicant for OPN NC ($1,200.00) does not pass any of the three tests of the cost criterion, but the cost included on the price list for OPN NC ($2,200.00) passes all three tests of the cost criterion.

When performed with the price list cost for OPN NC of $2,200.00, we noted the following calculation outcomes: § 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The average reasonable cost of $2,200.00 for OPN NC is 42.18 percent of the applicable APC payment amount for the service related to the category of devices of $5,215.40 (($2,200.00/$5,215.40) × 100 = 42.18 percent). Therefore, when utilizing the price list cost of $2,200.00 provided, we stated that we believe OPN NC meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $2,200.00 for OPN NC is 136.65 percent of the cost of the device-related portion of the APC payment amount for the related service of $1,609.99 ($2,200.00/$1,609.99) × 100 = 136.65 percent). Therefore, when utilizing the price list cost of $2,200.00 provided, we stated that we believe OPN NC meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $2,200.00 for OPN NC and the portion of the APC payment amount for the device of $1,609.99 is 11.31 percent of the APC payment amount for the related service of $5,215.40 ((($2,200.00 − $1,609.99)/$5,215.40) × 100 = 11.31 percent). Therefore, when utilizing the price list cost of $2,200.00 provided, we stated that we believe OPN NC meets the third cost significance requirement.

When performed with the product list cost for OPN NC of $1,200.00, we noted the following calculation outcomes: § 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The average reasonable cost of $1,200.00 for OPN NC is 23.01 percent of the applicable APC payment amount for the service related to the category of devices of $5,215.40 (($1,200.00/$5,215.40) × 100 = 23.01 percent). Therefore, when utilizing the product list cost of $1,200.00 provided, we stated that we believe OPN NC does not meet the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $1,200.00 for OPN NC is 74.53 percent of the cost of the device-related portion of the APC payment amount for the related service of $1,609.99 ($1,200.00/$1,609.99) × 100 = 74.53 percent). Therefore, when utilizing the product list cost of $1,200.00 provided, we stated that we believe OPN NC does not meet the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $1,200.00 for OPN NC and the portion of the APC payment amount for the device of $1,609.99 is negative 7.86 percent of the APC payment amount for the related service of $5,215.40 ((($1,200.00 − $1,609.99)/$5,215) × 100 =

−7.86 percent). Therefore, when utilizing the product list cost of $1,200.00 provided, we stated that we believe OPN NC does not meet the third cost significance requirement.

Based on the conflicting amounts provided for the reasonable cost of OPN NC, we questioned whether OPN NC meets the cost significance criterion. We welcomed additional information regarding this inconsistency on the estimated average reasonable cost of OPN NC.

We invited public comment on whether the OPN NC meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

We did not receive any comments regarding whether OPN NC meets the cost significance criteria as described at § 419.66(d). As noted in the proposed rule, the applicant provided two different amounts for the reasonable cost of OPN NC. For this final rule with comment period, we will use the submitted device cost of $2,200 stated in the price list in the proposed rule to perform our cost calculations. As such, based on our findings from the first, second, and third cost significance tests, we believe OPN NC meets the eligibility criterion at § 419.66(d).

After consideration of the public comments we received and our review of the device pass-through application, we are not approving OPN NC for transitional pass-through payment status in CY 2025 because the product does not meet eligibility criteria at § 419.66(c)(1) and (2).

(d) OSCAR® Peripheral Multifunctional Catheter

Biotronik, Inc. submitted an application for a new device category for transitional pass-through payment status for OSCAR® Peripheral Multifunctional Catheter (OSCAR®) for CY 2025. According to the applicant, OSCAR® is a tool used to simplify the treatment of peripheral artery disease (PAD), a disease process characterized by the narrowing of arteries that supply blood to the limbs, usually the legs. In severe cases, PAD can cause tissue death and gangrene, leading to amputation. Per the applicant, OSCAR® can simplify the process of peripheral interventions, reduce the time required to perform the procedure and the need for repeat procedures, reduce the risk of complications associated with changing out multiple medical devices, minimize radiation exposure, and enhance patient comfort.

Please refer to the online application posting for OSCAR®, available at *https://mearis.cms.gov/public/publications/device-ptp/DEP230601F6NM2*, for additional detail describing the device and the disease treated by the device.

Comment: A few commenters stated that OSCAR® meets the criteria for transitional pass-through payment. Commenters stated that they believe OSCAR® is highly effective and safe in crossing multiple occluded vessels of different morphologies above and below the knee, and is a necessary tool to treat patient with critical limb ischemia and calcific blockages of the arteries in the legs. One commenter asserted that OSCAR® will save money for hospitals because the device will result in less equipment use, faster procedure times, and higher rates of success and case completion.

Response: We appreciate the commenters' input and support for the OSCAR® application for transitional pass-through payment. We have taken these comments into consideration in our final determination regarding pass-through status for OSCAR®.

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), on July 5, 2022, the applicant received 510(k) clearance from FDA for OSCAR® as a device to be used for percutaneous transluminal interventions in the peripheral vasculature to provide support during access into, and to dilate stenoses in, femoral, popliteal and infrapopliteal arteries. The product is also intended for injecting radiopaque contrast media for angiography. We received the application for a new device category for transitional pass-through payment status for OSCAR® on June 1, 2023, which is within 3 years of the date of the initial FDA marketing authorization.

We invited public comment on whether OSCAR® meets the newness criterion at § 419.66(b)(1).

Comment: With respect to the newness criterion at § 419.66(b)(1), the applicant reiterated that the pass-through payment application for OSCAR® is within the timeframe of 3 years post-FDA approval; therefore, the newness criterion at § 419.66(b)(1) is met.

Response: We appreciate the applicant's input. We received the application for a new device category for transitional pass-through payment status for OSCAR® on June 1, 2023, which is within 3 years of July 5, 2022, the date of FDA 510(k) clearance. Based on our review of the application, we have determined that OSCAR® meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criteria at § 419.66(b)(3), the device must be an integral part of the service furnished, used for one patient only, come in contact with human tissue, and be surgically inserted or implanted, or applied in or on a wound or other skin lesion. The applicant did not explicitly state whether OSCAR® is integral to the service provided. While the applicant did not explicitly state whether the device is used for one patient only or whether it comes in contact with human tissue, per the device description, OSCAR® is surgically inserted into the lower extremity peripheral vascular system and is single-use.

We invited public comments on whether OSCAR® meets the eligibility criterion at § 419.66(b)(3).

Comment: The applicant submitted a comment confirming that the OSCAR® meets the eligibility criterion at § 419.66(b)(3) because it is an integral part of the service furnished, is used for one patient only, comes into contact with human tissue, and is surgically inserted or implanted.

Response: We appreciate the applicant's input. We agree with the applicant that OSCAR® is an integral part of the service furnished, used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted, or applied in or on a wound or other skin lesion. After consideration of the public comments received and our review of the application, we have determined that OSCAR® meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker). The applicant did not indicate whether OSCAR® is equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered, or if OSCAR® is a supply or material furnished incident to a service.

We invited public comment on whether OSCAR® meets the exclusion criterion at § 419.66(b)(4).

Comment: The applicant submitted a comment confirming that OSCAR® meets the eligibility criterion at § 419.66(b)(4) because it is not equipment, an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered. The applicant also clarified that OSCAR® is not a supply or material furnished incident to a service.

Response: We appreciate the applicant's input. We agree with the applicant that OSCAR® is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets, or a material or supply furnished incident to a service. After consideration of the public comments received and our review of the application, we have determined that OSCAR® meets the eligibility criterion at § 419.66(b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), the criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. The applicant asserted that OSCAR® is a combination device authorized by FDA with an indication to diagnose and treat peripheral vascular lesions, identify obstructions, and cross the areas of obstruction and restore blood flow using a single system. According to the applicant, no previous or existing device categories for pass-through payment appropriately describe OSCAR®. Per the applicant, OSCAR® has the functionality of multiple devices currently used during lower extremity peripheral vasculature interventions. The applicant provided multiple HCPCS codes that could describe some of the components of OSCAR®; however, only one of the codes provided, C1725 (Catheter, transluminal angioplasty, non-laser (may include guidance, infusion/perfusion capability)), is a pass-through device category HCPCS code, and, therefore, C1725 is the only device category we evaluated for this criterion. Per the applicant, the device category C1725 does not appropriately describe OSCAR® because OSCAR® can cover the functionality of support catheters, several sizes of angioplasty balloons, chronic total occlusion crossing devices, reentry catheters, resistant lesion preparation devices, and dissection-reducing devices. According to the applicant, current pass-through coding does not adequately capture OSCAR®'s full functionality and the added clinical and economic value derived from its simplification of peripheral vascular interventions.

We noted, based on the description the applicant provided, that when the OSCAR® support catheter and OSCAR® dilator are combined with the OSCAR® PTA balloon, the device is used to complete a transluminal angioplasty, which is consistent with the devices described by C1725. In this context, we stated that we believe OSCAR® may be similar to the devices described by C1725 and, therefore, may be appropriately described by C1725.

We invited public comment on whether OSCAR® meets the device category criterion at § 419.66(c)(1).

Comment: In response to our concerns that OSCAR® may be appropriately described by C1725, the applicant commented that while some functionality of OSCAR® is captured in C1725, OSCAR®'s functionality of crossing and lesion treatment is not described by C1725. According to the applicant, C1725 does not adequately capture OSCAR®'s multi-functionality because while C1725 describes non-laser catheters used for transluminal angioplasty, which may include guidance, infusion, or perfusion capability, OSCAR® facilitates the steps of percutaneous transluminal angioplasty (PTA) procedures through lesion access, lesion crossing, and lesions of different length treatment, achieved using only a single device for the entire procedure. The applicant reiterated that OSCAR® consists of a support catheter, dilator, and PTA, providing the possibility for several different configurations during peripheral vasculature intervention. Further, the applicant noted that with this versatility, OSCAR® also provides features that are not available with other devices, such as user-adjustable guidewire support for accessing and crossing lesions and a length-adjustable balloon for lesion-specific angioplasty.

Response: We appreciate the applicant's input. After consideration of the public comments received and our review of the application, we continue to believe that C1725 appropriately describes OSCAR® because, as described by the applicant, when the OSCAR® support catheter and OSCAR® dilator are combined with the OSCAR® PTA balloon, the device is used to complete a transluminal angioplasty, which is consistent with the function of devices that may appropriately be described by C1725. The applicant asserted that OSCAR® provides features that are not available with other devices, such as a user-adjustable guidewire for accessing and crossing lesions and a length-adjustable balloon for lesion-specific angioplasty. However, based on the information provided, it remains unclear whether some of these additional items are simply supplies incidental to the service. If these additional items are supplies incidental to a service, the inclusion of these supplies along with a device to streamline a service does not materially differentiate the device from similar devices. Therefore, the multi-functionality differences of OSCAR® described by the applicant would not distinguish it from other devices described by the pass-through device category C1725.

After consideration of the public comments received and our review of the application, we continue to believe that C1725 appropriately describes OSCAR®. Therefore, we have determined that OSCAR® does not meet the device category eligibility criterion at § 419.66(c)(1) because it is appropriately described by an existing category or a category previously in effect.

Comment: The applicant asserted that device category C1725 does not appropriately describe OSCAR® because the functionality of OSCAR® allows the operator to perform several procedural steps with only one device, which improves procedural efficiency, reduces radiation exposure for patient and operator, and reduces the number of devices used to complete the procedure. The applicant also stated that OSCAR® adds clinical and economic value derived from its simplification of peripheral vascular interventions.

Response: We appreciate the applicant's input. We believe these comments are more appropriately related to the substantial clinical improvement criterion at § 419.66(c)(2), and, therefore, we will take these comments into consideration in that discussion below.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the

device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The applicant claimed that OSCAR® represents a substantial clinical improvement over existing technologies in the diagnosis and management of peripheral artery disease because it uses less equipment, cuts down procedure time, and mitigates risks like vascular damage, infections, and radiation exposure, thereby enhancing clinical efficiency and safety.

The applicant provided four background documents supporting its substantial clinical improvement claim. Table 128 summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for OSCAR® for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

TABLE 128: SUBSTANTIAL CLINICAL IMPROVEMENT ASSERTIONS

Substantial Clinical Improvement: The technology significantly improves clinical outcomes relative to services or technologies previously available		
Applicant statements in support	**Supporting evidence provided by the applicant**	**Reference Title**
OSCAR® Peripheral Multifunctional Catheter matches its counterparts in diagnostic and therapeutic prowess. Its unique advantage lies in the ability to achieve these objectives using less equipment. This cuts down procedure time and mitigates risks like vascular damage, infections, and radiation exposure, thereby enhancing clinical efficiency and safety.	This clinical evaluation report demonstrates that the OSCAR® Peripheral Multifunctional Catheter, FDA approved in July 2022 for peripheral vasculature interventions, demonstrated high efficacy and safety in a U.S. study.	Deloose, K., Li, S., Salehi Evard, B. (2023) Clinical Evaluation Report. Biotronik. Unpublished.
	The OSCAR® Peripheral Multifunctional Catheter presents a 93 percent success in reducing stenosis with 0 percent procedural complications, surpassing other methods. It has a 90.1 percent crossing success, and 75 percent of users reported shorter procedural times, enhancing efficiency and patient safety.	Clinical Benefit Table for OSCAR. Biotronik. Unpublished.
	This document is an Evaluation of Market Acceptance for the OSCAR® Peripheral Multifunctional Catheter system (EMA).	Biotronik (2024, February 7). OSCAR Peripheral Multifunctional Catheter: Real-World User Evaluation [PowerPoint slides].
	The OSCAR® Peripheral Multifunctional Catheter EMA Evaluation of Market Acceptance (EMA) conducted from September 13, 2022, to November 10, 2022, assessed the performance and acceptance of OSCAR® Kits in 78 cases across 12 centers in the USA. The evaluation met all its ending criteria with impressive results.	Schroeder, H. (2023) Clinical OSCAR Evaluation of Market Acceptance Report. Biotronik. Unpublished.

After review of the information provided by the applicant, we stated we had the following concerns regarding whether OSCAR® meets the substantial clinical improvement criterion. First, the applicant did not submit peer-reviewed or published clinical evidence to substantiate clinical improvement over existing devices. The applicant submitted four background documents in support of OSCAR®: (1) a clinical benefit table, (2) a presentation on the Evaluation of Market Acceptance, (3) the OSCAR® U.S. Evaluation of Market Acceptance Report, and the (4) OSCAR® Clinical Evaluation Report. All four of these documents rely on data from the Evaluation of Market Acceptance. We noted these documents are not published or peer-reviewed, and reflect data collected for marketing purposes rather than clinical improvement purposes. The data included appear to be opinion-based survey questions asked of physicians recruited by the applicant for the Evaluation of Market Acceptance and noted that these documents suggest an implicit bias. We questioned the link between these documents and the claims the applicant made that OSCAR® shows substantial clinical improvement because it uses less equipment, cuts down procedure

time, and mitigates risks like vascular damage, infections, and radiation exposure, thereby enhancing clinical efficiency and safety. We requested clarification on how the supporting documents directly relate to the substantial clinical improvement claims.

Further, we questioned how a collection of devices currently available on the market consolidated into a single packaged product demonstrates substantial clinical improvement. According to the applicant, with OSCAR®, some procedures may be performed with a single device which cuts down procedure time and mitigates risks like vascular damage, infections, and radiation exposure, thereby enhancing clinical efficiency and safety. The applicant asserted several benefits of using OSCAR® over multiple devices, including reducing (1) the need to remove and replace multiple devices, which may reduce the incidence of complications like infection and vessel damage; (2) the need to use ill-fitting devices; (3) the need for multiple guidewires in several procedures; and (4) the incidence of complications, such as infections and vessel damage. However, we did not receive comparative data supporting the claim that OSCAR® offers superiority over currently available treatments in terms of clinical benefit or safety. The evidence provided did not discuss any advantages of using a single system of devices rather than multiple individual devices with diverse functionalities. We welcomed any additional evidence supporting these claims.

Furthermore, per the applicant, OSCAR® is effective in preparing intravascular lesions for advanced interventions, particularly stenting, and by ensuring optimal lesion preparation, OSCAR® elevates the success rate of these procedures, enhances patient safety, and streamlines institutional operations. According to the applicant, OSCAR® can treat chronic total occlusions (CTOs) and incorporates reentry capabilities, features traditionally found in standalone devices. The applicant asserted this integration enhances patient safety, simplifies procedures, and elevates the efficiency of operations. However, we noted that the applicant did not provide clinical information in support of these claims. Again, we welcomed any additional evidence supporting these claims.

In addition, we questioned whether OSCAR® can be sufficiently distinguished from similar existing technologies to demonstrate substantial clinical improvement. OSCAR® was determined to be substantially equivalent to a legally marketed device, the INFINITY Angioplasty Balloon Catheter™, which received 510(k) clearance on May 20, 2020. The FDA 510(k) summary for OSCAR® indicated that the devices share similar technological characteristics and that OSCAR® differs only in that it combines support catheters to be used with the dilator and balloon catheter. We did not receive data demonstrating how OSCAR® offers a substantial clinical improvement compared to the INFINITY Angioplasty Balloon Catheter™. We stated that we would be interested in additional information to demonstrate whether the nominated device demonstrates a substantial clinical benefit in comparison to INFINITY Angioplasty Balloon Catheter™.

Finally, per the applicant, there are six device types that it believed OSCAR® is most closely related to: (1) workhorse guidewires (Abbott, Boston Scientific, Terumo, Medtronic, Biotronik, Cook Medical, Cordis); (2) premium guidewires (Abbott, Asahi Intecc, Boston Scientific, Cook Medical and more); (3) workhorse & premium support catheters (Philips, Boston Scientific, Cook Medical, Medtronic, Asahi Intecc, Teleflex and more); (4) angioplasty balloons (Abbott, BD Interventional, Biotronik, Cook Medical, Medtronic and more); (5) lesion preparation balloons (Philips, Medtronic, BD Interventional and Cagent Vascular); and (6) chronic total occlusion and reentry devices. We stated that we do not believe that OSCAR® is similar to the workhorse guidewires and premium guidewires listed because OSCAR® does not include guidewires. We welcomed additional information illustrating how OSCAR® is similar to the listed workhorse guidewires and premium guidewires and evidence demonstrating the benefits of OSCAR® over these other devices.

While we noted that OSCAR® is comparable to other available technologies, we did not receive data demonstrating how OSCAR® offers a substantial clinical improvement compared to the workhorse guidewires and premium support catheters, angioplasty balloons, lesion preparation balloons, or chronic total occlusion and reentry devices and stated that we would be interested in additional evidence demonstrating the substantial clinical benefits of OSCAR® over these other devices.

We stated that additional evidence comparing OSCAR® to existing technologies would be particularly helpful to determine whether the device demonstrates substantial clinical improvement over currently available treatments in the clinical setting where it is most likely to be used. Specifically, we welcomed published peer-reviewed clinical trials that show improved clinical outcomes, such as reduction in mortality, complications, subsequent interventions, future hospitalizations, recovery time, pain, or a more rapid beneficial resolution of the disease process compared to the standard of care.

We invited public comment on whether OSCAR® meets the device category criterion at § 419.66(c)(2)(i).

Comment: In response to our concerns that the applicant did not provide sufficient peer-reviewed or published evidence to substantiate OSCAR®'s clinical improvement over existing devices, the applicant commented that other data sources are acceptable for transitional pass-through payment applications to prove substantial clinical improvement. Specifically, the applicant asserted that the provided documents show two sources of evidence: internal benchmark tests and a real-world user evaluation.

Per the applicant, the clinical benefit table provided summarizes the industry's state-of-the-art device procedural success and complication rates from published literature about similarly marketed devices. The applicant asserted that the real-world market evaluation compares OSCAR®'s internal benchmark tests to these published state-of-the-art benchmarks to determine whether OSCAR® met or exceeded the benchmarks. To evaluate market acceptance, the applicant explained that it conducted internal benchmark tests of OSCAR® in a real-world setup, without any exclusion criteria in terms of lesion characteristic and patient population. The applicant noted that it did this to obtain the opinion of different users—a method of user experience testing that is well-accepted in the field. Furthermore, the applicant stated that the real-world user experience data showed that OSCAR® has the potential to simplify procedures with one platform, which could reduce device escalations and lead to procedural efficiencies. According to the applicant, this potential simplification is especially important as staffing shortages and availability issues continue to plague U.S. facilities.

Response: We appreciate the applicant's input. We acknowledge that data sources other than peer-reviewed or published studies may be submitted for the purpose of supporting substantial clinical improvement in

transitional pass-through payment applications. CMS considers all submitted evidence when reviewing transitional pass-through payment applications, however, we note that higher levels of evidence, such as peer-reviewed controlled studies, will typically be more supportive and in some cases may be required to establish a substantial clinical improvement argument. We continue to believe that the predominance of the data submitted appears to be opinion-based survey questions asked of physicians for marketing purposes, is likely subject to implicit bias, and falls significantly short of demonstrating substantial clinical improvement. In addition, we do not believe that the documents submitted by the applicant demonstrate that OSCAR® mitigates risks like vascular damage, infections, and radiation exposure as claimed. Finally, we do not believe that the applicant has provided an appropriate level of evidence that the use of OSCAR® reduces procedure time, nor has the applicant established that a potential reduction in procedure time and/or the use of less equipment translates to a substantial improvement in treatment of the affected patient population. After consideration of the public comment received and our review of the application, we continue to have concerns about whether OSCAR® demonstrates substantial clinical improvement, and we believe that additional peer-reviewed evidence would be helpful.

Comment: In response to our concern whether OSCAR® can be sufficiently distinguished from a legally marketed device, the INFINITY Angioplasty Balloon Catheter™, to demonstrate substantial clinical improvement, the applicant commented that OSCAR® is not identical to the INFINITY Angioplasty Balloon Catheter™. Specifically, the applicant asserted that, in its 510(k) approval summary, FDA stated that OSCAR® is comparable to the predicate device rather than equivalent. According to the applicant, the term comparable indicates that OSCAR® has similar characteristics and intended use as the predicate device, but it does not imply that the two devices are identical. The applicant asserted that the INFINITY Angioplasty Balloon Catheter™ is indicated for PTA in the peripheral vasculature, including iliac, femoral, popliteal, infra-popliteal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae; whereas OSCAR® facilitates the steps of PTA procedures (lesion access, cross and treat lesions of different length) using a single device for the entire procedure to reduce procedural time and simplify steps.

Per the applicant, OSCAR® was designed to combine features of other marketed devices, such as support catheters and PTA balloon catheters. The applicant asserted the main benefits of OSCAR® are (1) the device's variable shaft stiffness which allows for lesion-adapted access and crossing, and (2) its length adjustability features which allow for precise adjustment of the balloon length to match the target lesion's length. The applicant further explained that these features allow OSCAR® to treat residual stenosis using a single balloon, rather than the typical treatment's multiple balloons, resulting in the potential benefits of lower device consumption, fewer device exchanges, reduced overall procedural time, and fewer stock-keeping units needed in the catheterization laboratory.

Response: We appreciate the applicant's input. While FDA determination of substantial equivalence cannot alone be used to conclude that a device demonstrates substantial clinical improvement as required by the regulation at 42 CFR 419.66(c)(2), we note that the FDA 510(k) summary provided by the applicant indicated that both the nominated and predicate devices share similar technological characteristics and that OSCAR® differs only in that it combines support catheters to be used with the dilator and balloon catheter. Specifically, OSCAR® was determined to be substantially equivalent to a legally marketed device, the INFINITY Angioplasty Balloon Catheter™, which received 510(k) clearance on May 20, 2020. The FDA 510(k) summary for OSCAR® indicated that the devices share similar technological characteristics and that OSCAR® differs only in that it combines support catheters to be used with the dilator and balloon catheter. While the applicant asserted that treatment of complex lesions with OSCAR® reduces device exchanges and procedural steps, procedure time, radiation exposure, contrast media, and crossing attempts, the applicant did not provide evidence that demonstrated how these reductions result in improved clinical outcomes. We did not receive data demonstrating how OSCAR® offers a substantial clinical improvement compared to the INFINITY Angioplasty Balloon Catheter™. We expressed concern in the proposed rule regarding the language in the FDA 510(k) summary because we could not determine whether OSCAR® could be distinguished from the INFINITY Angioplasty Balloon Catheter™ sufficiently to demonstrate substantial clinical improvement. Neither could we determine exactly how the nominated device is superior to its earlier legally marketed device, as per the applicant's assertion. After consideration of the public comment received and our review of the application, we maintain our concern that OSCAR® does not demonstrate a substantial clinical improvement compared to the predicate device, INFINITY Angioplasty Balloon Catheter™.

Comment: In response to our concerns that OSCAR® may be substantially similar to six device types that the applicant indicated OSCAR® is most closely related to, the applicant commented that OSCAR® reduces the need for multiple devices and may lower procedural costs. Specifically, the applicant clarified that OSCAR® requires a guidewire but replaces the need for support catheters and percutaneous balloons and may replace the need for chronic total occlusion devices, reentry catheters, or lesion preparation devices. In response to our request that the applicant submit additional evidence comparing OSCAR®'s clinical outcomes to those of existing technologies to help us determine whether the device demonstrates substantial clinical improvement, the applicant commented that this request is unreasonable with these types of tools in percutaneous transluminal interventions. Specifically, the applicant asserted that, in below-the-knee interventions, global user experience has shown OSCAR® to be definitive as it allows length adjustability, which they believe is an improvement over other balloon catheters used for angioplasty. The applicant concluded that real-world user experience has shown that OSCAR® aids in the treatment of complex lesions through the reduction of device exchanges and procedural steps, reduction of procedure time, reduction of radiation exposure, reduction of contrast media, and fewer crossing attempts.

Response: We appreciate the applicant's input. While the applicant asserted, both for this § 419.66(c)(2) criterion and the § 419.66(c)(1) criterion discussed above, that OSCAR® may reduce the need for support catheters, percutaneous balloons, chronic total occlusion devices, reentry catheters, or lesion preparation devices during percutaneous transluminal interventions, the applicant did not provide evidence demonstrating that OSCAR®'s potential to reduce the

number of devices improved clinical outcomes for patients with PAD. We maintain that these potential reductions in procedural time and cost compared to other devices do not translate to improved clinical outcomes, such as reduction in mortality, complications, subsequent interventions, future hospitalizations, recovery time, pain, or a more rapid beneficial resolution of the disease process, required to demonstrate substantial clinical improvement.

Regarding the applicant's statements that OSCAR® will save money for hospitals because hospitals will use less equipment, procedure times will be faster, and procedures will have higher success rates and case completion and, as a result, patients will avoid limb amputation, we appreciate the commenters' input. However, while reducing costs to the healthcare system is important, it is not a consideration for substantial clinical improvement for purposes of transitional pass-through payments. With respect to the higher success rates, case completion, and decrease in limb amputations, which could demonstrate substantial clinical improvement, the commenters did not provide evidence to support these claims. Similarly, regarding faster procedure times, no link was demonstrated between this and a substantial clinical improvement outcome, nor was evidence provided to support this claim. As such, we maintain our concern about whether the use of OSCAR® has a substantial clinical benefit compared to the six existing device types noted in the application and over other similar existing technologies.

After consideration of the public comments received and our review of the application, we continue to believe the applicant has not demonstrated substantial clinical improvement over existing technologies in the treatment of PAD. Therefore, we have determined that OSCAR® does not meet the substantial clinical improvement criterion at § 419.66(c)(2).

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that OSCAR® would be reported with HCPCS codes as shown in Table 129.

BILLING CODE 4120–01–P

TABLE 129: HCPCS CODES REPORTED WITH OSCAR®

HCPCS Code	Long Descriptor	SI	APC
36200**	Introduction of catheter, aorta	N	
36245**	Selective catheter placement, arterial system; each first order abdominal, pelvic, or lower extremity artery branch, within a vascular family	N	
36246**	Selective catheter placement, arterial system; initial second order abdominal, pelvic, or lower extremity artery branch, within a vascular family	N	
36247**	Selective catheter placement, arterial system; initial third order or more selective abdominal, pelvic, or lower extremity artery branch, within a vascular family	N	
36248**	Selective catheter placement, arterial system; additional second order, third order, and beyond, abdominal, pelvic, or lower extremity artery branch, within a vascular family (List in addition to code for initial second or third order vessel as appropriate)	N	
37184	Primary percutaneous transluminal mechanical thrombectomy, noncoronary, non-intracranial, arterial or arterial bypass graft, including fluoroscopic guidance and intraprocedural pharmacological thrombolytic injection(s); initial vessel	J1	5193
37220	Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal angioplasty	J1	5192
37221	Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed	J1	5193
37222**	Revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; with transluminal angioplasty (List separately in addition to code for primary procedure	N	
37223**	Revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)	N	
37224	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal angioplasty	J1	5192
37225	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with atherectomy, includes angioplasty within the same vessel, when performed	J1	5193
37226	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed	J1	5193
37227	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed	J1	5194
37228	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal angioplasty	J1	5193
37229	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with atherectomy, includes angioplasty within the same vessel, when performed	J1	5194
37230	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed	J1	5194
37231	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal stent placement(s)	J1	5194

HCPCS Code	Long Descriptor	SI	APC
	and atherectomy, includes angioplasty within the same vessel, when performed		
37232**	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal angioplasty (List separately in addition to code for primary procedure)	N	
37233**	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with atherectomy, includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)	N	
37234**	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)	N	
37235**	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)	N	
75625	Aortography, abdominal, by serialography, radiological supervision and interpretation	Q2	5183
75630	Aortography, abdominal plus bilateral iliofemoral lower extremity, catheter, by serialography, radiological supervision and interpretation	Q2	5183
75710	Angiography, extremity, unilateral, radiological supervision and interpretation	Q2	5183
75716	Angiography, extremity, bilateral, radiological supervision and interpretation	Q2	5183
75774**	Angiography, selective, each additional vessel studied after basic examination, radiological supervision and interpretation (List separately in addition to code for primary procedure)	N	
0238T	Transluminal peripheral atherectomy, open or percutaneous, including radiological supervision and interpretation; iliac artery, each vessel	J1	5194

**Denotes a HCPCS code that was not included in Addendum P to the CY 2023 OPPS/ASC final rule with comment period, with no CY 2023 HCPCS/CPT code level device offset amount available. We noted the applicant used the CY 2023 payment rates for the three tests of the cost criterion. We used the CY 2023 HCPCS/CPT code level device offset amounts for the HCPCS/CPT codes included in Addendum P to assess whether the device meets the cost significance criterion.

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To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). We noted that the applicant used the CY 2023 payment rates for the three tests of the cost criterion. For our calculations, we used APC 5183, which had a CY 2023 payment rate of $2,978.97 at the time the application was received. HCPCS code 75625 in APC 5183 had a CY 2023 device offset amount of $530.85 at the time the application was received.[130] According to the applicant, the cost of OSCAR® is $2,020.00.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of $2,020.00 for OSCAR® is 67.81 percent of the applicable APC payment amount for the service related to the category of devices of $2,978.97 (($2,020.00/$2,978.97) × 100 = 67.81 percent). Therefore, we stated that we believe OSCAR® meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $2,020.00 for OSCAR® is 380.52 percent of the cost of the device-related portion

[130] We noted the applicant selected APC 5192 and an APC payment rate of $5,061.89 for the three tests of the cost criteria. However, for our calculation, we selected APC 5183, which we believe had the lowest applicable APC payment rate of $2,978.97 found in Addendum P to the CY 2023 OPPS/ASC final rule with comment period, among the APCs related to the HCPCS/CPT codes provided by the applicant. We selected the HCPCS/CPT code level device offset amount of $530.85 related to HCPCS 75625 in APC 5183. Based on our initial assessment in the proposed rule, using the APC payment rate of $2,978.97 and the device offset amount of $530.85 would result in OSCAR® meeting the cost significance requirement.

of the APC payment amount for the related service of $530.85 (($2,020.00/$530.85) × 100 = 380.52 percent). Therefore, we stated that we believe OSCAR® meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $2,020.00 for OSCAR® and the portion of the APC payment amount for the device of $530.85 is 49.99 percent of the APC payment amount for the related service of $2978.97 ((($2,020.00 − $530.85)/$ 2,978.97) × 100 = 49.99 percent). Therefore, we stated that we believe OSCAR® meets the third cost significance requirement.

We invited public comment on whether OSCAR® meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

We did not receive any comments regarding whether OSCAR® meets the cost significance criteria as described at § 419.66(d). Based on our findings from the first, second, and third cost significance tests, we have determined that OSCAR® meets the cost significance criteria specified at § 419.66(d).

After consideration of the public comments, we received and our review of the device pass-through application, we are not approving OSCAR® for transitional pass-through payment status in CY 2025 because the product does not meet the device category eligibility criterion at § 419.66(c)(1) or the substantial clinical improvement criterion at § 419.66(c)(2).

Comment: The commenter recommended CMS calculate the device-related portion of APCs for purposes of determining device pass-through payment status eligibility and the device offset using only the cost of the devices replaced by the proposed device pass-through payment status device category. The commenter stated that many procedures with transitional pass-through devices require the use of multiple other devices, and the transitional pass-through device may replace only some (and in some cases none) of the devices included in the device-related portion of the APC. The commenter asserted that, if the device offset is calculated to include other devices that continue to be required to perform the procedure safely and successfully, without properly offsetting the cost of the nominated device, the final payment would fail to adequately reimburse facilities. The commenter requested that CMS also apply this methodology to the TPT applications for AGENT™ Paclitaxel-Coated Balloon Catheter, iFuse Bedrock Granite™ Implant System, Paradise® Ultrasound RDN System, and Symplicity Spyral™ RDN System applications.

Response: We thank the commenter's recommendation regarding the revision of the methodology for calculating the device-related portion of APCs for the purpose of determining the eligibility of transitional pass-through status of a nominated device. We will continue to consider this issue and any additional public comments related to it.

B. Device-Intensive Procedures

1. Background

Under the OPPS, prior to CY 2017, device-intensive status for procedures was determined at the APC level for APCs with a device offset percentage greater than 40 percent (79 FR 66795). Beginning in CY 2017, CMS began determining device-intensive status at the HCPCS code level. In assigning device-intensive status to an APC prior to CY 2017, the device costs of all the procedures within the APC were calculated and the geometric mean device offset of all of the procedures had to exceed 40 percent. Almost all of the procedures assigned to device-intensive APCs utilized devices, and the device costs for the associated HCPCS codes exceeded the 40-percent threshold. The no cost/full credit and partial credit device policy (79 FR 66872 through 66873) applies to device-intensive procedures and is discussed in detail in section IV.B.4 of this final rule with comment period. A related device policy was the requirement that certain procedures assigned to device-intensive APCs require the reporting of a device code on the claim (80 FR 70422) and is discussed in detail in section IV.B.3 of this final rule with comment period. For further background information on the device-intensive APC policy, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70421 through 70426).

a. HCPCS Code-Level Device-Intensive Determination

As stated earlier, prior to CY 2017, under the device-intensive methodology we assigned device-intensive status to all procedures requiring the implantation of a device that were assigned to an APC with a device offset greater than 40 percent and, beginning in CY 2015, that met the three criteria as listed. Historically, the device-intensive designation was at the APC level and applied to the applicable procedures within that APC. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658), we changed our methodology to assign device-intensive status at the individual HCPCS code level rather than at the APC level. Under this policy, a procedure could be assigned device-intensive status regardless of its APC assignment, and device-intensive APC designations were no longer applied under the OPPS or the ASC payment system.

We believe that a HCPCS code-level device offset is, in most cases, a better representation of a procedure's device cost than an APC-wide average device offset based on the average device offset of all of the procedures assigned to an APC. Unlike a device offset calculated at the APC level, which is a weighted average offset for all devices used in all of the procedures assigned to an APC, a HCPCS code-level device offset is calculated using only claims for a single HCPCS code. We believe that this methodological change results in a more accurate representation of the cost attributable to implantation of a high-cost device, which ensures consistent device-intensive designation of procedures with a significant device cost. Further, we believe a HCPCS code-level device offset removes inappropriate device-intensive status for procedures without a significant device cost that are granted such status because of their APC assignment.

Under our existing policy, procedures that meet the criteria listed in section IV.C.1.b of this final rule with comment period are identified as device-intensive procedures and are subject to all the policies applicable to procedures assigned device-intensive status under our established methodology, including our policies on device edits and no cost/full credit and partial credit devices discussed in sections IV.C.3 and IV.C.4 of this final rule with comment period.

b. Use of the Three Criteria To Designate Device-Intensive Procedures

We clarified our established policy in the CY 2018 OPPS/ASC final rule with comment period (82 FR 52474), where we explained that device-intensive procedures require the implantation of a device and additionally are subject to the following criteria:

- All procedures must involve implantable devices that would be reported if device insertion procedures were performed.

• The required devices must be surgically inserted or implanted devices that remain in the patient's body after the conclusion of the procedure (at least temporarily); and

• The device offset amount must be significant, which is defined as exceeding 40 percent of the procedure's mean cost.

We changed our policy to apply these three criteria to determine whether procedures qualify as device-intensive in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66926), where we stated that we would apply the no cost/full credit and partial credit device policy—which includes the three criteria listed previously—to all device-intensive procedures beginning in CY 2015. We reiterated this position in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70424), where we explained that we were finalizing our proposal to continue using the three criteria established in the CY 2007 OPPS/ASC final rule with comment period for determining the APCs to which the CY 2016 device intensive policy will apply. Under the policies we adopted in CYs 2015, 2016, and 2017, all procedures that require the implantation of a device and meet the previously described criteria are assigned device-intensive status, regardless of their APC placement.

2. Device-Intensive Procedure Policy

As part of our effort to better capture costs for procedures with significant device costs, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58944 through 58948), for CY 2019, we modified our criteria for device-intensive procedures. We had heard from interested parties that the criteria excluded some procedures that interested parties believed should qualify as device-intensive procedures. Specifically, we were persuaded by interested party arguments that procedures requiring expensive surgically inserted or implanted devices that are not capital equipment should qualify as device-intensive procedures, regardless of whether the device remains in the patient's body after the conclusion of the procedure. We agreed that a broader definition of device-intensive procedures was warranted, and made two modifications to the criteria for CY 2019 (83 FR 58948). First, we allowed procedures that involve surgically inserted or implanted single-use devices that meet the device offset percentage threshold to qualify as device-intensive procedures, regardless of whether the device remains in the patient's body after the conclusion of the procedure. We established this policy because we no longer believe that whether a device remains in the patient's body should affect a procedure's designation as a device-intensive procedure, as such devices could, nonetheless, comprise a large portion of the cost of the applicable procedure. Second, we modified our criteria to lower the device offset percentage threshold from 40 percent to 30 percent, to allow a greater number of procedures to qualify as device intensive. We stated that we believe allowing these additional procedures to qualify for device-intensive status will help ensure these procedures receive more appropriate payment in the ASC setting, which will help encourage the provision of these services in the ASC setting. In addition, we stated that this change would help to ensure that more procedures containing relatively high-cost devices are subject to the device edits, which leads to more correctly coded claims and greater accuracy in our claims data. Specifically, for CY 2019 and subsequent years, we finalized that device-intensive procedures will be subject to the following criteria:

• All procedures must involve implantable devices assigned a CPT or HCPCS code;

• The required devices (including single-use devices) must be surgically inserted or implanted; and

• The device offset amount must be significant, which is defined as exceeding 30 percent of the procedure's mean cost (83 FR 58945).

In addition, to further align the device-intensive policy with the criteria used for device pass-through payment status, we finalized, for CY 2019 and subsequent years, that for purposes of satisfying the device-intensive criteria, a device-intensive procedure must involve a device that:

• Has received FDA marketing authorization, has received an FDA investigational device exemption (IDE), and has been classified as a Category B device by FDA in accordance with §§ 405.203 through 405.207 and 405.211 through 405.215, or meets another appropriate FDA exemption from premarket review;

• Is an integral part of the service furnished;

• Is used for one patient only;

• Comes in contact with human tissue;

• Is surgically implanted or inserted (either permanently or temporarily); and

• Is not either of the following:

++ Equipment, an instrument, apparatus, implement, or item of the type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or

++ A material or supply furnished incident to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than a radiological site marker) (83 FR 58945).

In addition, for new HCPCS codes describing procedures requiring the implantation of devices that do not yet have associated claims data, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658), we finalized a policy for CY 2017 to apply device-intensive status with a default device offset set at 41 percent for new HCPCS codes describing procedures requiring the implantation or insertion of a device that did not yet have associated claims data until claims data are available to establish the HCPCS code-level device offset for the procedures. This default device offset amount of 41 percent was not calculated from claims data; instead, it was applied as a default until claims data were available upon which to calculate an actual device offset for the new code. The purpose of applying the 41-percent default device offset to new codes that describe procedures that implant or insert devices was to ensure ASC access for new procedures until claims data become available.

As discussed in the CY 2019 OPPS/ASC proposed rule and final rule with comment period (83 FR 37108 through 37109 and 58945 through 58946, respectively), in accordance with our policy stated previously to lower the device offset percentage threshold for procedures to qualify as device-intensive from greater than 40 percent to greater than 30 percent, for CY 2019 and subsequent years, we modified this policy to apply a 31-percent default device offset to new HCPCS codes describing procedures requiring the implantation of a device that do not yet have associated claims data until claims data are available to establish the HCPCS code-level device offset for the procedures. In conjunction with the policy to lower the default device offset from 41 percent to 31 percent, we continued our current policy of, in certain rare instances (for example, in the case of a very expensive implantable device), temporarily assigning a higher offset percentage if warranted by additional information such as pricing data from a device manufacturer (81 FR 79658). Once claims data are available for a new procedure requiring the implantation or insertion of a device, device-intensive status is applied to the code if the HCPCS code-level device offset is greater than 30 percent,

according to our policy of determining device-intensive status by calculating the HCPCS code-level device offset.

In addition, in the CY 2019 OPPS/ASC final rule with comment period, we clarified that since the adoption of our policy in effect as of CY 2018, the associated claims data used for purposes of determining whether or not to apply the default device offset are the associated claims data for either the new HCPCS code or any predecessor code, as described by CPT coding guidance, for the new HCPCS code. Additionally, for CY 2019 and subsequent years, in limited instances where a new HCPCS code does not have a predecessor code as defined by CPT, but describes a procedure that was previously described by an existing code, we use clinical discretion to identify HCPCS codes that are clinically related or similar to the new HCPCS code but are not officially recognized as a predecessor code by CPT, and to use the claims data of the clinically related or similar code(s) for purposes of determining whether or not to apply the default device offset to the new HCPCS code (83 FR 58946). Clinically related and similar procedures for purposes of this policy are procedures that have few or no clinical differences and use the same devices as the new HCPCS code. In addition, clinically related and similar codes for purposes of this policy are codes that either currently or previously describe the procedure described by the new HCPCS code. Under this policy, claims data from clinically related and similar codes are included as associated claims data for a new code, and where an existing HCPCS code is found to be clinically related or similar to a new HCPCS code, we apply the device offset percentage derived from the existing clinically related or similar HCPCS code's claims data to the new HCPCS code for determining the device offset percentage. We stated that we believe that claims data for HCPCS codes describing procedures that have minor differences from the procedures described by new HCPCS codes will provide an accurate depiction of the cost relationship between the procedure and the device(s) that are used, and will be appropriate to use to set a new code's device offset percentage, in the same way that predecessor codes are used. If a new HCPCS code has multiple predecessor codes, the claims data for the predecessor code that has the highest individual HCPCS-level device offset percentage is used to determine whether the new HCPCS code qualifies for device-intensive status. Similarly, in the event that a new HCPCS code does not have a predecessor code but has multiple clinically related or similar codes, the claims data for the clinically related or similar code that has the highest individual HCPCS level device offset percentage is used to determine whether the new HCPCS code qualifies for device-intensive status.

a. Change to the Device-Intensive Status Default Offset Methodology for New HCPCS Codes

As described above, under our existing policies for assigning a device offset percentage to new HCPCS codes, we first rely on the associated claims data for new HCPCS codes. For new HCPCS codes that do not have available claims data yet, we rely on any available claims data from a predecessor code for the new HCPCS code, as described by CPT coding guidance. We assign the device offset percentage to the new HCPCS code that is the device offset percentage of the predecessor code for which we have available claims data. If claims data from the new HCPCS or any predecessor code is unavailable, we use clinical discretion to identify HCPCS codes that are clinically related or similar to the new HCPCS code but are not officially recognized as a predecessor code by CPT, and to use the claims data of the clinically related or similar code(s) for purposes of determining a device offset percentage to the new HCPCS code (83 FR 58946). Clinically related and similar procedures for purposes of this policy are procedures that have few or no clinical differences and use the same devices. If a clinically similar procedure that uses the same devices is not available, then for new HCPCS codes describing procedures requiring the insertion or implantation of devices that do not yet have claims data (from either the new HCPCS code or any predecessor code), we apply a default device offset set at 31 percent.

As we stated previously, the purpose of applying the default device offset to new codes that describe procedures that implant or insert devices is to ensure access in the ASC setting for new procedures until claims data become available. Also, under the OPPS, the default device offset is useful for establishing a device amount for new device-intensive procedures. For example, under our policy for no cost/full credit or partial credit devices, we reduce the OPPS payment for device-intensive procedures by the lesser of the full or partial credit a hospital receives for a replaced device or the device offset amount. Additionally, we may remove the device offset amount from the OPPS payment for procedures that are terminated prior to administering anesthesia (since the device was not used for the procedure).

While we do allow for additional information in consideration of a higher offset percentage than the default device offset, it would be extremely rare that the appropriate determination of a device offset percentage would rely on pricing data or invoices from a device manufacturer rather than the default device offset percentage. However, we are aware that there may be certain situations where the default device offset percentage would not adequately reflect the existing device portion of the procedure's costs when compared to the cost of similar devices. This difference could impede our ability to accurately remove device offset amounts from new device-intensive procedures under the OPPS. As HOPDs and ASCs perform new procedures with significant device costs, we believe it is appropriate to modify our default device offset methodology to pay HOPDs and ASCs more appropriately when we lack claims data for these newer procedures. Therefore, for CY 2025 and subsequent calendar years, we proposed to modify our default device offset percentage policy for new device-intensive procedures. Specifically, for new HCPCS codes that both describe a procedure that requires the implantation or insertion of a single-use device that meets our requirements of a device as described above and lack claims data (from either the new HCPCS code or any predecessor code), we would apply a default device offset percentage that is the greater of 31 percent or the device offset percentage of the APC to which the procedure has been assigned. We proposed this methodological change for both the OPPS and ASC Payment System for CY 2025 and subsequent calendar years. We explained that we still believe that a HCPCS code-level device offset is, in most cases, a more accurate representation of a procedure's device cost than an APC-wide average device offset based on the average device offset of all the procedures assigned to an APC. However, because newer device-intensive procedures lack claims data, we believe the APC-wide average device offset percentage is, in many cases, a better reflection of the estimated device costs of the procedure than a default 31 percent offset. Additionally, there can be instances where the typical device costs of procedures in an APC can be significantly greater than the 31 percent default device offset. For these reasons, we proposed to modify our default device offset percentage for new device-

intensive procedures that describe the implantation or insertion of a single-use device that meets our requirements of a device (as described above) and that do not yet have associated claims data, by applying a default device offset percentage that is the greater of 31 percent or the device offset percentage of the APC to which the procedure has been assigned. We proposed to apply this policy to new procedures assigned to clinical APCs, but not to new procedures assigned to New Technology APCs.

As we indicated in the CY 2019 OPPS/ASC proposed rule and final rule with comment period, we may consider additional information for an offset percentage greater than the default offset percentage (which, for the proposed rule, is the greater of 31 percent or the APC-level offset percentage) for new HCPCS codes describing procedures requiring the implantation (or, in some cases, the insertion) of a device that do not yet have associated claims data, such as pricing data or invoices from a device manufacturer. This would be for our consideration in extremely rare circumstances, such as an extremely high-cost implantable device. While we explained that we believe our proposed modification to the default device offset policy would improve payment under the OPPS and ASC payment system, we would continue to accept additional information in consideration of an alternative offset percentage. This information would be directed to the Division of Outpatient Care, Mail Stop C4–01–26, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850, or electronically at *outpatientpps@cms.hhs.gov.* Additional information would be submitted prior to issuance of an OPPS/ASC proposed rule or as a public comment in response to an issued OPPS/ASC proposed rule. Device offset percentages would be set in each year's final rule with comment period.

Comment: While commenters supported our proposed change to determining default device offset percentages under the ASC payment system, many commenters recommended that we delay implementing our proposed change under the OPPS as we have not fully discussed the implications of such a change under the OPPS. Some stakeholders were concerned that our proposed default device offset methodology could inappropriately inflate the device offset amount for transitional pass-through cost significance tests, which utilize the device offset amounts under the OPPS.

Response: Under the OPPS, our proposal, if finalized, would apply whenever a default device offset percentage and the associated device offset amount are utilized. This includes determining eligibility for transitional pass-through payment status for devices, setting the payment amount for transitional pass-through devices, determining the payment amount for discontinued device-intensive procedures, and determining the maximum credit amount for a device-intensive procedure under our device credits policy. The purpose of our proposal was to improve the accuracy of the way in which we determine the device portion for device-intensive procedures in the absence of claims data. We believe the average device cost of the APC can better reflect the expected device portion of a new procedure without claims data than a default device offset of 31 percent since procedures assigned to a clinical APC often have similar device costs. We believe this improvement in the accuracy of determining the device portion of an APC payment should be applied in both settings rather than just one setting as the commenters recommend. We understand that the increased device portion that would result from this change in policy may reduce payment in the OPPS setting if such newer procedures are reported with a transitional pass-through device category or in situations with a device credit or a terminated procedure, but we do not believe it would be appropriate to assign a device offset amount that we believe is less accurate to avoid such a payment reduction under the OPPS. Since our policy has been to keep device costs constant between the OPPS and ASC payment system for device-intensive procedures to appropriately account for the device costs of certain surgical procedures and maintain beneficiary access in the ASC setting for device-intensive procedures, for which interested parties have expressed strong support, we are not accepting the commenter's recommendation to delay implementing our proposed change under the OPPS.

Comment: Several commenters noted that the device offset percentage for HCPCS code C9757 (Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and excision of herniated intervertebral disc, and repair of annular defect with implantation of bone anchored annular closure device, including annular defect measurement, alignment and sizing assessment, and image guidance; 1 interspace, lumbar) was inaccurate and did not reflect the total costs for the procedure. The manufacturer of the Barricaid device—a device which is used with HCPCS code C9757—noted that there was an abundance of misreported claims for HCPCS code C9757 which they believe has undermined the integrity of the claims data. The manufacturer and other commenters recommended that we assign a device offset percentage based on claims that reported the use of the Barricaid device, or invoices for the Barricaid device, or using the proposed default device offset methodology that would assign the greater of the APC wide device offset percentage or 31 percent. Commenters also recommended we implement a device-specific edit for this procedure and issue a technical direction letter to ensure appropriate device reporting when billing for HCPCS code C9757. Without such hospital guidance, the commenters believe hospitals may continue to not report the associated device, which they believe could impede our ability to properly set payment rates for device-intensive procedures.

Response: We appreciate commenters bringing this issue to our attention. We have taken these comments into consideration with respect to our modification of our device edits policy for CY 2025 in section IV.B.3 of this final rule with comment period. While we continue to rely on hospital claims data rather than external invoices or our default device offset methodology in determining device offset percentages when claims data is available, we believe the stakeholder raises an important issue regarding the nonreporting of device charges and potentially ''missing'' device costs from certain hospital outpatient claims. We are persuaded by commenters that a lack of a device edit for device-intensive procedures, particularly new technologies, might lead to an underreporting of device costs and total procedure costs and impede beneficiary access to such new technologies. Therefore, in conjunction with the modification to our finalized device edits policy as explained further in section IV.B.3 of this final rule with comment period, for procedures subject to our modified device edits policy for CY 2025 that cannot report modifier ''CG'' to bypass this claims processing edit, the device offset percentages calculated for CY 2025 (for the CPT/HCPCS code or its predecessor code) are based on hospital claims that reported a device code. We believe that hospital

outpatient claims that report a device code with device-intensive procedures provide, in general, a more accurate representation of the procedures' total costs. Therefore, based on claims data available for CY 2025 subject to this device-reporting requirement, HCPCS code C9757 has a device offset percentage that exceeds the device-intensive threshold and is assigned device-intensive status for CY 2025. Final CY 2025 device offset percentages based on claims data used for this CY 2025 OPPS/ASC final rule with comment period can be found in Addendum P.

Comment: Several commenters recommended that we assign device-intensive status to CPT code 52284 (Cystourethroscopy, with mechanical urethral dilation and urethral therapeutic drug delivery by drug-coated balloon catheter for urethral stricture or stenosis, male, including fluoroscopy, when performed) based on the cost of the device or using the default device offset percentage. Further, the manufacturer of the Optilume® device recommended we create a new HCPCS code to describe the Optilume® device or a claims processing edit as hospital claims data do not accurately report the device code and device cost.

Response: We continue to hear from stakeholders regarding hospital nonreporting of device charges. We note that CPT code 52284 was previously described by CPT code 0499T (Cystourethroscopy, with mechanical dilation and urethral therapeutic drug delivery for urethral stricture or stenosis, including fluoroscopy, when performed), which was effective from January 1, 2018, until January 1, 2024. Therefore, as explained further in section IV.B.3 of this final rule with comment period, in conjunction with our modified device edits policy for CY 2025, we are utilizing the device offset percentages calculated for CY 2025 based on hospital claims that reported a device code. Based on claims data available for CY 2025 subject to this device-reporting requirement, CPT code 0499T has a device offset percentage that exceeds our device-intensive threshold. Therefore, we are assigning device-intensive status to successor CPT code 52284 for CY 2025. Final CY 2025 device offset percentages based on claims data used for this CY 2025 OPPS/ASC final rule with comment period can be found in Addendum P.

Comment: One commenter recommended that we assign device-intensive status to CPT codes 0884T, 0885T, and 0886T, which became effective July 1, 2024.

Response: We proposed to assign these procedures device-intensive status in the July 2024 OPPS update and in Addendum P to the CY 2025 OPPS/ASC proposed rule. Since these are new procedures with no predecessor or clinically similar codes that use the same device, we are finalizing our proposal to assign device-intensive status to these three procedures and to use our default offset methodology to assign a device offset percentage to CPT codes 0884T, 0885T, and 0886T.

Comment: One commenter recommended that we restore device-intensive status to CPT code 27412 (Autologous chondrocyte implantation, knee). The commenter stated the procedure is always performed with HCPCS Code J7330 (Autologous cultured chondrocytes, implant), which they argue is a device. Further, the commenter argues the procedure has historically been device-intensive and should continue to have that designation.

Response: We disagree with the commenter. We believe we inadvertently assigned this procedure device-intensive status based on hospitals reporting significant device costs. However, as the commenter noted, CPT code 27412 is performed with J7330 which is categorized as a drug/biological and may have been incorrectly reported as an implantable device by certain hospitals. We note that J7330 is regulated as Human Cells, Tissues, and Cellular and Tissue-Based Products (HTC/Ps) by the FDA under 21 CFR part 1271 and is not regulated as a medical device by the FDA. Since CPT code 27412 does not involve a device that meets our requirement, we are not assigning device-intensive status to CPT code 27412.

Comment: One commenter was concerned that Addendum P did not reflect the device offset amount that is applied to the transitional pass-through device performed with CPT code 0505T (Endovenous femoral-popliteal arterial revascularization, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed, with crossing of the occlusive lesion in an extraluminal fashion). The commenter suggested that the device offset amount is $0.00 and Addendum P should reflect this amount.

Response: While we agree that the device offset amount for CPT code 0505T is $0.00 as we stated in the July 2024 OPPS Change Request, the amount in Addendum P reflects the total device-related costs of the procedure. In certain situations where an approved transitional pass-through device does not replace existing APC device costs, the amount reflected in Addendum P does not reflect the actual device offset amount that is applied against the separate payment for the transitional pass-through device.

Comment: Some commenters recommended that we assign device-intensive status to CPT code 0621T (Trabeculostomy ab interno by laser;) since the procedure was assigned a status indicator of ''E1''—Items, codes, and services not covered by any Medicare outpatient benefit category; statutorily excluded; not reasonable and necessary—in CY 2023 and the claims that would be used to determine device-intensive status are invalid and not usable for this purpose. Similarly, one commenter argued that our device offset percentage for CPT code 0795T (Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (*e.g.,* fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (*e.g.,* interrogation or programming), when performed; complete system (*i.e.,* right atrial and right ventricular pacemaker components)) should be revised to be set using the default device offset methodology as CPT code 0795T was also assigned status indicator of ''E1'' in CY 2023.

Response: We agree with the commenters that claims with a status indicator of ''E1'' may not be appropriate for determining device offset percentages and device offset amounts as this status indicator can be used for procedures that involve a device where such device has not received FDA marketing authorization or received FDA investigational device exemption. For purposes of determining device offset percentages, we will not use claims data from procedures that had a status indicator of ''E1'' for determining device offset percentages. We will revise our claims accounting narrative to reflect this change.

Comment: One commenter recommended that we evaluate, as part of rulemaking, procedures that utilize pass-through devices expiring mid-year using the latest final rule claims data available to determine the appropriate APC assignment when the device no

longer has transitional pass-through status.

Response: We thank the commenter for this recommendation and note we already conduct such an evaluation in our proposed and final rule ratesetting process. Devices for which pass-through status is expiring at any point in the prospective year are packaged in our ratesetting process for that prospective year so that we may reevaluate the APC assignments of these technologies as the commenter noted.

Comment: One commenter recommended that we update the device offset percentages from predecessor codes annually rather than just in the first year we calculate the device offset percentage from the predecessor code.

Response: We agree with the commenter and will refine our process for applying device offset percentages to use available claims data from predecessor codes annually rather than just in the first year.

Comment: Commenters supported the proposed device offset percentage for CPT codes:

- 0421T (Transurethral waterjet ablation of prostate, including control of post-operative bleeding, including ultrasound guidance, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included when performed));
- 0737T (Xenograft implantation into the articular surface);
- 0816T (Open insertion or replacement of integrated neurostimulation system for bladder dysfunction including electrode(s) (*e.g.,* array or leadless), and pulse generator or receiver, including analysis, programming, and imaging guidance, when performed, posterior tibial nerve; subfascial);
- 0817T (Revision or removal of integrated neurostimulation system for bladder dysfunction, including analysis, programming, and imaging, when performed, posterior tibial nerve; subcutaneous);
- 66989 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (*e.g.,* irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (*e.g.,* iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with insertion of intraocular (*e.g.,* trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more);
- 66991 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (*e.g.,* irrigation and aspiration or phacoemulsification); with insertion of intraocular (*e.g.,* trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more);
- 0671T (Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more);
- 66683 (Implantation of iris prosthesis, including suture fixation and repair or removal of iris, when performed);
- C9781 (Arthroscopy, shoulder, surgical; with implantation of subacromial spacer (*e.g.,* balloon), includes debridement (*e.g.,* limited or extensive), subacromial decompression, acromioplasty, and biceps tenodesis when performed).

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing our proposal with modification to apply a default device offset percentage that is the greater of 31 percent or the device offset percentage of the APC to which the procedure has been assigned for a new HCPCS code that describes a procedure that requires the implantation or insertion of a single-use device that meets the definition of a device for purposes of our device offset policy and for which the procedure lacks claims data (from either the new HCPCS code or any predecessor code). Also, in conjunction with the modification to our finalized device edits policy as explained further in section IV.B.3 of this final rule with comment period, for procedures subject to our modified device edits policy for CY 2025 that cannot report modifier ''CG'' to bypass this claims processing edit, the device offset percentages calculated for CY 2025 (for the CPT/HCPCS code or its predecessor code) are based on hospital claims that reported a device code, as we believe that hospital outpatient claims that report a device code for these device-intensive procedures provide, in general, a more accurate representation of the procedures' total costs. We are also finalizing, for purposes of determining device offset percentages, that we will not use claims data from procedures that had a status indicator of ''E1'' during the calendar year we are using for ratesetting and determining device offset percentages. Lastly, we are refining our process for applying device offset percentages to use available claims data from predecessor codes annually, rather than the first year of the successor code's activation date, until we have available claims data from the successor code.

The full listing of the final CY 2025 device-intensive procedures, which utilize the revised default device offset policy we are finalizing, can be found in Addendum P to the proposed rule (which is available via the internet on the CMS website). Further, our claims accounting narrative contains a description of our device offset percentage calculation. Our claims accounting narrative for this final rule can be found under supporting documentation for this CY 2025 OPPS/ASC final rule with comment period on our website at: *https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps*.

3. Device Edit Policy

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66795), we finalized a policy and implemented claims processing edits that require any of the device codes used in the previous device-to-procedure edits to be present on the claim whenever a procedure code assigned to any of the APCs listed in Table 5 of the CY 2015 OPPS/ASC final rule with comment period (the CY 2015 device-dependent APCs) was reported on the claim. In addition, in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70422), we modified our previously existing policy and applied the device coding requirements exclusively to procedures that require the implantation of a device assigned to a device-intensive APC. In the CY 2016 OPPS/ASC final rule with comment period, we also finalized our policy that the claims processing edits are such that any device code, when reported on a claim with a procedure assigned to a device-intensive APC (listed in Table 42 of the CY 2016 OPPS/ASC final rule with comment period (80 FR 70422)), will satisfy the edit.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658 through 79659), we changed our policy for CY 2017 and subsequent years to apply the CY 2016 device coding requirements to the newly defined device-intensive procedures. For CY 2017 and subsequent years, we also specified that any device code, when reported on a claim with a device-intensive procedure, will satisfy the

edit. In addition, we created HCPCS code C1889 to recognize devices furnished during a device-intensive procedure that are not described by a specific Level II HCPCS Category C-code. Reporting HCPCS code C1889 with a device-intensive procedure will satisfy the edit requiring a device code to be reported on a claim with a device-intensive procedure. In the CY 2019 OPPS/ASC final rule with comment period, we revised the description of HCPCS code C1889 to remove the specific applicability to device-intensive procedures (83 FR 58950). For CY 2019 and subsequent years, the description of HCPCS code C1889 is ''Implantable/insertable device, not otherwise classified.''

In the CY 2024 OPPS/ASC final rule with comment period (88 FR 81758 through 81759), we finalized our proposal to establish a procedure-to-device edit for the procedures assigned to APC 5496 (Level 6 Intraocular Procedures) and require hospitals to report the correct device HCPCS codes when reporting any of the four procedures—CPT codes 0308T, 0616T, 0617T, and 0618T. While we noted that interested parties have previously recommended in past rulemaking that we reestablish all of our previous procedure-to-device edits, we did not expect to extend this policy beyond the procedures assigned to APC 5496 (Level 6 Intraocular Procedures). This APC represents a unique situation—the APC (which was the Level 5 Intraocular APC in previous years) had been a Low Volume APC (fewer than 100 claims in a claims year) since we established our Low Volume APC policy, the procedures associated with this APC have significant procedure costs often greater than $15,000, and the procedures associated with this APC require the implantation of a high-cost intraocular device. Additionally, in our review of claims data for some of the procedures, we noticed unusual coding, charge, and cost data. These claims had an outsized impact because of the low volume of claims for the APC which impeded our ability to determine a payment rate accurately and appropriately for APC 5496 (Level 6 Intraocular Procedures). Further, because of the low volume of procedures assigned to this APC, we did not believe the reinstatement of procedure-to-device edits for the four procedures assigned to this APC would be administratively burdensome to hospitals. We finalized our proposal to modify our device edits policy to require a procedure-to-device edit for procedures assigned to APC 5496 (Level 6 Intraocular Procedures) for CY 2024. We proposed to continue this policy for APC 5496 (Level 6 Intraocular Procedures) for CY 2025 and subsequent CYs in the CY 2025 OPPS/ASC proposed rule and noted that new CPT placeholder code 6X004 (Implantation of iris prosthesis, including suture fixation and repair or removal of iris, when performed) is replacing CPT code 0616T (Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; without removal of crystalline lens or intraocular lens, without insertion of intraocular lens) effective January 1, 2025. Additionally, CPT codes 0617T and 0618T currently assigned to APC 5496 (Level 6 Intraocular Procedures) will be deleted effective January 1, 2025. Therefore, for CY 2025, the procedure-to-device edit for procedures assigned to APC 5496 (Level 6 Intraocular Procedures) would apply to CPT code 0308T and 66683 (placeholder code 6X004). We did not propose any other changes to our device edit policy for CY 2025.

Comment: One commenter supported our proposal to continue our procedure-to-device edit for the insertion of the Artificial Iris—from CPT code 0616T, which will be deleted on January 1, 2025, to CPT code 66683 will become active on January 1, 2025.

Response: We thank the commenters for their support. We are finalizing our proposal to apply the procedure-to-device edit for predecessor code 0616T to successor code 66683.

Comment: Several commenters recommended reinstating a claims processing edit to improve hospital reporting of device costs. In particular, the manufacturer of the device Barricaid recommended we implement a device-specific edit for this procedure and issue a technical direction letter to ensure correct device code reporting with HCPCS code C9757 (Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and excision of herniated intervertebral disc, and repair of annular defect with implantation of bone anchored annular closure device, including annular defect measurement, alignment and sizing assessment, and image guidance; 1 interspace, lumbar). Additionally, the manufacturer of the Optilume® device recommended we create a new HCPCS code to describe the Optilume® device or a claims processing edit as hospital claims data do not accurately report the device code and device cost on hospital outpatient claims with the appropriate procedure code—CPT code 52284 (Cystourethroscopy, with mechanical urethral dilation and urethral therapeutic drug delivery by drug-coated balloon catheter for urethral stricture or stenosis, male, including fluoroscopy, when performed). A few commenters requested that we implement a device edit for CPT code 30469 (Repair of nasal valve collapse with low energy, temperature-controlled (*i.e.,* radiofrequency) subcutaneous/submucosal remodeling) to allow additional years of claims data to determine its device-intensive status as they claim hospitals have been slow to update their chargemasters. Further, one device manufacturer reiterated a longstanding recommendation that we reinstate all our previous device-to-procedure edits.

Response: We appreciate commenters bringing to our attention their concerns regarding our assignment of device offset percentages and hospital reporting of device costs. We believe commenters raise an important issue that there may have been instances when a newly created procedure code loses device-intensive status if the device cost fluctuates below the device-intensive threshold of 30 percent of the total procedure cost and then is never able to regain device-intensive status because hospitals are no longer required to report a device code on the claim with that procedure. The commenters have indicated to us that the presence of the device edit requirement can have a significant impact on the device portion and geometric mean cost of a procedure. For example, the geometric mean cost was $9,218.47 for hospitals that reported a device code with HCPCS code C9757 and $6,287.47 for hospitals that did not report a device code. The geometric mean cost was $5,277.22 for hospitals that reported a device code with CPT code 52284 and $3,791.95 for hospitals that did not report a device code. Additionally, removing claims from hospitals that do not report a device code with these procedures increased the device offset percentage for HCPCA code C9757 from 23.62 percent to 43.21 percent and from 32.17 percent to 32.225 percent for CPT code 52284. These results highlight the impact that hospital reporting of device codes can have on our assignment of device offset percentages, device-intensive status, and the geometric mean cost of a procedure and these results impacted our final CY 2025 device-intensive policy as described in section IV.B.2 of this final rule with comment period. We are persuaded by commenters that are our existing device edits policy may be insufficient for

certain procedures, particularly newer technologies with device costs that fluctuate around our device-intensive threshold.

After consideration of the public comments we received, we are finalizing our proposal with modification. While historically our device edits policy has only applied to procedures that are device-intensive based on the most recent claims data available, for CY 2025 and subsequent calendar years, we are finalizing a policy to apply our device edit policy permanently once a procedure is designated as a device-intensive procedure in a given year. For the procedures designated as device-intensive for CY 2025, we propose that the device edit requirement would apply in CY 2025 and subsequent calendar years as well. We are concerned that the loss of an applicable device edit may impact hospital reporting of device costs and impede our ability to properly set payment rates and determine appropriate device offset percentages for device-intensive procedures. Additionally, we are finalizing a policy to reinstate our device edits policy for procedures that have been device-intensive since we began assigning device-intensive status at the HCPCS code level on January 1, 2017. We believe that by applying our device edit policy to procedures that were device-intensive on or after January 1, 2017, we might continue to receive device cost information for relatively new procedures with limited claims data, which may have been impacted by our policy to require that only existing device-intensive procedures be subject to our device edits policy. For CY 2025, under our modified device edits policy, our device edits requirement will apply to procedures that are device-intensive in CY 2025 as well as procedures that have been device-intensive on or after January 1, 2017.

4. Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices

a. Background

To ensure equitable OPPS payment when a hospital receives a device without cost or with full credit, in CY 2007, we implemented a policy to reduce the payment for specified device-dependent APCs by the estimated portion of the APC payment attributable to device costs (that is, the device offset) when the hospital receives a specified device at no cost or with full credit (71 FR 68071 through 68077). Hospitals were instructed to report no cost/full credit device cases on the claim using the ''FB'' modifier on the line with the procedure code in which the no cost/full credit device is used. In cases in which the device is furnished without cost or with full credit, hospitals were instructed to report a token device charge of less than $1.01. In cases in which the device being inserted is an upgrade (either of the same type of device or to a different type of device) with a full credit for the device being replaced, hospitals were instructed to report as the device charge the difference between the hospital's usual charge for the device being implanted and the hospital's usual charge for the device for which it received full credit. In CY 2008, we expanded this payment adjustment policy to include cases in which hospitals receive partial credit of 50 percent or more of the cost of a specified device. Hospitals were instructed to append the ''FC'' modifier to the procedure code that reports the service provided to furnish the device when they receive a partial credit of 50 percent or more of the cost of the new device. We refer readers to the CY 2008 OPPS/ASC final rule with comment period for more background information on the ''FB'' and ''FC'' modifiers payment adjustment policies (72 FR 66743 through 66749).

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75007), beginning in CY 2014, we modified our policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. For CY 2013 and prior years, our policy had been to reduce OPPS payment by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device. For CY 2014, we reduced OPPS payment, for the applicable APCs, by the full or partial credit a hospital receives for a replaced device. Specifically, under this modified policy, hospitals are required to report on the claim the amount of the credit in the amount portion for value code ''FD'' (Credit Received from the Manufacturer for a Replaced Device) when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device. For CY 2014, we also limited the OPPS payment deduction for the applicable APCs to the total amount of the device offset when the ''FD'' value code appears on a claim. For CY 2015, we continued our policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit and to use the three criteria established in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68072 through 68077) for determining the APCs to which our CY 2015 policy will apply (79 FR 66872 through 66873). In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70424), we finalized our policy to no longer specify a list of devices to which the OPPS payment adjustment for no cost/full credit and partial credit devices would apply and instead apply this APC payment adjustment to all replaced devices furnished in conjunction with a procedure assigned to a device-intensive APC when the hospital receives a credit for a replaced specified device that is 50 percent or greater than the cost of the device.

b. Policy for No Cost/Full Credit and Partial Credit Devices

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79659 through 79660), for CY 2017 and subsequent years, we finalized a policy to reduce OPPS payment for device-intensive procedures, by the full or partial credit a provider receives for a replaced device, when a hospital furnishes a specified device without cost or with a full or partial credit. Under our current policy, hospitals continue to be required to report on the claim the amount of the credit in the amount portion for value code ''FD'' when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device.

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75007), we adopted a policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit by the lesser of the device offset amount for the APC or the amount of the credit. We adopted this change in policy in the preamble of the CY 2014 OPPS/ASC final rule with comment period and discussed it in subregulatory guidance, including Chapter 4, section 61.3.6 of the Medicare Claims Processing Manual. Further, in the CY 2021 OPPS/ASC final rule with comment period (85 FR 86017 through 86018, 86302), we made conforming changes to our regulations at § 419.45(b)(1) and (2) that codified this policy.

We did not propose any changes, and we did not receive any public comments related to our policies regarding

payment for no cost/full credit and partial credit devices for CY 2025.

V. OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals

A. OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals

1. Background

Section 1833(t)(6) of the Act provides for temporary additional payments or ''transitional pass-through payments'' for certain drugs and biologicals. Throughout this final rule with comment period, the term ''biological'' is used because this is the term that appears in section 1861(t) of the Act. A ''biological'' as used in this final rule with comment period includes (but is not necessarily limited to) a ''biological product'' or a ''biologic'' as defined under section 351 of the PHS Act. As enacted by the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), this pass-through payment provision requires the Secretary to make additional payments to hospitals for: current orphan drugs for rare diseases and conditions, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act; current drugs and biologicals and brachytherapy sources used in cancer therapy; and current radiopharmaceutical drugs and biologicals. ''Current'' refers to those types of drugs or biologicals mentioned above that are hospital outpatient services under Medicare Part B for which transitional pass-through payment was made on the first date the hospital OPPS was implemented.

Transitional pass-through payments also are provided for certain ''new'' drugs and biologicals that were not being paid for as an HOPD service as of December 31, 1996, and whose cost is ''not insignificant'' in relation to the OPPS payments for the procedures or services associated with the new drug or biological. For pass-through payment purposes, radiopharmaceuticals are included as ''drugs.'' As required by statute, transitional pass-through payments for a drug or biological described in section 1833(t)(6)(C)(i)(II) of the Act can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made for the drug as a hospital outpatient service under Medicare Part B. Final CY 2025 pass-through drugs and biologicals and their designated APCs are assigned status indicator ''G'' in Addenda A and B to this final rule with comment period (which are available on the CMS website).[131]

Section 1833(t)(6)(D)(i) of the Act specifies that the pass-through payment amount, in the case of a drug or biological, is the amount by which the amount determined under section 1842(o) of the Act for the drug or biological exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the drug or biological. The methodology for determining the pass-through payment amount is set forth in regulations at 42 CFR 419.64. These regulations specify that the pass-through payment equals the amount determined under section 1842(o) of the Act minus the portion of the APC payment that CMS determines is associated with the drug or biological.

Section 1847A of the Act establishes the average sales price (ASP) methodology, which is used for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. The ASP methodology, as applied under the OPPS, uses several sources of data as a basis for payment, including the ASP, the wholesale acquisition cost (WAC), and the average wholesale price (AWP). In this final rule with comment period, the term ''ASP methodology'' and ''ASP-based'' are inclusive of all data sources and methodologies described therein. Additional information on the ASP methodology can be found on our website at: *https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price*.

The pass-through application [132] and review process for drugs and biologicals is described on our website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/pass-through-payment-status-new-technology-ambulatory-payment-classification-apc*.

2. Transitional Pass-Through Payment Period for Pass-Through Drugs, Biologicals, and Radiopharmaceuticals and Quarterly Expiration of Pass-Through Status

As required by statute, transitional pass-through payments for a drug or biological described in section 1833(t)(6)(C)(i)(II) of the Act can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made for the drug or biological as a hospital outpatient service under Medicare Part B. Our current policy is to accept pass-through applications on a quarterly basis and to begin pass-through payments for approved pass-through drugs and biologicals on a quarterly basis through the next available OPPS quarterly update after the approval of a drug's or biological's pass-through status. However, prior to CY 2017, we expired pass-through status for drugs and biologicals on an annual basis through notice-and-comment rulemaking (74 FR 60480). In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79662), we finalized a policy change, beginning with pass-through drugs and biologicals approved in CY 2017 and subsequent calendar years, to allow for a quarterly expiration of pass-through payment status for drugs, biologicals, and radiopharmaceuticals to afford a pass-through payment period that is as close to a full 3 years as possible for all pass-through drugs, biologicals, and radiopharmaceuticals.

This change eliminated the variability of the pass-through payment eligibility period, which previously varied based on when a particular application was initially received. We adopted this change for pass-through approvals beginning on or after CY 2017, to allow, on a prospective basis, for the maximum pass-through payment period for each pass-through drug without exceeding the statutory limit of 3 years. Notice of drugs for which pass-through payment status is ending during the calendar year is included in the quarterly OPPS Change Request transmittals.

Comment: One commenter expressed support for our policy of including radiopharmaceuticals as drugs eligible for pass-through status in the OPPS. In addition, this commenter supported our policy to allow drug pass-through status to expire on a quarterly basis to allow all drugs to have as close to three years of pass-through status as possible.

Response: We appreciate the support of the commenter for our policies.

Comment: Several commenters requested that we confirm that our proposal to pay separately for diagnostic radiopharmaceuticals with a per day cost greater than $630 that is described in section II.A.3.c of this final rule with comment period would not alter the qualification or payment methodology for those diagnostic radiopharmaceuticals applying for pass-through status under the OPPS.

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[131] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient*.

[132] To apply for OPPS transitional Pass-Through Payment Status and New Technology Ambulatory Payment Classification (APC), applicants complete an application that is subject to the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*). This information collection (CMS–10008) is currently approved under OMB control number of 0938–0802 and has an expiration date of January 31, 2025.

Response: The commenter is correct. This policy, which we are finalizing in section II.A.3.c of this final rule with comment period, is separate from the policies described in this section of this final rule with comment period, which describes the payment methodology for products that qualify for OPPS pass-through status.

3. Drugs and Biologicals With Expiring Pass-Through Payment Status in CY 2024

There are 25 drugs and biologicals for which pass-through payment status expires by December 31, 2024, as listed in Table 130. These drugs and biologicals will have received OPPS pass-through payment for 3 years during the period of April 1, 2021, through December 31, 2024. In accordance with the policy finalized in CY 2017 and described earlier, pass-through payment status for drugs and biologicals approved in CY 2017 and subsequent years will expire on a quarterly basis, with a pass-through payment period as close to 3 years as possible.

With the exception of those groups of drugs and biologicals that are always packaged when they do not have pass-through payment status (specifically, anesthesia drugs; drugs, biologicals, and radiopharmaceuticals [133] that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure), our standard methodology for providing payment for drugs and biologicals with expiring pass-through payment status in an upcoming calendar year is to determine the product's estimated per day cost and compare it with the OPPS drug packaging threshold for that calendar year, which will be $140 for CY 2025 for all drugs, biologicals, and therapeutic radiopharmaceuticals (for diagnostic radiopharmaceuticals we will provide separate payment when their per day cost exceeds the threshold we are adopting of $630). These policies are discussed further in section V.B.1 of this final rule with comment period. If the estimated per day cost for the drug or biological is less than or equal to the applicable OPPS drug packaging threshold, we package payment for the drug or biological into the payment for the associated procedure in the upcoming calendar year. If the estimated per day cost of the drug or biological is greater than the OPPS drug packaging threshold, we provide separate payment at the applicable ASP methodology-based payment amount (which is generally ASP plus 6 percent), as discussed further in section V.B.2 of this final rule with comment period.

[133] We are finalizing our proposal to pay separately for diagnostic radiopharmaceuticals with per-day costs above a threshold. This category of policy-packaged drugs that function as supplies in a diagnostic test or procedure includes diagnostic radiopharmaceuticals with per-day costs below the threshold for the applicable year. Please refer to Section II.A.3.c. for more information regarding this policy.

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TABLE 130: DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH PAYMENT STATUS WILL END BY DECEMBER 31, 2024

CY 2024 HCPCS Code	Long Descriptor	CY 2024 Status Indicator	CY 2024 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J0224	Injection, lumasiran, 0.5 mg	G	9407	04/01/2021	03/31/2024
J7212	Factor viia (antihemophilic factor, recombinant)-jncw (sevenfact), 1 microgram	G	9395	04/01/2021	03/31/2024
Q5122	Injection, pegfilgrastim-apgf, biosimilar, (nyvepria), 0.5 mg	G	9406	04/01/2021	03/31/2024
A9593	Gallium ga-68 psma-11, diagnostic, (ucsf), 1 millicurie	G	9409	07/01/2021	06/30/2024
A9594	Gallium ga-68 psma-11, diagnostic, (ucla), 1 millicurie	G	9410	07/01/2021	06/30/2024
J0741	Injection, cabotegravir and rilpivirine, 2mg/3mg	G	9414	07/01/2021	06/30/2024
J1305	Injection, evinacumab-dgnb, 5mg	G	9416	07/01/2021	06/30/2024
J1426	Injection, casimersen, 10 mg	G	9412	07/01/2021	06/30/2024
J1448	Injection, trilaciclib, 1mg	G	9415	07/01/2021	06/30/2024
J9247	Injection, melphalan flufenamide, 1mg	G	9417	07/01/2021	06/30/2024
J9348	Injection, naxitamab-gqgk, 1 mg	G	9408	07/01/2021	06/30/2024
J9353	Injection, margetuximab-cmkb, 5 mg	G	9418	07/01/2021	06/30/2024
Q2054	Lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9413	07/01/2021	06/30/2024
Q5123	Injection, rituximab-arrx, biosimilar, (riabni), 10 mg	G	9411	07/01/2021	06/30/2024

CY 2024 HCPCS Code	Long Descriptor	CY 2024 Status Indicator	CY 2024 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J1823	Injection, inebilizumab-cdon, 1 mg	G	9394	10/01/2021	09/30/2024
J2406	Injection, oritavancin (kimyrsa), 10 mg	G	9427	10/01/2021	09/30/2024
J9061	Injection, amivantamab-vmjw, 10 mg	G	9432	10/01/2021	09/30/2024
J9272	Injection, dostarlimab-gxly, 100 mg	G	9431	10/01/2021	09/30/2024
J9359	Injection, loncastuximab tesirine-lpyl, 0.075 mg	G	9205	10/01/2021	09/30/2024
Q2055	Idecabtagene vicleucel, up to 460 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9422	10/01/2021	09/30/2024
A9595	Piflufolastat f-18, diagnostic, 1 millicurie	G	9430	01/01/2022	12/31/2024
J0219	Injection, avalglucosidase alfa-ngpt, 4 mg	G	9433	01/01/2022	12/31/2024
J0491	Injection, anifrolumab-fnia, 1 mg	G	9434	01/01/2022	12/31/2024
J9021	Injection, asparaginase, recombinant, (rylaze), 0.1 mg	G	9437	01/01/2022	12/31/2024
J9071	Injection, cyclophosphamide, (auromedics), 5 mg	G	9203	01/01/2022	12/31/2024

4. Drugs, Biologicals, and Radiopharmaceuticals With Pass-Through Payment Status Expiring in CY 2025

We proposed to end pass-through payment status in CY 2025 for 28 drugs and biologicals. These drugs and biologicals, which were initially approved for pass-through payment status between April 1, 2022, and January 1, 2023, are listed in Table 131. The APCs and HCPCS codes for these drugs and biologicals, which have pass-through payment status that will end by December 31, 2025, are assigned status indicator ''G'' (Pass-Through Drugs and Biologicals) in Addenda A and B to this final rule with comment period (which are available on the CMS website).[134] The APCs and HCPCS codes for these drugs and biologicals are assigned status indicator ''G'' only for the duration of their pass-through status.

[134] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

Section 1833(t)(6)(D)(i) of the Act sets the amount of pass-through payment for pass-through drugs and biologicals (the pass-through payment amount) as the difference between the amount authorized under section 1842(o) of the Act and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. For CY 2025, we are continuing our policy to pay for pass-through drugs and biologicals using the ASP methodology, meaning a

payment rate based on ASP, WAC, or AWP, as applicable. This payment rate is generally ASP plus 6 percent, equivalent to the payment rate these drugs and biologicals would receive in the physician's office setting in CY 2025. We note that, under the OPD fee schedule, separately payable drugs assigned to an APC are generally payable at ASP plus 6 percent. Therefore, a $0 pass-through payment amount would continue to be paid for pass-through drugs and biologicals under the CY 2025 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which is generally ASP plus 6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which is generally ASP plus 6 percent, is $0.

In the case of policy-packaged drugs (which include the following: anesthesia drugs; drugs, biologicals, and radiopharmaceuticals [135] that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure), their pass-through payment amount will continue to be equal to a payment rate calculated using the ASP methodology, meaning a payment rate based on ASP, WAC, or AWP. This payment rate will generally continue to be ASP plus 6 percent for CY 2025, minus a payment offset for the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. We note that if not for the pass-through payment status of these policy-packaged products, payment for these products would be packaged into the associated procedure and therefore, there are associated OPD fee schedule amounts for them.

We will continue our policy to update pass-through payment rates on a quarterly basis on the CMS website during CY 2025 if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass-through payment drugs or biologicals are necessary. For a full description of this policy, we refer readers to the CY 2006 OPPS/ASC final rule with comment period (70 FR 68632 through 68635).

For CY 2025, consistent with our CY 2024 policy for diagnostic and therapeutic radiopharmaceuticals, we would continue to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through payment status based on the ASP methodology. As stated earlier, for purposes of pass-through payment, we consider radiopharmaceuticals to be drugs under the OPPS. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through payment status during CY 2025, we would continue to follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which is generally ASP plus 6 percent. If ASP data are not available for a radiopharmaceutical, we would continue to provide pass-through payment at WAC plus 3 percent (consistent with our policy in section V.B.2.a of this final rule with comment period), the equivalent payment provided for pass-through drugs and biologicals without ASP information. Additional detail on the WAC plus 3 percent payment policy can be found in section V.B.2.a of this final rule with comment period. If WAC information also is not available, we would continue to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

We refer readers to Table 131 below for the list of drugs and biologicals with pass-through payment status expiring during CY 2025.

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[135] We are finalizing our proposal to pay separately for diagnostic radiopharmaceuticals with per-day costs above a threshold. This category of policy-packaged drugs that function as supplies in a diagnostic test or procedure includes diagnostic radiopharmaceuticals with per-day costs below the threshold for the applicable year. Please refer to section II.A.3.c. for more information regarding this policy.

TABLE 131: DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS EXPIRING IN CY 2025

CY 2024 HCPCS Code	CY 2025 HCPCS Code	Long Descriptor	CY 2024 Status Indicator	CY 2024 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J0248	J0248	Injection, remdesivir, 1 mg	G	9200	04/01/2022	03/31/2025
J9304	J9304	Injection, pemetrexed (PEMFEXY), 10mg	G	9442	04/01/2022	03/31/2025
J3299	J3299	Injection, triamcinolone acetonide (xipere), 1 mg	G	9358	04/01/2022	03/31/2025
J2779	J2779	Injection, ranibizumab, via intravitreal implant (susvimo), 0.1 mg	G	9439	04/01/2022	03/31/2025
J9331	J9331	Injection, sirolimus protein-bound particles, 1 mg	G	9241	04/01/2022	03/31/2025
J2998	J2998	Injection, plasminogen, human-tvmh, 1 mg	G	9206	04/01/2022	03/31/2025
J9273	J9273	Injection, tisotumab vedotin-tftv, 1 mg	G	9204	04/01/2022	03/31/2025
C9088	C9088	Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg	G	9440	04/01/2022	03/31/2025
Q2056	Q2056	Ciltacabtagene autoleucel, up to 100 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9498	07/01/2022	06/30/2025

CY 2024 HCPCS Code	CY 2025 HCPCS Code	Long Descriptor	CY 2024 Status Indicator	CY 2024 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J1302	J1302	Injection, sutimlimab-jome, 10 mg	G	9444	07/01/2022	06/30/2025
A9596	A9596	Gallium ga-68 gozetotide, diagnostic, (illuccix), 1 millicurie	G	9443	07/01/2022	06/30/2025
J9274	J9274	Injection, tebentafusp-tebn, 1 microgram	G	9446	07/01/2022	06/30/2025
J1306	J1306	Injection, inclisiran, 1 mg	G	9004	07/01/2022	06/30/2025
Q5125	Q5125	Injection, filgrastim-ayow, biosimilar, (releuko), 1 microgram	G	9447	07/01/2022	06/30/2025
J2356	J2356	Injection, tezepelumab-ekko, 1 mg	G	9008	07/01/2022	06/30/2025
J2777	J2777	Injection, faricimab-svoa, 0.1 mg	G	9496	07/01/2022	06/30/2025
J9332	J9332	Injection, efgartigimod alfa-fcab, 2 mg	G	9010	07/01/2022	06/30/2025
A9800	A9800	Gallium ga-68 gozetotide, diagnostic, (locametz), 1 millicurie	G	9055	10/01/2022	09/30/2025
C9101	C9101	Injection, oliceridine, 0.1 mg	G	9049	10/01/2022	09/30/2025
A9607	A9607	Lutetium lu 177 vipivotide tetraxetan, therapeutic, 1 millicurie	G	9054	10/01/2022	09/30/2025
J9298	J9298	Injection, nivolumab and relatlimab-rmbw, 3 mg/1 mg	G	9057	10/01/2022	09/30/2025

CY 2024 HCPCS Code	CY 2025 HCPCS Code	Long Descriptor	CY 2024 Status Indicator	CY 2024 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
A9602	A9602	Fluorodopa f-18, diagnostic, per millicurie	G	9053	10/01/2022	09/30/2025
J1952	J1952	Leuprolide injectable, camcevi, 1 mg	G	9050	10/01/2022	09/30/2025
Q5126	Q5126	Injection, bevacizumab-maly, biosimilar, (alymsys), 10 mg	G	9048	10/01/2022	09/30/2025
J0225	J0225	Injection, vutrisiran, 1 mg	G	9009	01/01/2023	12/31/2025
J1932	J1932	Injection, lanreotide, (cipla), 1 mg	G	9051	01/01/2023	12/31/2025
J2327	J2327	Injection, risankizumab-rzaa, intravenous, 1 mg	G	9013	01/01/2023	12/31/2025
Q5124	Q5124	Injection, ranibizumab-nuna, biosimilar, (byooviz), 0.1 mg	G	9017	01/01/2023	12/31/2025

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We did not receive any public comments on our proposal and therefore, we are finalizing our proposal to end pass-through payment status in CY 2025 for 28 drugs and biologicals.

5. Drugs, Biologicals, and Radiopharmaceuticals With Pass-Through Payment Status Continuing Through CY 2025

We proposed to continue pass-through payment status in CY 2025 for 80 drugs and biologicals. These drugs and biologicals, which were approved for pass-through payment status with effective dates beginning between April 1, 2023, and January 1, 2025, are listed in Table 132. The APCs and HCPCS codes for these drugs and biologicals, which have pass-through payment status that would continue after December 31, 2025, are assigned status indicator ''G'' in Addenda A and B to this final rule with comment period (which are available on the CMS website).[136]

Section 1833(t)(6)(D)(i) of the Act sets the amount of pass-through payment for pass-through drugs and biologicals (the pass-through payment amount) as the difference between the amount authorized under section 1842(o) of the Act and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. For CY 2025, we are continuing our policy to pay for pass-through drugs and biologicals at a payment rate based on the ASP methodology, which may be based on ASP, WAC, or AWP, but is generally ASP plus 6 percent, which is equivalent to the payment rate these drugs and biologicals would receive in the physician's office setting in CY 2025. We will continue with our policy of paying a $0 pass-through payment amount for pass-through drugs and biologicals that are not policy-packaged under the CY 2025 OPPS, because the difference between the amount authorized under section 1842(o) of the Act, which would generally be ASP plus 6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which would also generally be ASP plus 6 percent, is $0.

In the case of policy-packaged drugs (which include the following: anesthesia drugs; drugs, biologicals, and radiopharmaceuticals[137] that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure), their pass-through payment amount would continue to be equal to a payment rate based on the ASP methodology, which may be based on ASP, WAC, or AWP, but would generally be ASP plus 6 percent for CY 2025, minus a payment offset for any predecessor drug products contributing to the pass-through payment. We note if not for the pass-through payment status of these policy-packaged products, payment for these products would be

[136] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

[137] We are finalizing our proposal to pay separately for diagnostic radiopharmaceuticals with per-day costs above a threshold. This category of policy-packaged drugs that function as supplies in a diagnostic test or procedure includes diagnostic radiopharmaceuticals with per-day costs below the threshold for the applicable year. Please refer to section II.A.3.c. for more information regarding this policy.

packaged into the associated procedure and therefore, there are associated OPD fee schedule amounts for them.

We are continuing our policy to update pass-through payment rates on a quarterly basis on our website during CY 2025 if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass-through payment drugs or biologicals are necessary. For a full description of this policy, we refer readers to the CY 2006 OPPS/ASC final rule with comment period (70 FR 68632 through 68635).

For CY 2025, consistent with our CY 2024 policy for diagnostic and therapeutic radiopharmaceuticals, we proposed to continue our policy to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through payment status based on the ASP methodology. As stated earlier, for purposes of pass-through payment, we consider radiopharmaceuticals to be drugs under the OPPS. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through payment status during CY 2025, we will continue to follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which would generally be ASP plus 6 percent. If ASP data are not available for a radiopharmaceutical, we would provide pass-through payment at WAC plus 3 percent (consistent with our policy in section V.B.2.a of this final rule with comment period), the equivalent payment provided for pass-through drugs and biologicals without ASP information. Additional detail on the WAC plus 3 percent payment policy can be found in section V.B.2.a of this final rule with comment period. If WAC information also is not available, we would provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

The drugs and biologicals that would have pass-through payment status expire after December 31, 2025, are shown in Table 132.

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TABLE 132: DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS EXPIRING AFTER CY 2025

CY 2024 HCPCS Code	CY 2025 HCPCS Code	Long Descriptor	CY 2024 Status Indicator	CY 2024 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
C9144	C9144	Injection, bupivacaine (posimir), 1 mg	G	9106	04/01/2023	03/31/2026
C9145	C9145	Injection, aprepitant, (aponvie), 1 mg	G	9107	04/01/2023	03/31/2026
J9063	J9063	Injection, mirvetuximab soravtansine-gynx, 1 mg	G	9109	04/01/2023	03/31/2026
J9347	J9347	Injection, tremelimumab-actl, 1 mg	G	9110	04/01/2023	03/31/2026
J9380	J9380	Injection, teclistamab-cqyv, 0.5 mg	G	9111	04/01/2023	03/31/2026
J9381	J9381	Injection, teplizumab-mzwv, 4 mcg	G	9112	04/01/2023	03/31/2026
J0218	J0218	Injection, olipudase alfa-rpcp, 1 mg	G	9113	04/01/2023	03/31/2026
J1411	J1411	Injection, etranacogene dezaparvovec-drlb, per therapeutic dose	G	9138	04/01/2023	03/31/2026
J1449	J1449	Injection, eflapegrastim-xnst, 0.1 mg	G	9114	04/01/2023	03/31/2026
J1747	J1747	Injection, spesolimab-sbzo, 1 mg	G	9115	04/01/2023	03/31/2026
J1954	J1954	Injection, leuprolide acetate for depot suspension (lutrate), 7.5 mg	G	9136	04/01/2023	03/31/2026
J2403	J2403	Chloroprocaine hcl ophthalmic, 3% gel, 1 mg	G	9116	04/01/2023	03/31/2026
Q5128	Q5128	Injection, ranibizumab-eqrn (cimerli), biosimilar, 0.1 mg	G	9117	04/01/2023	03/31/2026
Q5130	Q5130	Injection, pegfilgrastim-pbbk (fylnetra), biosimilar, 0.5 mg	G	9118	04/01/2023	03/31/2026

CY 2024 HCPCS Code	CY 2025 HCPCS Code	Long Descriptor	CY 2024 Status Indicator	CY 2024 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J2329	J2329	Injection, ublituximab-xiiy, 1 mg	G	9149	07/01/2023	6/30/2026
J1440	J1440	Fecal microbiota, live - jslm, 1 ml	G	9142	07/01/2023	6/30/2026
Q5129	Q5129	Injection, bevacizumab-adcd (vegzelma), biosimilar, 10 mg	G	9159	07/01/2023	6/30/2026
J9056	J9056	Injection, bendamustine hydrochloride (vivimusta), 1 mg	G	9154	07/01/2023	6/30/2026
J0208	J0208	Injection, sodium thiosulfate,100 mg	G	9119	07/01/2023	6/30/2026
J2781	J2781	Injection, pegcetacoplan, 1 mg	G	9158	07/01/2023	6/30/2026
J1961	J1961	Injection, lenacapavir, 1 mg	G	9155	07/01/2023	6/30/2026
J9350	J9350	Injection, mosunetuzumab-axgb, 1 mg	G	9150	07/01/2023	6/30/2026
J0402	J0402	Injection, aripiprazole, (abilify asimtufii), 1 mg	G	9246	10/01/2023	9/30/2026
J7214	J7214	Injection, factor viii/von willebrand factor complex, recombinant (altuviiio), per factor viii i.u.	G	9277	10/01/2023	9/30/2026
J0184	J0184	Injection, amisulpride, 1 mg	G	9247	10/01/2023	9/30/2026
J9058	J9058	Injection, bendamustine hydrochloride (apotex), 1 mg	G	9151	10/01/2023	9/30/2026
J0577	J0577	Injection, buprenorphine extended-release (brixadi), less than or equal to 7 days of therapy	G	0732	10/01/2023	9/30/2026
J0578	J0578	Injection, buprenorphine extended release (brixadi), greater than 7 days and up to 28 days of therapy	G	0733	10/01/2023	9/30/2026

CY 2024 HCPCS Code	CY 2025 HCPCS Code	Long Descriptor	CY 2024 Status Indicator	CY 2024 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J9321	J9321	Injection, epcoritamab-bysp, 0.1 mg	G	9250	10/01/2023	9/30/2026
A9608	A9608	Flotufolastat F 18, diagnostic, 1 millicurie	G	9254	10/01/2023	9/30/2026
J1304	J1304	Injection, tofersen, 1 mg	G	9262	10/01/2023	9/30/2026
J2799	J2799	Injection, risperidone, (uzedy), 1 mg	G	9266	10/01/2023	9/30/2026
J7353	J7353	Anacaulase-bcdb, 8.8% gel, 1 gram	G	0742	01/01/2024	12/31/2026
J3401	J3401	Beremagene geperpavec-svdt for topical administration, containing nominal 5 x 10^9 pfu/mL vector genomes, per 0.1 mL	G	0716	01/01/2024	12/31/2026
J7354	J7354	Cantharidin for topical administration, 0.7%, single unit dose applicator (3.2 mg)	G	0707	01/01/2024	12/31/2026
A9601	A9601	Flortaucipir f 18 injection, diagnostic, 1 millicurie	G	0709	01/01/2024	12/31/2026
J0177	J0177	Injection, aflibercept hd, 1 mg	G	0704	01/01/2024	12/31/2026
J2782	J2782	Injection, avacincaptad pegol, 0.1 mg	G	0705	01/01/2024	12/31/2026
J9072	J9072	Injection, cyclophosphamide, (dr. reddy's), 5 mg	G	0719	01/01/2024	12/31/2026
J0589	J0589	Injection, daxibotulinumtoxina-lanm, 1 unit	G	0703	01/01/2024	12/31/2026
J1413	J1413	Injection, delandistrogene moxeparvovec-rokl, per therapeutic dose	G	0714	01/01/2024	12/31/2026
J1323	J1323	Injection, elranatamab-bcmm, 1 mg	G	0708	01/01/2024	12/31/2026

CY 2024 HCPCS Code	CY 2025 HCPCS Code	Long Descriptor	CY 2024 Status Indicator	CY 2024 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J9286	J9286	Injection, glofitamab-gxbm, 2.5 mg	G	0720	01/01/2024	12/31/2026
J0174	J0174	Injection, lecanemab-irmb, 1 mg	G	9157	01/01/2024	12/31/2026
J2508	J2508	Injection, pegunigalsidase alfa-iwxj, 1 mg	G	0715	01/01/2024	12/31/2026
J7165	J7165	Injection, prothrombin complex concentrate, human-lans, per i.u. of factor ix activity	G	0702	01/01/2024	12/31/2026
J0349	J0349	Injection, rezafungin, 1 mg	G	9267	01/01/2024	12/31/2026
J9333	J9333	Injection, rozanolixizumab-noli, 1 mg	G	0721	01/01/2024	12/31/2026
J3055	J3055	Injection, talquetamab-tgvs, 0.25 mg	G	0706	01/01/2024	12/31/2026
J1412	J1412	Injection, valoctocogene roxaparvovec-rvox, per mL, containing nominal 2 × 10^13 vector genomes	G	0713	01/01/2024	12/31/2026
J0217	J0217	Injection, velmanase alfa-tycv, 1 mg	G	0710	01/01/2024	12/31/2026
J9029	J9029	Intravesical instillation, nadofaragene firadenovec-vncg, per therapeutic dose	G	0717	01/01/2024	12/31/2026
C9167	J7171	Injection, adamts13, recombinant-krhn, 10 iu	G	0727	04/01/2024	03/31/2027
J9248	J9248	Injection, melphalan (hepzato), 1 mg	G	0730	04/01/2024	03/31/2027
C9168	J2267	Injection, mirikizumab-mrkz, 1 mg	G	0728	04/01/2024	03/31/2027

CY 2024 HCPCS Code	CY 2025 HCPCS Code	Long Descriptor	CY 2024 Status Indicator	CY 2024 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J2277	J2277	Injection, motixafortide, 0.25 mg	G	0729	04/01/2024	03/31/2027
C9166	J3247	Injection, secukinumab, intravenous, 1 mg	G	0725	04/01/2024	03/31/2027
J3394	J3394	Injection, lovotibeglogene autotemcel, per treatment	G	0748	07/01/2024	06/30/2027
J3393	J3393	Injection, betibeglogene autotemcel, per treatment	G	0746	07/01/2024	06/30/2027
J3263	J3263	Injection, toripalimab-tpzi, 1 mg	G	0745	07/01/2024	06/30/2027
J0911	J0911	Instillation, taurolidine 1.35 mg and heparin sodium 100 units (central venous catheter lock for adult patients receiving chronic hemodialysis)	G	0744	07/01/2024	06/30/2027
J7355	J7355	Injection, travoprost, intracameral implant, 1 microgram	G	0749	07/01/2024	06/30/2027
A9506	A9506	Graphite crucible for preparation of technetium Tc 99m-labeled carbon aerosol, each	G	0760	07/01/2024	06/30/2027
C9172	J1414	Injection, fidanacogene elaparvovec-dzkt, per therapeutic dose	G	0773	10/01/2024	09/30/2027
C9169	J9028	Injection, nogapendekin alfa inbakicept-pmln, for intravesical use, 1 microgram	G	0767	10/01/2024	09/30/2027
J9345	J9345	Injection, retifanlimab-dlwr, 1 mg	G	9280	10/01/2024	09/30/2027
Q5133	Q5133	Injection, tocilizumab-bavi (tofidence), biosimilar, 1 mg	G	0786	10/01/2024	09/30/2027
Q5135	Q5135	Injection, tocilizumab-aazg (tyenne), biosimilar, 1 mg	G	0784	10/01/2024	09/30/2027

CY 2024 HCPCS Code	CY 2025 HCPCS Code	Long Descriptor	CY 2024 Status Indicator	CY 2024 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
C9170	J9026	Injection, tarlatamab-dlle, 1 mg	G	0768	10/01/2024	09/30/2027
J9172	J9172	Injection, docetaxel (docivyx), 1 mg	G	0757	10/01/2024	09/30/2027
J9324	J9324	Injection, pemetrexed (pemrydi rtu), 10 mg	G	0782	10/01/2024	09/30/2027
J1434	J1434	Injection, fosaprepitant (focinvez), 1 mg	G	0761	10/01/2024	09/30/2027
J1203	J1203	Injection, cipaglucosidase alfa-atga, 5 mg	G	0737	10/01/2024	09/30/2027
C9171	A9615	Injection, pegulicianine, 1 mg	G	0772	10/01/2024	09/30/2027
A9697	A9697	Injection, carboxydextran-coated superparamagnetic iron oxide, per study dose	G	0814	01/01/2025	12/31/2027
N/A	C9173	Injection, filgrastim-txid (nypozi), biosimilar, 1 microgram	G	0811	01/01/2025	12/31/2027
J0175	J0175	Injection, donanemab-azbt, 2 mg	G	0765	01/01/2025	12/31/2027
N/A	J0870	Injection, imetelstat, 1 mg	G	0813	01/01/2025	12/31/2027
J2468	J2468	Injection, palonosetron hydrochloride (posfrea), 25 micrograms	G	0815	01/01/2025	12/31/2027
J9329	J9329	Injection, tislelizumab-jsgr, 1mg	G	0816	01/01/2025	12/31/2027

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We did not receive any public comments on our proposal to continue pass-through payment status in CY 2025 for 80 drugs and biologicals and we are finalizing it as proposed. Additionally, we are finalizing our proposal to continue our policy to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through payment status based on the ASP methodology.

B. OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Payment Status

1. Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals

a. Packaging Threshold

In accordance with section 1833(t)(16)(B) of the Act, the threshold for establishing separate APCs for payment of drugs and biologicals was set to $50 per administration during CYs 2005 and 2006. In CY 2007, we used the four-quarter moving average Producer Price Index (PPI) levels for Pharmaceutical Preparations (Prescription) to trend the $50 threshold forward from the third quarter of CY 2005 (when the Pub. L. 108–173 mandated threshold became effective) to the third quarter of CY 2007. We then rounded the resulting dollar amount to the nearest $5 increment in order to determine the CY 2007 threshold amount of $55. Using the same methodology as that used in CY 2007 (which is discussed in more detail in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68085 through 68086)), we set the packaging threshold for establishing separate APCs for drugs and biologicals at $135 for CY 2024 (88 FR 81776 through 81777).

Following the CY 2007 methodology, for the CY 2025 OPPS/ASC proposed rule, we used the most recently available four quarter moving average PPI levels to trend the $50 threshold forward from the third quarter of CY 2005 to the third quarter of CY 2025 and round the resulting dollar amount ($140.81) to the nearest $5 increment, which yielded a figure of $140. In performing this calculation, we used the most recent forecast of the quarterly index levels for the PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics series code WPUSI07003) from IGI. IGI is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the various price indexes including the PPI Pharmaceuticals for Human Use (Prescription). Based on these calculations using the CY 2007 OPPS methodology, we proposed a packaging threshold for CY 2025 of $140 for drugs, biologicals, and therapeutic radiopharmaceuticals.

We proposed in section II.A.3.c of the CY 2025 OPPS/ASC proposed rule (89 FR 59213 through 59222) to pay separately for diagnostic radiopharmaceuticals with a per-day cost above the proposed packaging threshold for CY 2025 of $630. We also proposed that starting in CY 2026 and subsequent years, we would update this threshold by the PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics series code WPUSI07003) from IHS Global, Inc (IGI). For the diagnostic radiopharmaceutical packaging threshold, we proposed to use the same methodology as that used in CY 2007 (which is discussed in more detail in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68085 and 68086)) to calculate the update to the OPPS drug packaging threshold. Specifically, we proposed that starting for the CY 2026 rulemaking, we would use the most recently available four quarter moving average PPI levels to trend the final CY 2025 threshold forward from the third quarter of CY 2024 to the third quarter of CY 2025 and round the resulting dollar amount to the nearest $5 increment. We refer readers to section II.A.3.c.(4) of the CY 2025 OPPS/ASC proposed rule for information regarding our proposal to update the proposed diagnostic radiopharmaceutical packaging threshold in future years. We refer readers to section II.A.3.c of this final rule with comment period for additional details on our proposal to provide for separate payment for certain diagnostic radiopharmaceuticals, the comments we received on the proposal, and our final policy regarding separate payment for certain diagnostic radiopharmaceuticals in CY 2025.

We received no comments on our proposal to increase the drug packaging threshold to $140. We are finalizing our proposal without modification to apply a drug packaging threshold of $140 for CY 2025.

b. Packaging of Payment for HCPCS Codes That Describe Certain Drugs, Certain Biologicals, and Certain Radiopharmaceuticals Under the Cost Thresholds

To determine the proposed CY 2025 packaging status for all nonpass-through drugs, biologicals, diagnostic and therapeutic radiopharmaceuticals that are not policy packaged, we calculated, on a HCPCS code-specific basis, the per day cost of all drugs, biologicals, and therapeutic radiopharmaceuticals that had a HCPCS code in CY 2023 and were paid (via packaged or separate payment) under the OPPS. We used data from CY 2023 claims processed through December 31, 2023, for this calculation. However, we did not perform this calculation for those drugs and biologicals with multiple HCPCS codes that include different dosages, as described in section V.B.1.d of this final rule with comment period, or for the following policy-packaged items that we propose to continue to package in CY 2025: anesthesia drugs; drugs, biologicals, and contrast agents and other drugs that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure. Consistent with our policy described in section V.B.5, in situations where we have no claims data and must determine if these products exceed the per-day cost threshold, we estimated the average number of units of each product that would typically be furnished to a patient during one day in the hospital outpatient setting and utilized the ASP methodology to determine whether their payment will be packaged as well as their payment status indicators.

In order to calculate the per day costs for drugs, biologicals, diagnostic radiopharmaceuticals, and therapeutic radiopharmaceuticals to determine their proposed packaging status in CY 2025, we used the methodology that was described in detail in the CY 2006 OPPS proposed rule (70 FR 42723 through 42724) and finalized in the CY 2006 OPPS final rule with comment period (70 FR 68636 through 68638). For each drug and biological HCPCS code, we used an estimated payment rate based on the ASP methodology, which is generally ASP plus 6 percent (which is the payment rate we proposed for separately payable drugs and biologicals for CY 2025, as discussed in more detail in section V.A.1 of this final rule with comment period) to calculate the CY 2025 proposed rule per day costs. We used the manufacturer-submitted ASP data from the fourth quarter of CY 2023 (data that were used for payment purposes in the physician's office setting, effective April 1, 2024) to determine the CY 2025 OPPS/ASC proposed rule per day cost.

As is our standard methodology, for CY 2025, we proposed to use payment rates based on the ASP data from the fourth quarter of CY 2023 for budget neutrality estimates, packaging determinations, impact analyses, and completion of Addenda A and B to the

CY 2025 OPPS/ASC proposed rule (which are available via the internet on the CMS website) because these are the most recent data available for use at the time of development of the CY 2025 OPPS/ASC proposed rule. These data also are the basis for drug payments in the physician's office setting, effective April 1, 2024. Exceptions to our standard methodology include:

- For therapeutic radiopharmaceuticals that do not have pass-through status as of October 1, 2024, and do not have an ASP-based payment rate, we did not use a payment rate based on WAC or AWP for those items, consistent with our policy described in section V.B.3.a of the CY 2025 OPPS/ASC proposed rule. We used their mean unit cost derived from the CY 2023 hospital claims data to determine their per day cost.
- For diagnostic radiopharmaceuticals that do not have pass-through status as of October 1, 2024, we used their mean unit cost derived from the CY 2023 hospital claims data to determine their per day cost. We did not use an ASP-based, WAC-based, or AWP-based payment rate for those items unless there was no mean unit cost reported for the product, consistent with our proposed policy described in section V.B.3.b of the CY 2025 OPPS/ASC proposed rule.
- For items other than diagnostic or therapeutic radiopharmaceuticals that did not have either an ASP-based payment rate, a payment rate based on WAC, or a payment rate based on AWP, we used mean unit cost of the items derived from the CY 2023 hospital claims data to determine their per day cost.

We proposed to package drugs, biologicals, and therapeutic radiopharmaceuticals with a per day cost less than or equal to $140 and identify items with a per day cost greater than $140 as separately payable unless they are policy-packaged. For diagnostic radiopharmaceuticals, we propose to package those items with a per day cost less than or equal to $630 and identify items with a per day cost greater than $630 as separately payable. Consistent with our past practice, we cross-walked historical OPPS claims data from the CY 2023 HCPCS codes that were reported to the CY 2023 HCPCS codes that we display in Addendum B to the CY 2025 OPPS/ASC proposed rule (which is available on the CMS website) [138] for proposed payment in CY 2025.

[138] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

Our policy during previous cycles of OPPS rulemaking has been to use updated ASP and claims data to make final determinations of the packaging status of HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals for the OPPS/ASC final rule with comment period. We note that it is also our policy to make an annual packaging determination for a HCPCS code only when we develop the OPPS/ASC final rule with comment period for the update year. Only HCPCS codes that are identified as separately payable in the final rule with comment period are subject to quarterly updates. For our calculation of per day costs of HCPCS codes for drugs, biologicals, and radiopharmaceuticals in the CY 2025 OPPS/ASC proposed rule, we proposed to use ASP data from the fourth quarter of CY 2023, which is the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective April 1, 2024, along with updated hospital claims data from CY 2023. We note that we also proposed to use these data for budget neutrality estimates and impact analyses for the CY 2025 OPPS/ASC proposed rule.

Payment rates for HCPCS codes for separately payable drugs and biologicals included in Addenda A and B of this CY 2025 OPPS/ASC final rule with comment period are based on ASP data from the second quarter of CY 2024. These data are the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective October 1, 2024. These payment rates would then be updated in the January 2025 OPPS update, based on the most recent ASP data to be used for physicians' office and OPPS payment as of January 1, 2025. For drugs and biologicals that do not currently have a payment rate based on ASP, WAC, or AWP, for therapeutic radiopharmaceuticals that do not currently have an ASP payment rate, and for all diagnostic radiopharmaceuticals, we calculated their mean unit cost from all of the CY 2023 claims data and updated cost report information available for this final rule with comment period to determine their final per day cost.

All the comments we received regarding calculating per-day costs of drugs, biologicals, and radiopharmaceuticals pertained to our proposal to provide for separate payment for certain diagnostic radiopharmaceuticals for CY 2025. We address comments on the proposal in section II.A.3.c., where we are finalizing our proposal regarding calculating the per-day cost of diagnostic radiopharmaceuticals for purposes of determining eligibility for separate payment as proposed. We refer readers to section II.A.3.c of this final rule with comment period for a summary of the comments we received, our responses, and our final policy regarding separate payment for certain diagnostic radiopharmaceuticals in CY 2025.

After consideration of the public comments we received, we are finalizing our proposal regarding the calculation of per day costs of drugs, biologicals, therapeutic radiopharmaceuticals, and diagnostic radiopharmaceuticals without modification.

Because we use updated data to determine the packaging status of HCPCS codes for drugs, biologicals and radiopharmaceuticals for this final rule with comment period, the packaging status of some HCPCS codes for drugs, biologicals, and radiopharmaceuticals in this final rule with comment period may differ from the same HCPCS codes' packaging status determined based on the data used for proposed rule. Under such circumstances, we propose to continue to follow the established policies initially adopted for the CY 2005 OPPS (69 FR 65780) in order to more equitably pay for those drugs whose costs fluctuate relative to the proposed CY 2025 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2024. These established policies have not changed for many years and are the same as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70434). Specifically, for CY 2025 and subsequent years, consistent with our historical practice, we proposed to apply the following policies to those HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals whose relationship to the drug packaging threshold changes based on the updated drug packaging threshold and on the final updated data:

- HCPCS codes for drugs, biologicals, and radiopharmaceuticals that were paid separately in CY 2024 and that are proposed for separate payment in CY 2025, and that then have per day costs equal to or less than the CY 2025 final rule drug packaging threshold or diagnostic radiopharmaceutical packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2025 final rule, would continue to receive separate payment in CY 2025.
- HCPCS codes for drugs, biologicals, and radiopharmaceuticals that were packaged in CY 2024 and that are proposed for separate payment in CY 2025, and that then have per day costs

equal to or less than the CY 2025 final rule drug packaging threshold or diagnostic radiopharmaceutical packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2025 final rule, would remain packaged in CY 2025.

- HCPCS codes for drugs, biologicals, and radiopharmaceuticals for which we proposed packaged payment in CY 2025 but that then have per-day costs greater than the CY 2025 final rule drug packaging threshold or diagnostic radiopharmaceutical packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2025 final rule, would receive separate payment in CY 2025.

We did not receive any public comments on our proposal and are finalizing it without modification.

c. Policy-Packaged Drugs, Biologicals, and Radiopharmaceuticals

As mentioned earlier in this section, under the OPPS, we package several categories of nonpass-through drugs, biologicals, and radiopharmaceuticals, regardless of the cost of the products. Because the products are packaged according to the policies in 42 CFR 419.2(b), we refer to these packaged drugs, biologicals, and radiopharmaceuticals as ''policy-packaged'' drugs, biologicals, and radiopharmaceuticals. These policies are either longstanding or based on longstanding principles and inherent to the OPPS and are as follows:

- Anesthesia, certain drugs, biologicals, and other pharmaceuticals; medical and surgical supplies and equipment; surgical dressings; and devices used for external reduction of fractures and dislocations (§ 419.2(b)(4));
- Intraoperative items and services (§ 419.2(b)(14));
- Drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including but not limited to, diagnostic radiopharmaceuticals,[139] contrast agents, and pharmacologic stress agents) (§ 419.2(b)(15)); and
- Drugs and biologicals that function as supplies when used in a surgical procedure (including, but not limited to, skin substitutes and similar products that aid wound healing and implantable biologicals) (§ 419.2(b)(16)).

The policy at § 419.2(b)(16) is broader than the policy at § 419.2(b)(14). As we stated in the CY 2015 OPPS/ASC final rule with comment period: ''We consider all items related to the surgical outcome and provided during the hospital stay in which the surgery is performed, including postsurgical pain management drugs, to be part of the surgery for purposes of our drug and biological surgical supply packaging policy'' (79 FR 66875). The category described by § 419.2(b)(15) is large and includes diagnostic radiopharmaceuticals that have a per day cost below the finalized diagnostic radiopharmaceutical packaging threshold that we discuss in section II.A.3 of this CY 2025 OPPS/ASC final rule,[140] contrast agents, stress agents, and some other products. The category described by § 419.2(b)(16) includes skin substitutes and some other products. We believe it is important to reiterate that cost consideration is not a factor when determining whether an item is a surgical supply (79 FR 66875).

Comment: One commenter recommended that CMS continue to apply radiolabeled product edits to the nuclear medicine procedures to ensure that all packaged costs are included on nuclear medicine claims in order to establish appropriate payment rates in the future. The commenter was concerned that many providers performing nuclear medicine procedures are not including the cost of diagnostic radiopharmaceuticals used for the procedures in their claim submissions. The commenter believes this lack of drug cost reporting could be causing the cost of nuclear medicine procedures to be underreported and therefore requested that the radiolabeled product edits be reinstated. The commenter believes that after more than ten years without the radiolabeled product edits in place providers may not be as knowledgeable about ensuring radiolabeled products are reported with nuclear medicine procedures. The commenter believes reinstating the edits will improve billing accuracy.

Response: We appreciate the commenter's feedback; however, we are not reinstating the radiolabeled product edits for nuclear medicine procedures, which required a diagnostic radiopharmaceutical to be present on the same claim as a nuclear medicine procedure for payment to be made under the OPPS. As previously discussed in the CY 2020 OPPS/ASC final rule with comment period (85 FR 86033 and 86034), the edits were in place between CY 2008 and CY 2014 (78 FR 75033). We believe the period of time in which the edits were in place was sufficient for hospitals to gain experience reporting procedures involving radiolabeled products and to become accustomed to ensuring that they code and report charges so that their claims fully and appropriately reflect the costs of those radiolabeled products. As with all other items and services recognized under the OPPS, we expect hospitals to code and report their costs appropriately, regardless of whether there are claims processing edits in place.

We welcome ongoing dialogue and engagement from interested parties regarding suggestions for payment changes for consideration in future rulemaking.

d. Packaging Determination for HCPCS Codes That Describe the Same Drug or Biological but Different Dosages

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60490 through 60491), we finalized a policy to make a single packaging determination for a drug, rather than an individual HCPCS code, when a drug has multiple HCPCS codes describing different dosages because we believe that adopting the standard HCPCS code-specific packaging determinations for these codes could lead to inappropriate payment incentives for hospitals to report certain HCPCS codes instead of others. We continue to believe that making packaging determinations on a drug-specific basis eliminates payment incentives for hospitals to report certain HCPCS codes for drugs and allows hospitals flexibility in choosing to report all HCPCS codes for different dosages of the same drug or only the lowest dosage HCPCS code. Therefore, we proposed to continue our policy to make packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, for those HCPCS codes that describe the same drug or biological but different dosages in CY 2025.

In order to propose a packaging determination that is consistent across all HCPCS codes that describe different dosages of the same drug or biological, we aggregated both our CY 2023 claims data and our pricing information, which is based on the ASP methodology,

[139] In this rule we adopt a policy to pay separately beginning in CY 2025 for diagnostic radiopharmaceuticals with per-day costs above a threshold. This category of policy-packaged drugs that function as supplies in a diagnostic test or procedure would include diagnostic radiopharmaceuticals with per-day costs at or below the threshold for the applicable year. Please refer to section II.A.3.c. for more information regarding this policy.

[140] In section II.A.3 of this rule, we adopt a policy to pay separately for diagnostic radiopharmaceuticals with per-day costs above a d threshold. This category of policy-packaged drugs that function as supplies in a diagnostic test or procedure includes diagnostic radiopharmaceuticals with per-day costs below the threshold for the applicable year. Please refer to section II.A.3.c. for more information regarding this policy.

generally ASP plus 6 percent, across all of the HCPCS codes that describe each distinct drug or biological in order to determine the mean units per day of the drug or biological in terms of the HCPCS code with the lowest dosage descriptor. The following drugs did not have pricing information available for the ASP methodology for the CY 2025 OPPS/ASC proposed rule; and, as is our current policy for determining the packaging status of other drugs, we used the mean unit cost available from the CY 2023 claims data to make the proposed packaging determinations for them: HCPCS code C9257 (Injection, bevacizumab, 0.25 mg); HCPCS code J3471 (injection, hyaluronidase, ovine, preservative free, per 1 usp unit (up to 999 usp units)); HCPCS code J3472 (Injection, hyaluronidase, ovine, preservative free, per 1000 usp units); HCPCS code J7100 (Infusion, dextran 40,500 ml); and HCPCS code J7110 (Infusion, dextran 75,500 ml).

For all other drugs and biologicals that have HCPCS codes describing different doses, we then multiplied the proposed weighted average ASP methodology based payment rate, which is generally ASP plus 6 percent, per-unit payment amount across all dosage levels of a specific drug or biological by the estimated units per day for all HCPCS codes that describe each drug or biological from our claims data to determine if the estimated per day cost of each drug or biological is less than or equal to the proposed CY 2025 drug packaging threshold of $140 (in which case all HCPCS codes for the same drug or biological would be packaged) or greater than the proposed CY 2025 drug packaging threshold of $140 (in which case all HCPCS codes for the same drug or biological would be separately payable). The proposed packaging status of each drug and biological HCPCS code to which this methodology would apply in CY 2025 is displayed in Table 133.

TABLE 133: HCPCS CODES TO WHICH THE CY 2025 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY APPLIES

CY 2025 HCPCS Code	CY 2025 Long Descriptor	CY 2025 Status Indicator (SI)
C9257	Injection, bevacizumab, 0.25 mg	K
J9035	Injection, bevacizumab, 10 mg	K
J1460	Injection, gamma globulin, intramuscular, 1 cc	K
J1560	Injection, gamma globulin, intramuscular over 10 cc	K
J1642	Injection, heparin sodium, (heparin lock flush), per 10 units	N
J1644	Injection, heparin sodium, per 1000 units	N
J2788	Injection, rho d immune globulin, human, minidose, 50 micrograms (250 i.u.)	N
J2790	Injection, rho d immune globulin, human, full dose, 300 micrograms (1500 i.u.)	N
J3471	Injection, hyaluronidase, ovine, preservative free, per 1 usp unit (up to 999 usp units)	N
J3472	Injection, hyaluronidase, ovine, preservative free, per 1000 usp units	N
J7030	Infusion, normal saline solution, 1000 cc	N
J7040	Infusion, normal saline solution, sterile (500 ml=1 unit)	N
J7050	Infusion, normal saline solution, 250 cc	N
J7100	Infusion, dextran 40, 500 ml	N
J7110	Infusion, dextran 75, 500 ml	N
J7515	Cyclosporine, oral, 25 mg	N
J7502	Cyclosporine, oral, 100 mg	N

We proposed that our policy to make packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, for those HCPCS codes that describe the same drug or biological but different dosages in CY 2025 would also apply to diagnostic radiopharmaceuticals. In order to propose a packaging determination that is consistent across all HCPCS codes that describe different dosages of the same diagnostic radiopharmaceutical, we would aggregate our CY 2023 claims data across all of the HCPCS codes that describe each distinct diagnostic radiopharmaceutical in order to determine the mean units per day of the diagnostic radiopharmaceutical in terms of the HCPCS code with the lowest dosage descriptor. We would then analyze the aggregate per day cost of the

diagnostic radiopharmaceutical to determine if the per day cost is less than or equal to the proposed CY 2025 diagnostic radiopharmaceutical packaging threshold of $630 (in which case all HCPCS codes for the same diagnostic radiopharmaceutical would be packaged) or greater than the proposed CY 2025 diagnostic radiopharmaceutical packaging threshold of $630 (in which case all HCPCS codes for the same diagnostic radiopharmaceutical would be separately payable). There are currently no diagnostic radiopharmaceuticals that this policy would apply to.

We did not receive any public comments on our proposal and are finalizing it without modification.

2. Payment for Drugs and Biologicals Without Pass-Through Status That Are Not Packaged

a. Payment for Specified Covered Outpatient Drugs (SCODs) and Other Separately Payable Drugs and Biologicals

Section 1833(t)(14) of the Act defines certain separately payable radiopharmaceuticals, drugs, and biologicals and mandates specific payments for these items. Under section 1833(t)(14)(B)(i) of the Act, a ''specified covered outpatient drug'' (known as a SCOD) is defined as a covered outpatient drug, as defined in section 1927(k)(2) of the Act, for which a separate APC has been established and that either is a radiopharmaceutical agent or a drug or biological for which payment was made on a pass-through basis on or before December 31, 2002.

Under section 1833(t)(14)(B)(ii) of the Act, certain drugs and biologicals are designated as exceptions and are not included in the definition of SCODs. These exceptions are—

- A drug or biological for which payment is first made on or after January 1, 2003, under the transitional pass-through payment provision in section 1833(t)(6) of the Act.
- A drug or biological for which a temporary HCPCS code has not been assigned.
- During CYs 2004 and 2005, an orphan drug (as designated by the Secretary).

Section 1833(t)(14)(A)(iii) of the Act requires that payment for SCODs in CY 2006 and subsequent years be equal to the average acquisition cost for the drug for that year as determined by the Secretary, subject to any adjustment for overhead costs and considering the hospital acquisition cost survey data collected by the Government Accountability Office (GAO) in CYs 2004 and 2005, and later periodic surveys conducted by the Secretary as set forth in the statute. If hospital acquisition cost data are not available, the law requires that payment be equal to payment rates established under the methodology described in section 1842(o), section 1847A, or section 1847B of the Act, as calculated and adjusted by the Secretary as necessary for purposes of paragraph (14). We refer to this alternative methodology as the ''statutory default.'' Most physician Part B drugs are paid at ASP plus 6 percent in accordance with section 1842(o) and section 1847A of the Act.

Section 1833(t)(14)(E)(ii) of the Act provides for an adjustment in OPPS payment rates for SCODs to consider overhead and related expenses, such as pharmacy services and handling costs. Section 1833(t)(14)(E)(i) of the Act required MedPAC to study pharmacy overhead and related expenses and to make recommendations to the Secretary regarding whether, and if so how, a payment adjustment should be made to compensate hospitals for overhead and related expenses. Section 1833(t)(14)(E)(ii) of the Act authorizes the Secretary to adjust the weights for ambulatory procedure classifications for SCODs to consider the findings of the MedPAC study.[141]

It has been our policy since CY 2006 to apply the same treatment to all separately payable drugs and biologicals, which include SCODs, and drugs and biologicals that are not SCODs. Therefore, we apply the payment methodology in section 1833(t)(14)(A)(iii) of the Act to SCODs, as required by statute, but we also apply it to separately payable drugs and biologicals that are not SCODs, which is a policy determination rather than a statutory requirement. For CY 2023 and subsequent years, we finalized a policy to apply section 1833(t)(14)(A)(iii)(II) of the Act to all separately payable drugs and biologicals, including SCODs. Although we do not distinguish SCODs in this discussion, we note that we are required to apply section 1833(t)(14)(A)(iii)(II) of the Act to SCODs; but we also are applying this provision to other separately payable drugs and biologicals, consistent with our history of using the same payment methodology for all separately payable drugs and biologicals.

For a detailed discussion of our OPPS drug payment policies from CY 2006 to CY 2012, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68383 through 68385). In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68386 through 68389), we first adopted the statutory default policy to pay for separately payable drugs and biologicals at ASP plus 6 percent based on section 1833(t)(14)(A)(iii)(II) of the Act. We have continued this policy of paying for separately payable drugs and biologicals at the statutory default for CYs 2014 through 2024.

In the case of a drug or biological during an initial sales period in which data on the prices for sales of the drug or biological are not sufficiently available from the manufacturer, section 1847A(c)(4) of the Act permits the Secretary to make payments that are based on WAC. Under section 1833(t)(14)(A)(iii)(II) of the Act, the amount of payment for a separately payable drug equals the average price for the drug for the year established under, among other authorities, section 1847A of the Act. As explained in greater detail in the CY 2019 PFS final rule, under section 1847A(c)(4) of the Act, although payments may be based on WAC, unlike section 1847A(b) of the Act (which specifies that payments using ASP or WAC must be made with a 6 percent add-on), section 1847A(c)(4) of the Act does not require that a particular add-on amount be applied to WAC-based pricing for this initial period when ASP data are not available. Consistent with section 1847A(c)(4) of the Act, in the CY 2019 PFS final rule (83 FR 59661 to 59666), we finalized a policy that, effective January 1, 2019, WAC-based payments for Part B drugs made under section 1847A(c)(4) of the Act will utilize a 3-percent add-on in place of the 6 percent add-on that was being used according to our policy in effect as of CY 2018. For the CY 2019 OPPS, we followed the same policy finalized in the CY 2019 PFS final rule (83 FR 59661 to 59666). Since CY 2020, we have continued to utilize a 3 percent add-on instead of a 6 percent add-on for drugs that are paid based on WAC pursuant to our authority under section 1833(t)(14)(A)(iii)(II) of the Act (84 FR 61318 and 85 FR 86039), which provides, in part, that the amount of payment for a SCOD is the average price of the drug in the year established under section 1847A of the Act. We also apply this provision to non-SCOD separately payable drugs. Because we establish the average price for a drug paid based on WAC under section 1847A of the Act as

[141] Medicare Payment Advisory Committee. June 2005 Report to the Congress. Chapter 6: Payment for pharmacy handling costs in hospital outpatient departments. Available at: *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/June05_ch6.pdf.*

WAC plus 3 percent instead of WAC plus 6 percent, we believe it is appropriate to price separately payable drugs paid based on WAC at the same amount under the OPPS. Our policy to pay for drugs and biologicals at WAC plus 3 percent, rather than WAC plus 6 percent, applies whenever WAC-based pricing is used for a drug or biological under section 1847A(c)(4). We refer readers to the CY 2019 PFS final rule (83 FR 59661 to 59666) for additional background on this policy.

Consistent with our current policy, payments for separately payable drugs and biologicals are included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act. Also, the budget neutral weight scalar is not applied in determining payments for these separately payable drugs and biologicals.

Separately payable drug, biological, and radiopharmaceutical payment rates are listed in Addenda A and B to the CY 2025 OPPS/ASC proposed rule (available on the CMS website).[142] These addenda provide the proposed CY 2025 payment rates based on the ASP methodology for separately payable nonpass-through drugs, biologicals, and radiopharmaceuticals and the ASP methodology for pass-through drugs, biologicals, and radiopharmaceuticals. Except for proposed payment rates for radiopharmaceuticals, these rates are based either on ASP information that is the basis for calculating payment rates for drugs and biologicals in the physician's office setting effective April 1, 2024, or WAC, AWP, or mean unit cost from CY 2023 claims data and updated cost report information available for the CY 2025 OPPS/ASC proposed rule. For nonpass-through therapeutic radiopharmaceuticals, payment rates are based on ASP data or mean unit cost. We proposed in section II.A.3.c.(5) to pay separately at mean unit cost for diagnostic radiopharmaceuticals with per day costs above the proposed threshold; the payment rates proposed for qualifying diagnostic radiopharmaceuticals are entirely mean unit cost. In general, these published proposed payment rates are not the same as the actual January 2025 payment rates. This is because payment rates for drugs, biologicals, and therapeutic radiopharmaceuticals with ASP information for January 2025 will be determined through the standard quarterly process where ASP data submitted by manufacturers for the third quarter of CY 2024 (July 1, 2024, through September 30, 2024) will be used to set the payment rates that are released for the quarter beginning in January 2025 in December 2024. In addition, in Addenda A and B to the CY 2025 OPPS/ASC proposed rule, payment rates for drugs, biologicals, and therapeutic radiopharmaceuticals for which there was no ASP, WAC, or AWP information available for April 2024, as well as all separately payable diagnostic radiopharmaceuticals, are based on mean unit cost in the available CY 2023 claims data. If new pricing information becomes available for payment for the quarter beginning in January 2025, we will price payment for these drugs, biologicals, therapeutic radiopharmaceuticals, and diagnostic radiopharmaceuticals based on their newly available information. Finally, there may be drugs, biologicals and therapeutic radiopharmaceuticals that have ASP, WAC, or AWP information available for the proposed rule (reflecting April 2024 ASP data) that do not have ASP, WAC, or AWP information available for the quarter beginning in January 2025. These drugs, biologicals and therapeutic radiopharmaceuticals would then be paid based on mean unit cost data derived from CY 2023 hospital claims. Therefore, the proposed payment rates listed in Addenda A and B to the CY 2025 OPPS/ASC proposed rule are not for January 2025 payment purposes and are only illustrative of the CY 2025 OPPS payment methodology using the most recently available information at the time of issuance of the CY 2025 OPPS/ASC proposed rule.

We note that payment amounts for most drugs separately payable under Medicare Part B are determined using the methodology in section 1847A of the Act, and in many cases, payment is based on the average sales price (ASP) plus a statutorily mandated 6 percent add-on.

For CY 2025, we proposed to clarify that only ASP data or, if ASP data are not available, mean unit cost data, would be used to set payment rates for separately payable nonpass-through therapeutic radiopharmaceuticals under the OPPS as described further in section V.B.3.a of the proposed rule. We proposed for CY 2025 to use mean unit cost data to set payment rates for separately payable nonpass-through diagnostic radiopharmaceuticals for which we propose separate payment because their cost exceeds the per-day threshold. Otherwise, we are not proposing any changes to our policies for payment for separately payable drugs and biologicals; and we propose to continue our payment policy that has been in effect since CY 2013 to pay for separately payable drugs and biologicals in accordance with section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default).

Most of the comments we received regarding our proposed policy for separately payable drugs, biologicals, and radiopharmaceuticals pertained to our proposal to pay separately for certain diagnostic radiopharmaceuticals in CY 2025. We refer readers to section II.A.3.c of this final rule with comment period for a summary of the comments we received, our responses to those comments, and our final policy for separate payment for certain diagnostic radiopharmaceuticals in CY 2025.

Comment: Multiple commenters expressed their approval for our proposal to pay separately payable for drugs and biologicals, but not radiopharmaceuticals, at ASP plus 6 percent. One commenter supported our proposal to continue to pay for new non-pass-through Part B drugs and biologicals during an initial sales period (two quarters) for which ASP pricing data are not yet available at a rate of wholesale acquisition cost (WAC) plus 3%. The commenter also supported our proposal that if ASP and WAC data are unavailable, Medicare would pay 95% of the average wholesale price (AWP).

Response: We appreciate the commenters' support for our policies.

After consideration of the public comments we received, we are finalizing without modification our proposals regarding the payment methodology for separately payable drugs, biologicals, and radiopharmaceuticals.

b. Biosimilar Biological Products

For CY 2024, we finalized the exception of biosimilars from the OPPS threshold packaging policy when their reference products are separately paid (88 FR 81783 through 81785). This policy allows for separate payment for biosimilars even if the biosimilar's per-day cost is below the packaging threshold if the biosimilar's reference product is separately paid. This policy removes the financial incentive to use a more expensive separately payable biological and promotes biosimilar use as a lower cost alternative to higher cost reference products.

Payment rates for drugs and biologicals (including biosimilars) under Medicare Part B are determined using the methodology in section 1847A of the Act, and in many cases, payment is based on the average sales price (ASP) plus a statutorily mandated 6 percent add-on. Additionally, Section 11403 of the IRA requires that a qualifying

[142] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

biosimilar be paid at ASP plus 8 percent of the reference product's ASP rather than 6 percent during the applicable 5-year period. Section 1847A(b)(8)(B)(ii) of the Act defines the applicable 5-year period for a qualifying biosimilar for which payment has been made using ASP (that is, payment under section 1847A(b)(8) of the Act) as of September 30, 2022, as the 5-year period beginning on October 1, 2022. For a qualifying biosimilar for which payment is first made using ASP during the period beginning October 1, 2022, and ending December 31, 2027, the statute defines the applicable 5-year period as the 5-year period beginning on the first day of such calendar quarter of such payment (88 FR 81783). These payment rates are published in the quarterly release of Addendum B or ASP pricing files.

c. Invoice Drug Pricing for CY 2026

In recent years there has been an increasing number of drug and biological HCPCS codes for which ASP, WAC, AWP, and mean unit cost information is not available. These are often HCPCS codes for new drugs or biologicals that have been approved for marketing, but for which the manufacturer does not have sales data, and WAC, AWP, and mean unit cost information is not available. As a result, we are unable to assign a payable status indicator to these drugs or biologicals due to a lack of payment data. The numbers of drug and biological HCPCS codes without payment rates from Addendum B for the CY 2022 through CY 2024 OPPS/ASC final rules with comment period are listed in Table 134.

TABLE 134: NUMBER OF DRUG AND BIOLOGICAL HCPCS CODES WITHOUT PAYMENT INFORMATION FOR CY 2022 TO CY 2024

	CY 2022 Final Rule	CY 2023 Final Rule	CY 2024 Final Rule
Number of drug and biological HCPCS codes without payment information	77	85	109

To provide appropriate payment rates for these drugs and biologicals without pricing data, we proposed to adopt an invoice pricing policy beginning in CY 2026. Because this policy necessitates significant operational changes to implement, we proposed to implement it beginning in CY 2026, rather than CY 2025. For CY 2025, we proposed that the affected drugs and biologicals would continue to be assigned a non-payable status indicator until we implement our invoice pricing policy, if adopted. We believe invoice pricing is appropriate for use under the OPPS because it provides temporary drug or biological cost information to generate a representative payment rate for a drug or biological and supports the utilization of new drug or biological HCPCS codes. Otherwise, the new drug and biological HCPCS codes would not receive payment under the OPPS, which would discourage their use by providers. Currently, the Physician Fee Schedule utilizes invoice pricing for drugs and biologicals when other types of pricing information are not available.

We proposed that, for separately payable drugs or biologicals for which CMS does not provide a payment rate in Addendum B, which would indicate to MACs that CMS does not have pricing information (specifically, that ASP, WAC, AWP, and mean unit cost information is not available to determine a payment rate), MACs would calculate the payment based on provider invoices. The drug or biological invoice cost would be the net acquisition cost minus any rebates, chargebacks, or post-sale concessions. Before calculating an invoice-based payment amount, MACs would use the provider invoice to determine that: (a) the drug is not policy packaged; and (b) the per-day cost of the drug, biological, therapeutic radiopharmaceutical or diagnostic radiopharmaceutical is above the threshold packaging amount, as applicable. If both conditions are met, we proposed that MACs would use the provider invoice amount to set a payment rate for the separately payable drug, biological, or radiopharmaceutical until its payment amount becomes available to CMS. We generally would expect invoice pricing to be temporary, lasting two to three quarters, for qualified drugs required to report ASP under 1847A of the Act. For drug products that are not required to report ASP under 1847A of the Act (*i.e.,* diagnostic pharmaceuticals), we proposed that invoice pricing may be used longer term until a MUC can be calculated. We proposed that we would not begin using invoice pricing for drugs, biologicals, and radiopharmaceuticals without pricing information until CY 2026 because we would need to make technical updates to outpatient hospital claims to allow the hospitals to report drug invoice pricing. We noted that we intended to work with the National Uniform Billing Committee (NUBC) in order to create a value code that would allow for the reporting of invoice prices of drugs, biologicals, and radiopharmaceuticals for purposes of this policy.

Comment: Some commenters opposed our proposed drug invoice pricing policy, citing their concerns that the operational burden this policy would place on providers may lead to providers forgoing reimbursement. These commenters believe it is not feasible to provide these invoices because it would require considerable time and effort to track, document, and submit the necessary information because of the varied arrangements through which hospitals acquire drugs, as well as pricing variability and discount structures. Furthermore, commenters have concerns with using acquisition cost minus any rebates, chargebacks, or post-sale concessions because rebates are often made months after sale and commenters believed it would impede cash flow to hold claims for months until the rebate process has completed.

These commenters urged CMS to work with manufacturers to report ASP and other pricing data in a timely

manner so that CMS will have up-to-date cost information. Alternatively, commenters suggested that CMS use WAC or AWP, as it does for other drugs without ASP data. WAC data is typically available in advance of ASP data and soon after a drug is on the market.

Response: We appreciate the feedback from the commenters. We note that this policy would only apply to drugs where ASP, WAC, AWP, or mean unit cost information is not available. We will continue to examine the operational effect of this policy. We note that this policy has been in effect under the PFS and there is no evidence that healthcare professionals paid under the PFS forgo reimbursement for drugs paid at invoice prices because of administrative burden. We also note that the proposed effective date for this policy is January 1, 2026, which would allow providers a year to prepare for any operational changes.

Comment: Some commenters opposed the proposed drug invoice pricing policy, citing concerns with participating 340B providers' disclosure of their 340B drug acquisition cost, which the commenters stated is proprietary data. Some commenters believed that we should exempt 340B providers from the proposed policy if we move forward with the proposal.

Response: We understand providers' concerns regarding 340B drug acquisition cost data, and we note that it is not the intention of this policy to collect 340B drug acquisition cost data. Our policy goal is to provide temporary payment for these new drugs until their ASP, WAC, or AWP becomes available and would likely affect only a few new drugs each quarter. Invoice-based payment will result in collection of drug acquisition cost data for only a few drugs for only a short period of time, and only if the provider wants to submit the invoice in order to receive payment for the drug. We also note that CMS does not disclose proprietary data; we only disclose summarized population drug payment data in mean unit cost for ratesetting purposes.

Comment: Some commenters supported our proposal to permit invoice pricing or suggested we permit the MACs to pay at WAC or continue our current approach to make retroactive adjustments to payment status and to update quarterly payment files as new data becomes available.

Response: We thank the commenters who supported our proposal to allow invoice pricing. We believe the invoice pricing policy we are finalizing in this rule is a more appropriate and efficient way for us to pay for these drugs than our current approach of making retroactive adjustments. We note that this invoice pricing proposal only applies when data from a number of other payment methodologies, including WAC, are not available.

After consideration of the public comments we received, we are finalizing our proposal without modification for CY 2026 to allow MACs to use the provider invoice amount to set a payment rate for a separately payable drug, biological, or radiopharmaceutical until its payment amount becomes available and CMS provides a payment rate in Addendum B. HCPCS code(s) with missing payment rate in Addendum B for a separately payable drug, biological, or radiopharmaceutical will indicate to MACs that CMS does not have pricing information (specifically, that ASP, WAC, AWP, and mean unit cost information is not available to determine a payment rate) for a product, and MACs would then calculate the payment for the product based on provider invoices.

3. Payment Policy for Radiopharmaceuticals

For a complete history of the OPPS payment policy for radiopharmaceuticals, we refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65811), the CY 2006 OPPS final rule with comment period (70 FR 68655), and the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524).

a. Payment Policy for Therapeutic Radiopharmaceuticals

In the CY 2023 OPPS/ASC final rule with comment period, we adopted as final our proposal to continue our longstanding payment policy for therapeutic radiopharmaceuticals for CY 2023 and subsequent years. Accordingly, this payment policy for therapeutic radiopharmaceuticals will continue to apply in CY 2025.

Specifically, our policy of paying for separately payable pass-through therapeutic radiopharmaceuticals under the ASP methodology adopted for separately payable drugs and biologicals described in section V.A.1 of the proposed rule will continue to apply for CY 2025. We will pay for separately payable nonpass-through therapeutic radiopharmaceuticals through a modified ASP methodology where we pay at ASP plus 6 percent if ASP data are available. However, if ASP information is unavailable for a separately payable nonpass-through therapeutic radiopharmaceutical, we will continue to base the payment rate on mean unit cost data derived from hospital claims. Our policy not to use WAC or AWP to establish payment for separately payable nonpass-through therapeutic radiopharmaceuticals if ASP is not available will continue for CY 2025. We explained our rationale in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524 through 60525) when we first adopted our policy to apply the principles of separately payable drug pricing to therapeutic radiopharmaceuticals.

We note that in the CY 2024 OPPS final rule with comment period (88 FR 81786), we stated that the ASP payment methodology for separately payable nonpass-through therapeutic radiopharmaceuticals did allow for using WAC or AWP to establish a payment rate for these items. This was an error and conflicted with the policy implemented in CY 2010 and continued in subsequent years. The statement also conflicted with the policy that we proposed and finalized for CY 2023 and subsequent years in the CY 2023 OPPS/ASC final rule with comment period (87 FR 71969). The policy implemented in CY 2010 regarding ASP payment for separately payable nonpass-through therapeutic radiopharmaceuticals remains our intended policy. Therefore, we will pay for all nonpass-through separately payable therapeutic radiopharmaceuticals at ASP plus 6 percent based on the statutory default described in section 1833(t)(14)(A)(iii)(II) of the Act. For a full discussion of ASP-based payment for therapeutic radiopharmaceuticals, we refer readers to the CY 2010 OPPS/ASC final rule with comment period (74 FR 60520 through 60521). We will rely on CY 2023 mean unit cost data derived from hospital claims data for payment rates for separately payable nonpass-through therapeutic radiopharmaceuticals for which ASP data are unavailable and update the payment rates for these products according to our usual process for updating the payment rates for separately payable drugs and biologicals on a quarterly basis if updated ASP information becomes available.

The proposed CY 2025 payment rates for separately payable nonpass-through therapeutic radiopharmaceuticals were included in Addenda A and B of the CY 2025 OPPS/ASC proposed rule (which are available on the CMS website).[143]

The final CY 2025 payment rates for separately payable nonpass-through therapeutic radiopharmaceuticals are included in Addenda A and B of this

[143] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

final rule with comment period (which are available on the CMS website).[144]

b. Payment Policy for Diagnostic Radiopharmaceuticals

For CY 2025, we proposed, as described in section II.A.3 of the CY 2025 OPPS/ASC proposed rule, to pay separately for diagnostic radiopharmaceuticals with a per day cost above our proposed diagnostic radiopharmaceutical packaging threshold (proposed at $630 for CY 2025). We proposed to pay for pass-through diagnostic radiopharmaceuticals based on ASP, WAC, and AWP.

We proposed to base the payment rate for separately payable nonpass-through diagnostic radiopharmaceuticals on mean unit cost data derived from hospital claims. As discussed in section II.A.3.c.(5), we did not propose to use ASP data when mean unit cost data are available for a separately payable nonpass-through diagnostic radiopharmaceutical, but we sought comment on using ASP for setting the payment rate for nonpass-through diagnostic radiopharmaceuticals in the future. Additionally, we did not propose to use WAC or AWP as a basis for payment for nonpass-through diagnostic radiopharmaceuticals when mean unit cost data derived from hospital claims is available. We believe that paying for nonpass-through diagnostic radiopharmaceuticals using mean unit cost would appropriately pay for the average price of a nonpass-through separately payable diagnostic radiopharmaceutical. In our view, MUC is an appropriate proxy for the average price for a diagnostic radiopharmaceutical for a given year, as it is calculated based on the average costs for a particular year and is directly reflective of the actual cost data that hospitals submit to CMS. As we stated in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60523), we believe that WAC or AWP is not an appropriate proxy to provide OPPS payment for radiopharmaceuticals because these pricing methodologies do not include discounts. Specifically, the absence of appropriate ASP reporting could result in payment for a separately payable diagnostic radiopharmaceutical based on WAC or AWP indefinitely, a result which we believe would be inappropriate, as these pricing metrics do not capture all of the pricing discounts that may be reflected in the ASP.

Additionally, we proposed to base the initial payment for new diagnostic radiopharmaceuticals with HCPCS codes that do not have pass-through status or claims data on ASP, and on the WAC for these products if ASP data for these diagnostic radiopharmaceuticals are not available. If the WAC also is unavailable, we proposed to make payment for new diagnostic radiopharmaceuticals at 95 percent of the products' most recent AWP. We believe the volume of products in this category will typically be very low; however, in these rare situations, we believe it would be appropriate to use ASP until a MUC is established for new diagnostic radiopharmaceuticals with HCPCS codes that do not have passthrough status or claims data.

Please refer to section II.A.3.c of this final rule with comment period for information regarding our payment policies for diagnostic radiopharmaceuticals, including our policy to pay separately for diagnostic radiopharmaceuticals above a certain cost threshold, comments we received, and our final policies for CY 2025. The final CY 2025 payment rates for separately payable nonpass-through diagnostic radiopharmaceuticals are included in Addenda A and B of this final rule with comment period (which are available on the CMS website).[145]

4. Payment for Blood Clotting Factors

For CY 2025, we proposed to continue our established policy to provide payment for blood clotting factors using the same methodology as other separately payable drugs and biologicals under the OPPS and to continue to pay a furnishing fee. For a full discussion of our established payment policy for blood clotting factors, please refer to the CY 2023 OPPS/ASC final rule with comment period (87 FR 71969 through 71970). In accordance with our policy as finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765), we will announce the actual figure of the percent change in the applicable CPI and the updated furnishing fee calculation based on that figure through the applicable program instructions and posting on the CMS website at *https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price*.

We did not receive any public comments on our proposal and are finalizing it without modification.

5. Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals With HCPCS Codes but Without OPPS Hospital Claims Data

In the CY 2023 OPPS/ASC final rule with comment period, we adopted as final our proposal to continue our longstanding payment policy for nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data for CY 2023 and subsequent years. Therefore, for CY 2025, this policy will continue to apply. For a detailed discussion of the payment policy and methodology, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70442 through 70443). Consistent with our policy, because we have no claims data and must determine if these products exceed the per-day cost threshold, we estimated the average number of units of each product that would typically be furnished to a patient during one day in the hospital outpatient setting and utilized the ASP methodology to determine whether their payment will be packaged as well as their payment status indicators.

We did not receive any public comments on our proposal and are finalizing it without modification.

6. Requirement in the CY 2025 Physician Fee Schedule Proposed Rule for HOPDs and ASCs To Report Discarded Amounts of Certain Single-Dose or Single-Use Package Drugs

Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–9, November 15, 2021) (''the Infrastructure Act'') amended section 1847A of the Act to re-designate subsection (h) as subsection (i) and insert a new subsection (h), which requires manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. We explained in the CY 2025 OPPS/ASC proposed rule that the CY 2025 PFS proposed rule included proposals related to the discarded drug refund policy, including proposals that may impact hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs). Similar to our CY 2023 and CY 2024 notice in the OPPS/ASC proposed rule (87 FR 71988), we wanted to ensure interested parties were aware of these proposals and knew to refer to the CY 2025 PFS proposed rule for a full description of the proposed policy. Interested parties were asked to submit comments on any proposals to implement section 90004 of the Infrastructure Act to the CY 2025 PFS

[144] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

[145] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

proposed rule. We noted that public comments on these proposals would be addressed in the CY 2025 PFS final rule with comment period.

7. High-Cost/Low-Cost Threshold for Packaged Skin Substitutes

a. Background

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74938), we unconditionally packaged skin substitute products into their associated surgical procedures as part of a broader policy to package all drugs and biologicals that function as supplies when used in a surgical procedure. As part of the policy to package skin substitutes, we also finalized a methodology that divides the skin substitutes into a high-cost group and a low-cost group, to ensure adequate resource homogeneity among APC assignments for the skin substitute application procedures (78 FR 74933). In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66886), we stated that skin substitutes are best characterized as either surgical supplies or devices because of their required surgical application and because they share significant clinical similarity with other surgical devices and supplies.

Skin substitutes assigned to the high-cost group are described by HCPCS codes 15271 through 15278. Skin substitutes assigned to the low-cost group are described by HCPCS codes C5271 through C5278. Geometric mean costs for the various procedures are calculated using only claims for the skin substitutes that are assigned to each group. Specifically, claims billed with HCPCS codes 15271, 15273, 15275, or 15277 are used to calculate the geometric mean costs for procedures assigned to the high-cost group, and claims billed with HCPCS codes C5271, C5273, C5275, or C5277 are used to calculate the geometric mean costs for procedures assigned to the low-cost group (78 FR 74935).

Each of the HCPCS codes described earlier are assigned to one of the following three skin procedure APCs according to the geometric mean cost for the code: APC 5053 (Level 3 Skin Procedures): HCPCS codes C5271, C5275, and C5277; APC 5054 (Level 4 Skin Procedures): HCPCS codes C5273, 15271, 15275, and 15277; or APC 5055 (Level 5 Skin Procedures): HCPCS code 15273. In CY 2024, the payment rate for APC 5053 (Level 3 Skin Procedures) was $599.02, the payment rate for APC 5054 (Level 4 Skin Procedures) was $1,739.33, and the payment rate for APC 5055 (Level 5 Skin Procedures) was $3,421.82. This information is also available in Addenda A and B of the CY 2024 final rule with comment period (88 FR 81540) (the Addenda A and B are available on the CMS website *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*).

We have continued the high-cost/low-cost categories policy since CY 2014. Under the current policy, skin substitutes in the high-cost category are reported with the skin substitute application CPT codes, and skin substitutes in the low-cost category are reported with the analogous skin substitute HCPCS C-codes. For a discussion of the CY 2014 and CY 2015 methodologies for assigning skin substitutes to either the high-cost group or the low-cost group, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 74932 through 74935) and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66882 through 66885).

For a discussion of the high-cost/low-cost methodology that was adopted in CY 2016 and has been in effect since then, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70434 through 70435). Beginning in CY 2016, we adopted a policy where we determined the high-cost/low-cost status for each skin substitute product based on either a product's geometric mean unit cost (MUC) exceeding the geometric MUC threshold or the product's per day cost (PDC) (the total units of a skin substitute multiplied by the mean unit cost and divided by the total number of days) exceeding the PDC threshold. We assigned each skin substitute that exceeded either the MUC threshold or the PDC threshold to the high-cost group. In addition, we assigned any skin substitute with a MUC or a PDC that did not exceed either the MUC threshold or the PDC threshold to the low-cost group (87 FR 71976).

However, some skin substitute manufacturers have raised concerns about significant fluctuation in both the MUC threshold and the PDC threshold from year to year using the methodology developed in CY 2016. The fluctuation in the thresholds may result in the reassignment of several skin substitutes from the high-cost group to the low-cost group, which, under current payment rates, can be a difference of over $1,000 in the payment amount for the same procedure. In addition, these interested parties were concerned that the inclusion of cost data from skin substitutes with pass-through payment status in the MUC and PDC calculations would artificially inflate the thresholds. Skin substitute interested parties requested that CMS consider alternatives to the current methodology used to calculate the MUC and PDC thresholds and whether it might be appropriate to establish a new cost group in between the low-cost group and the high-cost group to allow for assignment of moderately priced skin substitutes to a newly created middle group.

We share the goal of promoting payment stability for skin substitute products and their related procedures as price stability allows hospitals using such products to more easily anticipate future payments associated with these products. We have attempted to limit year-to-year shifts for skin substitute products between the high-cost and low-cost groups through multiple initiatives implemented since CY 2014, including: establishing separate skin substitute application procedure codes for low-cost skin substitutes (78 FR 74935); using a skin substitute's MUC calculated from outpatient hospital claims data instead of an average of ASP plus 6 percent as the primary methodology to assign products to the high-cost or low-cost group (79 FR 66883); and establishing the PDC threshold as an alternate methodology to assign a skin substitute to the high-cost group (80 FR 70434 through 70435).

To allow additional time to evaluate concerns and suggestions from interested parties about the volatility of the MUC and PDC thresholds, in the CY 2018 OPPS/ASC proposed rule (82 FR 33627), we proposed that a skin substitute that was assigned to the high-cost group for CY 2017 would be assigned to the high-cost group for CY 2018, even if it did not exceed the CY 2018 MUC or PDC thresholds. We finalized this policy in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59347). For more detailed information and discussion regarding the goals of this policy and the subsequent comment solicitations in CY 2019 and CY 2020 regarding possible alternative payment methodologies for graft skin substitute products, please refer to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59347); the CY 2019 OPPS/ASC final rule with comment period (83 FR 58967 to 58968); and the CY 2020 OPPS/ASC final rule with comment period (84 FR 61328 to 61331).

b. Packaged Skin Substitutes for CY 2025

For CY 2025, consistent with our policy since CY 2016, we proposed to continue to determine the high-cost/low-cost status for each skin substitute product based on either a product's

geometric MUC exceeding the geometric MUC threshold or the product's PDC (the total units of a skin substitute multiplied by the MUC and divided by the total number of days) exceeding the PDC threshold. Consistent with the methodology as established in the CY 2014 OPPS/ASC through CY 2018 OPPS/ASC final rules with comment period, we analyzed CY 2023 claims data to calculate the MUC threshold (a weighted average of all skin substitutes' MUCs) and the PDC threshold (a weighted average of all skin substitutes' PDCs). The proposed CY 2025 MUC threshold is $50 per cm² (rounded to the nearest $1) and the proposed CY 2025 PDC threshold is $840 (rounded to the nearest $1). Also, the availability of a HCPCS code for a particular human cell, tissue, or cellular or tissue-based product (HCT/P) does not mean that that product is appropriately regulated solely under section 361 of the PHS Act and the FDA regulations in 21 CFR part 1271. Manufacturers of HCT/Ps should consult with the FDA Tissue Reference Group (TRG) or obtain a determination through a Request for Designation (RFD) on whether their HCT/Ps are appropriately regulated solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.

For CY 2025, as we did for CY 2024, we proposed to assign each skin substitute that exceeds either the MUC threshold or the PDC threshold to the high-cost group. In addition, we propose to assign any skin substitute that does not exceed either the MUC threshold or the PDC threshold to the low-cost group except that we propose that any skin substitute product that is assigned to the high-cost group in CY 2024 would be assigned to the high-cost group for CY 2025, regardless of whether it exceeds or falls below the CY 2025 MUC or PDC threshold. This policy was established in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59346 through 59348).

For CY 2025, we proposed to continue to assign skin substitutes with pass-through payment status to the high-cost category. We proposed to assign skin substitutes with pricing information but without claims data to calculate a geometric MUC or PDC to either the high-cost or low-cost category based on the product's ASP plus 6 percent payment rate as compared to the MUC threshold. If ASP is not available, we proposed to use WAC plus 3 percent to assign a product to either the high-cost or low-cost category. Finally, if neither ASP nor WAC is available, we proposed to use 95 percent of AWP to assign a skin substitute to either the high-cost or low-cost category. We proposed to continue to use WAC plus 3 percent instead of WAC plus 6 percent to conform to our proposed policy described in section V.B.2.b of the proposed rule to establish a payment rate of WAC plus 3 percent for separately payable drugs and biologicals that do not have ASP data available. We proposed that any skin substitute product that is assigned a code in the HCPCS A2XXX series would be assigned to the high-cost skin substitute group including new products without pricing information. New skin substitutes without pricing information that are not assigned a code in the HCPCS A2XXX series would be assigned to the low-cost category until pricing information is available to compare to the CY 2024 MUC and PDC thresholds. For a discussion of our policy under which we assign skin substitutes without pricing information that are not assigned a code in the HCPCS A2XXX series to the low-cost category until pricing information is available, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70436).

The CY 2025 OPPS/ASC proposed rule (89 FR 59373 through 593777) includes the proposed CY 2025 cost category assignment for each skin substitute product.

Comment: The HOP Panel recommended, and several commenters supported, ending the packaging of the graft skin substitute administration add-on codes (CPT codes 15272, 15274, 15276, and 15278; HCPCS codes C5272, C5274, C5276, and C5278). The HOP Panel and the commenters requested that these codes be assigned to APCs that reflect the estimated costs of these service codes. Commenters claimed that packaging the graft skin substitute administration add-on codes eliminates the variation in payment for wound care treatments based on the size of the wound. They assert that providers are discouraged from treating wounds between 26 and 99 cm² and over 100 cm² in the outpatient hospital setting because of the financial losses they experience to provide such care. One of the commenters cited a recent study finding that between 2014 and 2019 treatment for larger area wounds has shifted from the outpatient hospital setting to the physician office setting where payment for individual services better reflects their cost because of the fee-for-service structure of physician payment. Commenters believe that packaging graft skin substitute administration add-on codes disrupts the methodology of how the American Medical Association (AMA), the organization that manages CPT service codes, intended graft skin substitute procedures to be paid. The commenters explained that CPT codes describe the actual amount of the graft skin substitute product that is used for an individual service when the amount of product used is 25 cm² or more. Commenters believe that when more than 25 cm² of product is used for a service that the cost of product used in excess of 25 cm² should be paid at cost by making the add-on code reporting the additional product separately payable in addition to the cost to apply the graft skin substitute product. Commenters believe always packaging the cost of graft skin substitute products into the cost of the associated application procedures no matter how much product is used is an indiscriminate form of payment that, according to the commenters, does not promote payment accuracy or patient care and may raise health equity concerns because providers are not compensated for the cost of using more than 25 cm² of graft skin substitute product for a wound. One commenter asserted that providers rarely experience a financial gain from performing a graft skin substitute application procedure and, in most cases, providers experience a financial loss when performing graft skin substitute procedures.

Response: We do not agree that we should pay separately for graft skin substitute add-on codes under the OPPS. The OPPS is a prospective payment system rather than a fee-for-service payment system. That means that we generally attempt to make one payment for all the services billed with the primary medical procedure, including add-on procedures such as the ones described by CPT codes 15272, 15274, 15276, and 15278, and HCPCS codes C5272, C5274, C5276, and C5278. More specifically, we calculate the OPPS payment rate by first calculating the geometric mean cost of the procedure. This calculation includes claims for individual services that used a lower level of resources and claims for individual services that used a higher level of resources. The resulting geometric mean cost will reflect the average service cost for a given medical procedure. Next, we group the medical procedure with other medical procedures with clinical and resource similarity in an APC and calculate the geometric mean of these related procedures to generate a base payment rate for all procedures assigned to the APC. Skin substitutes are surgical supplies and are packaged into the cost of the associated procedure. The application of graft skin substitutes

cannot occur unless a graft skin substitute is used. So, the cost of the product will be reflected in the overall cost of the application procedure.

Despite the text of the descriptors for CPT codes 15271 and 15275 and HCPCS codes C5271 and C5275, the geometric mean service cost of these procedures is likely not the cost of the procedures plus 25 cm^2 of graft skin substitute product. Instead, the geometric mean service cost should reflect the geometric mean of the cost of the graft skin substitute application procedure plus the cost of graft skin substitute product for all procedures where less than 100 cm^2 of product is used. The commenters claimed that most graft skin substitute procedures use substantially more than 25 cm^2 of graft skin substitute product. Therefore, the geometric mean cost of these procedures would account for the average amount of product used by providers over 25 cm^2.

A prospective payment system like the OPPS is designed to pay providers the geometric mean cost of the primary service they provide, and such a system encourages efficiencies and cost-savings in the administration of health care. However, a prospective payment system is not intended to discourage providers from rendering medically necessary care to patients. For example, it is possible that a provider could experience a financial loss when they perform a service where a patient receives 85 cm^2 of a graft skin substitute product, but that same provider could see a financial gain when the next patient receives a skin graft where 40 cm^2 of product is used. Paying separately for add-on codes for the administration of graft skin substitutes in a prospective payment system defeats the goals of such a payment system. Therefore, we will continue to package the add-on codes for the administration of graft skin substitutes in the OPPS to encourage cost-savings and efficiencies with wound care treatment. If providers are paid at cost or nearly at cost for each individual service they render, there is no incentive for them to control costs.

Add-on codes for the administration of graft skin substitutes should be packaged with the primary medical service to be able to establish a geometric mean payment rate that gives providers incentives to keep their costs in line with typical providers throughout the Medicare program. The need for cost efficiencies in the application of graft skin substitutes to treat wounds is no different than the need for cost efficiencies in other procedures administered in the outpatient hospital setting. Packaging product costs with the costs of the associated procedures is not an indiscriminate method of paying for medical care nor is it a system where providers lose money on most of the procedures they administer and rarely receive more payment than the cost of the procedure. Prospective payment methodology helps to control the cost of hospital care, while incentivizing providers to provide quality care in an efficient manner. Packaging add-on codes to have a uniform distribution of costs for individual procedure is critical for prospective payment. Therefore, we believe that add-on codes, including the add-on codes for the administration of graft skin substitutes, should remain packaged to maintain the integrity of the OPPS.

Comment: The HOP Panel recommended, and several commenters supported, ensuring that the payment rate for graft skin substitute procedures be the same no matter where on the body the graft skin substitute product is applied to the patient. There are four graft skin substitute application procedures for high-cost skin substitute products (CPT codes 15271, 15273, 15275, and 15277) and a similar four graft skin substitute application procedures for low-cost skin substitute products (HCPCS codes C5271, C5273, C5275, and C5277). Commenters claim that the cost to apply graft skin substitute products does not depend on the location of the wound because the same amount of product is used on the wound and the same clinical resources are used to treat the wound independent of the location of the wound. Other commenters made a similar request, asking that CPT code 15277 (Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1 percent of body area of infants and children) that is currently assigned to APC 5054 (Level 4 Skin Procedures) be reassigned to APC 5055 (Level 5 Skin Procedures). That would mean that the two graft skin substitute application procedures for the application of high-cost skin substitute products for wounds greater than 100 cm^2 (CPT codes 15273 and 15277) would be in the same APC. One commenter expressed their concern that CMS seems to not understand that provider resources and graft skin substitute product used for the procedures described by CPT codes 15273 and 15277 and for the procedures described by HCPCS codes C5273 and C5277 are the same, and that CPT codes 15273 and 15277 must be assigned to the same APC and C5273 and C5277 also must be assigned to the same APC.

Response: The reason there are four CPT codes describing graft skin substitute application services is that there are different CPT codes for applying graft skin substitutes for wounds up to 100 cm^2 and for wounds that are greater than 100 cm^2; and there are different CPT codes for applying graft skin substitutes to the trunk, arms, and legs as compared to the face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, fingers, and toes. We appreciate commenters' concerns and note that the two current codes describing the application of high-cost graft skin substitutes for wounds less than 100 cm^2 (CPT codes 15271 and 15275) have been assigned to the same APC (5054), and the two current codes describing the application of low-cost graft skin substitutes for wounds less than 100 cm^2 (HCPCS codes C5271 and C5275) have been assigned to the same APC (5053). Because they are currently included in the same APC, the OPPS payment for them is the same; and this payment policy is consistent with the recommendation from the HOP Panel and other commenters. This means for the application of graft skin substitute products up to 100 cm^2, the location where the graft skin substitute is applied does not affect the payment rate for the service.

We note that the code describing the application of high-cost products for wounds that are greater than 100 cm^2 on the trunk, arms, and legs (CPT code 15273) has been assigned to a higher-paying APC (APC 5055) than the APC assignment for the code describing the application of high-cost graft skin substitute products for wounds greater than 100 cm^2 on the face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hand, feet, fingers, and toes (CPT code 15277), which is assigned to APC 5054. Likewise, the code describing the application of low- cost products for wounds that are greater than 100 cm^2 on the trunk, arms, and legs (HCPCS code C5273) has been assigned to a higher-paying APC (APC 5054) than the code for the application of low-cost graft skin substitute products for wounds greater than 100 cm^2 on the face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hand, feet, fingers, and toes (HCPCS code C5277), which is assigned to APC 5054. The differences in costs that have determined APC assignments for these services for wounds greater than 100 cm^2 have been supported by historical cost data. We also note that none of these service codes are in violation of the 2 times rule, which requires that the geometric mean cost of significant items

and services within an APC group to be no more than two-times the geometric mean cost of the lowest geometric mean cost for a significant item or service within the same APC group.

In response to the claim of one of the commenters that we do not understand that similar amounts of product and resources are used for the procedures described by CPT codes 15273 and 15277 or for the procedures described by HCPCS codes C5273 and C5277, we note that the cost data for CY 2023 and for many years prior show substantial cost differences between the procedures described by CPT codes 15273 and 15277 and likewise for the procedures described by HCPCS codes C5273 and C5277. We set our payment rates based on claims cost data which continue to show that these procedures have substantial cost differences and should be assigned to different APCs.

Comment: The HOP Panel recommended, and several commenters supported, that all new graft skin substitute products be assigned to the low-cost group whether they have a Q-code or an A-code until cost data become available for the product. Commenters believe it is not appropriate that products assigned Q-codes are assigned to the low-cost group while products assigned A-codes are assigned to the high-cost group. Commenters note that A-codes are being assigned to graft skin substitute products that have FDA 510(k) clearance but are not synthetic products, which conflicts with the expectation of the commenters that only graft skin substitute products that would have been described by the now-deleted HCPCS code C1849 (Skin substitute, synthetic, resorbable, per square centimeter) be assigned to the high-cost group. More broadly, commenters believed that no category of graft skin substitute products should be assigned to the high-cost group until there is cost data supporting that assignment.

Response: We appreciate the concerns of the commenters. However, we decided on an approach that would ensure that any graft skin substitute product that could potentially have been described by deleted HCPCS code C1849 be included in the high-cost group. As explained in the CY 2023 OPPS final rule (87 FR 71980 and 71981), we wanted to ensure that graft skin substitute products that were described by HCPCS code C1849 or could potentially be described by HCPCS code C1849 would be granted time to develop the cost data necessary to allow us to determine if the product should stay in the high-cost group, which provides stability for the payment of these graft skin substitute products. We wanted to avoid having products with less than two years of claims data that were originally in the high-cost group be reassigned to the low-cost group simply because of a lack of available data.

Also, as discussed in the CY 2023 OPPS final rule (87 FR 71981), the current categorization of skin substitutes as either synthetic or non-synthetic is not mutually exclusive given the expansion of skin substitute products that may contain both biological and synthetic elements. Having products with both biological and synthetic elements leads to difficulty defining which of the products assigned to the A2XXX series would be considered ''synthetic'' and described by HCPCS code C1849. Therefore, for CY 2023, we finalized a policy, which will continue for CY 2025, to assign to the high-cost group any skin substitute product that is assigned a code in the HCPCS A2XXX series including new products without pricing information. This policy gives the broadest definition of products that could have been described by HCPCS code C1849 and ensures that none of those graft skin substitute products would be assigned to the low-cost group until we receive cost data for them.

Comment: One commenter supported having us realign both the high-cost and low-cost application procedure codes to potentially higher-paying APC groups that reflect the current average sales prices of graft skin substitute products as manufacturers now are required to submit average sales prices for graft skin substitute products. The commenter believes combining ASP prices for graft skin substitutes and the cost of the graft skin substitute application procedures would better reflect the costs of those procedures than our current methodology of using cost data from claims to assign application procedures to APCs.

Response: We disagree with the commenter that using ASP instead of using claims cost data would be a preferrable method for estimating the graft skin substitute product cost of graft skin substitute application procedures. It is unclear from the commenter's suggestion how the product cost of the graft skin substitute would be calculated if not using the charges reported by providers. Presumably, their approach would involve extracting the units of graft skin substitute product used on a particular packaged service and then multiplying by an ASP on file to revise the cost of packaged procedure to reflect the ASP price of the graft skin substitute product units. We do not believe this is a feasible approach and it appears to be a different approach to pricing one group of packaged supplies as compared to how all other packaged supplies are priced in the OPPS. We normally use a provider's reported charges for supplies and use the appropriate cost-to-charge ratio to estimate the contribution of the supply cost to the overall cost of the procedure.

Comment: One commenter supported our current policy not to assign graft skin substitute products that are not in sheet form (*e.g.,* gel, powder, ointment, foam, liquid, or injected) to any APC group, because these products cannot be reported with the graft skin substitute application codes of CPT codes 15271 through 15278 (the high-cost group) or with HCPCS codes C5271 through C5278 (the low-cost group). The commenter notes that skin substitutes that are not in sheet form are used primarily for clinic visits and the debridement of chronic wounds. Also, according to the commenter, the use of skin substitutes that are not in sheet form does not conform to the AMA's directions for the application of skin substitute products.

Response: We appreciate the commenter's support of our policy.

Comment: One commenter requested that skin substitute products that receive an FDA approval through either the Premarket Approval (PMA) process, the Biological License Application (BLA) process, or the New Drug Application (NDA) process no longer be packaged in the OPPS, but instead be separately payable at a rate of ASP + 6 percent. In addition, the commenter requested that two previously approved skin substitute products, Apligraf and Dermagraft, should no longer be packaged and should be paid separately at a rate of ASP + 6 percent because these products are now regulated by the Center for Biologics Evaluation and Research (CBER) within the FDA. CBER is the center within FDA that regulates biological products for human use. The commenter notes the rigorous process that biological products must go through to confirm their safety and effectiveness to receive either a PMA, BLA, or NDA approval. The commenter states that when Apligraf and Dermagraft received their FDA approval, the products had a review process comparable to the reviews done for a PMA, BLA, or NDA approval. The commenter believes the intensive review process that skin substitute products undergo to get a PMA, BLA, or NDA approval should allow those products to be separately paid rather than packaged in the OPPS.

Response: The commenter appears to be referencing comments that were previously made for the CY 2014 OPPS/

ASC final rule with comment period (78 FR 74931) where commenters asserted that specified covered outpatient drugs (SCODs) under section 1833(t)(14)(B) of the Act cannot be packaged in the OPPS and instead must be paid separately. Section 1833(t)(14)(B) of the Act defines a SCOD as a ''covered outpatient drug (as defined in section 1927(k)(2))''. Covered outpatient drugs under section 1927(k)(2) of the Act are generally limited to products approved as drugs by the FDA, biologicals licensed under section 351 of the Public Health Service Act, and insulin. However, skin substitute products that have either a PMA, BLA, or NDA are still considered to be supplies under the policy we implemented in CY 2014 OPPS/ASC final rule with comment period (78 FR 74938). Under our policy, we unconditionally packaged skin substitute products into their associated surgical procedures as part of a broader policy to package all drugs and biologicals that function as supplies when used in a surgical procedure. Finally, as we explained in finalizing our policies of packaging diagnostic radiopharmaceuticals and contrast agents in the CY 2008 OPPS final rule (72 FR 66766), CMS has the authority to package the payment of SCODs in the OPPS and we may consider additional packaging options for SCODs and other separately payable drugs in the future (78 FR 74931).

Comment: Several commenters supported our current skin substitute payment policy to assign graft skin substitute products to either a high-cost or a low-cost group based on the product's cost. Likewise, commenters also supported our policy of keeping graft skin substitute products in the high-cost group once the cost of the product exceeds either the MUC or the PDC threshold for at least one year even if in future years the cost of the product is less than either the MUC or PDC threshold.

Response: We appreciate the commenters' support of our policies.

Comment: The manufacturer of the products described by HCPCS codes Q4122 (Dermacell, dermacell awm or dermacell awm porous, per square centimeter) and Q4150 (Allowrap dds or dry, per square centimeter) requested that these graft skin substitute products continue to be assigned to the high-cost skin substitute group for CY 2025.

Response: Based on their cost data and our policies, we are finalizing that both HCPCS codes Q4122 (Dermacell, dermacell awm or dermacell awm porous, per square centimeter) and Q4150 (Allowrap dds or dry, per square centimeter) will remain in the high-cost group for CY 2025.

Comment: The manufacturer of the products described by HCPCS codes Q4148 (Neox cord 1k, neox cord rt, or clarix cord 1k, per square centimeter) and Q4156 (Neox 100 or clarix 100, per square centimeter) requested that these graft skin substitute products continue to be assigned to the high-cost skin substitute group for CY 2025.

Response: Based on their cost data and our policies, we are finalizing that both HCPCS codes Q4148 (Neox cord 1k, neox cord rt, or clarix cord 1k, per square centimeter) and Q4156 (Neox 100 or clarix 100, per square centimeter) will remain in the high-cost group for CY 2025.

After consideration of the public comments we received, we are finalizing our proposals without modification. Our final policies are to:

- Continue to assign skin substitutes with pass-through payment status to the high-cost category.
- Assign skin substitutes with pricing information but without claims data to calculate a geometric MUC or PDC to either the high-cost or low-cost category based on the product's ASP plus 6 percent payment rate as compared to the MUC threshold. If ASP is not available for the product, we will use WAC plus 3 percent to assign a product to either the high-cost or low-cost category. Finally, if neither ASP nor WAC is available, we will use 95 percent of AWP to assign a skin substitute to either the high-cost or low-cost category.
- Continue to use WAC plus 3 percent instead of WAC plus 6 percent to conform to our policy described in section V.B.2.b of this final rule with comment period to establish a payment rate of WAC plus 3 percent for separately payable drugs and biologicals that do not have ASP data available.
- Assign any skin substitute product that is assigned a code in the HCPCS A2XXX series to the high-cost skin substitute group, including new products without pricing information. New skin substitutes without pricing information that are not assigned a code in the HCPCS A2XXX series would be assigned to the low-cost category until pricing information is available to compare to the CY 2024 MUC and PDC thresholds.

Finally, we have updated the MUC and PDC thresholds for CY 2025. The final MUC threshold will be $50 per cm^2 (rounded to the nearest $1) and the final PDC threshold will be $833 (rounded to the nearest $1). Table 135 includes the final CY 2024 cost category assignment for each skin substitute product.

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TABLE 135: SKIN SUBSTITUTE ASSIGNMENTS TO HIGH-COST AND LOW-COST GROUPS FOR CY 2025

CY 2025 HCPCS Code	CY 2025 Short Descriptor	CY 2024 High/Low Cost Assignment	CY 2025 High/Low Cost Assignment
A2001	Innovamatrix ac, per sq cm	High	High
A2002	Mirragen adv wnd mat per sq	High	High
A2005	Microlyte matrix, per sq cm	High	High
A2006	Novosorb synpath per sq cm	High	High
A2007	Restrata, per sq cm	High	High
A2008	Theragenesis, per sq cm	High	High
A2009	Symphony, per sq cm	High	High
A2010	Apis, per square centimeter	High	High
A2011	Supra sdrm, per sq cm	High	High
A2012	Suprathel, per sq cm	High	High
A2013	Innovamatrix fs, per sq cm	High	High
A2015	Phoenix wnd mtrx, per sq cm	High	High
A2016	Permeaderm b, per sq cm	High	High
A2017	Permeaderm glove, each	High	High
A2018	Permeaderm c, per sq cm	High	High
A2019	kerecis marigen shld sq cm	High	High
A2020	ac5 wound system	High	High
A2021	neomatrix per sq cm	High	High
A2022	Innovabrn/innovamatx xl sqcm	High	High
A2024	Resolve matrix per sq cm	High	High
A2025	Miro3d per cubic cm	High	High
A2027	Matriderm, per square centimeter	High	High
A2028	Micromatrix flex, per mg	High	High
A2029	Mirotract wound matrix sheet, per cubic centimeter	High	High
A4100	Skin sub fda clrd as dev nos	Low	Low
C9363	Integra meshed bil wound mat	High	High
Q4100	Skin substitute, nos	Low	Low
Q4101	Apligraf	High	High
Q4102	Oasis wound matrix	Low	Low
Q4103	Oasis burn matrix	High	High*
Q4104	Integra bmwd	High	High
Q4105	Integra drt or omnigraft	High	High
Q4106	Dermagraft	High	High
Q4107	Graftjacket	High	High
Q4108	Integra matrix	High	High
Q4110	Primatrix	High	High
Q4111	Gammagraft	Low	Low
Q4115	Alloskin	Low	Low

CY 2025 HCPCS Code	CY 2025 Short Descriptor	CY 2024 High/Low Cost Assignment	CY 2025 High/Low Cost Assignment
Q4116	Alloderm	High	High
Q4117	Hyalomatrix	Low	Low
Q4121	Theraskin	High	High
Q4122	Dermacell, awm, porous sq cm	High	High
Q4123	Alloskin	High	High*
Q4124	Oasis tri-layer wound matrix	Low	Low
Q4126	Memoderm/derma/tranz/integup	High	High
Q4127	Talymed	High	High
Q4128	Flexhd/allopatchhd/matrixhd	High	High
Q4132	Grafix core, grafixpl core	High	High
Q4133	Grafix stravix prime pl sqcm	High	High
Q4134	Hmatrix	High	High
Q4135	Mediskin	High	High*
Q4136	Ezderm	Low	Low
Q4137	Amnioexcel biodexcel, 1 sq cm	High	High
Q4138	Biodfence dryflex, 1cm	High	High
Q4140	Biodfence 1cm	High	High
Q4141	Alloskin ac, 1cm	High	High*
Q4143	Repriza, 1cm	High	High*
Q4146	Tensix, 1cm	High	High*
Q4147	Architect ecm px fx 1 sq cm	High	High
Q4148	Neox rt or clarix cord	High	High
Q4150	Allowrap ds or dry 1 sq cm	High	High
Q4151	Amnioband, guardian 1 sq cm	High	High
Q4152	Dermapure 1 square cm	High	High
Q4153	Dermavest, plurivest sq cm	High	High
Q4154	Biovance 1 square cm	High	High
Q4156	Neox 100 or clarix 100	High	High
Q4157	Revitalon 1 square cm	High	High*
Q4158	Kerecis omega3, per sq cm	High	High*
Q4159	Affinity 1 square cm	High	High
Q4160	Nushield 1 square cm	High	High
Q4161	Bio-connekt per square cm	High	High*
Q4163	Woundex, bioskin, per sq cm	High	High
Q4164	Helicoll, per square cm	High	High*
Q4165	Keramatrix, per square cm	Low	Low
Q4166	Cytal, per square centimeter	Low	Low
Q4167	Truskin, per square centimeter	High	High
Q4169	Artacent wound, per sq cm	High	High
Q4170	Cygnus, per sq cm	High	High*
Q4173	Palingen or palingen xplus	High	High

CY 2025 HCPCS Code	CY 2025 Short Descriptor	CY 2024 High/Low Cost Assignment	CY 2025 High/Low Cost Assignment
Q4175	Miroderm, per square cm	High	High
Q4176	Neopatch, per sq centimeter	High	High
Q4178	Floweramniopatch, per sq cm	High	High
Q4179	Flowerderm, per sq cm	High	High*
Q4180	Revita, per sq cm	High	High
Q4181	Amnio wound, per square cm	High	High
Q4182	Transcyte, per sq centimeter	High	High
Q4183	Surgigraft, 1 sq cm	High	High
Q4184	Cellesta or duo per sq cm	High	High*
Q4186	Epifix 1 sq cm	High	High
Q4187	Epicord 1 sq cm	High	High
Q4188	Amnioarmor 1 sq cm	High	High*
Q4190	Artacent ac 1 sq cm	High	High*
Q4191	Restorigin 1 sq cm	High	High*
Q4193	Coll-e-derm 1 sq cm	High	High
Q4194	Novachor 1 sq cm	High	High*
Q4195	Puraply 1 sq cm	High	High
Q4196	Puraply am 1 sq cm	High	High
Q4197	Puraply xt 1 sq cm	High	High
Q4198	Genesis amnio membrane 1 sq cm	High	High
Q4199	Cygnus matrix, per sq cm	High	High
Q4200	Skin te 1 sq cm	High	High*
Q4201	Matrion 1 sq cm	High	High
Q4203	Derma-gide, 1 sq cm	High	High
Q4204	Xwrap 1 sq cm	Low	Low
Q4205	Membrane graft or wrap sq cm	High	High
Q4208	Novafix per sq cm	High	High
Q4209	Surgraft per sq cm	High	High*
Q4211	Amnion bio or axobio sq cm	High	High
Q4214	Cellesta cord per sq cm	Low	Low
Q4216	Artacent cord per sq cm	Low	High
Q4217	Woundfix biowound plus xplus	High	High*
Q4218	Surgicord per sq cm	High	High*
Q4219	Surgigraft dual per sq cm	High	High
Q4220	Bellacell HD, Surederm sq cm	Low	Low
Q4221	Amniowrap2 per sq cm	High	High
Q4222	Progenamatrix, per sq cm	High	High*
Q4224	Hhf10-p per sq cm	Low	Low
Q4225	Amniobind, per sq cm	Low	Low
Q4226	Myown harv prep proc sq cm	High	High
Q4227	Amniocore per sq cm	High	High

CY 2025 HCPCS Code	CY 2025 Short Descriptor	CY 2024 High/Low Cost Assignment	CY 2025 High/Low Cost Assignment
Q4229	Cogenex amnio memb per sq cm	High	High*
Q4232	Corplex, per sq cm	High	High
Q4234	Xcellerate, per sq cm	High	High
Q4235	Amniorepair or altiply sq cm	High	High
Q4236	Carepatch per sq cm	Low	Low
Q4237	cryo-cord, per sq cm	High	High*
Q4238	Derm-maxx, per sq cm	High	High
Q4239	Amnio-maxx or lite per sq cm	High	High*
Q4247	Amniotext patch, per sq cm	Low	Low
Q4248	Dermacyte Amn mem allo sq cm	High	High
Q4249	Amniply, per sq cm	High	High*
Q4250	AmnioAMP-MP per sq cm	High	High
Q4251	Vim, per square centimeter	Low	Low
Q4252	Vendaje, per square centimet	Low	High
Q4253	Zenith amniotic membrane psc	High	High*
Q4254	Novafix dl per sq cm	High	High*
Q4255	Reguard, topical use per sq	Low	Low
Q4256	Mlg complet, per sq cm	Low	Low
Q4257	Relese, per sq cm	Low	Low
Q4258	Enverse, per sq cm	High	High*
Q4259	Celera per sq cm	Low	Low
Q4260	Signature apatch, per sq cm	Low	Low
Q4261	Tag, per square centimeter	Low	Low
Q4262	Dual layer impax, per sq cm	Low	High
Q4263	Surgraft tl, per sq cm	Low	Low
Q4264	Cocoon membrane, per sq cm	Low	Low
Q4265	Neostim tl per sq cm	Low	Low
Q4266	Neostim per sq cm	Low	Low
Q4267	Neostim dl per sq cm	Low	Low
Q4268	Surgraft ft per sq cm	Low	High
Q4269	Surgraft xt per sq cm	Low	Low
Q4270	Complete sl per sq cm	Low	Low
Q4271	Complete ft per sq cm	Low	Low
Q4272	Esano a, per sq cm	Low	Low
Q4273	Esano aaa, per sq cm	Low	Low
Q4274	Esano ac, per sq cm	Low	Low
Q4275	Esano aca, per sq cm	Low	Low
Q4276	Orion, per sq cm	Low	Low
Q4278	Epieffect, per sq cm	High	High
Q4279	Vendaje ac, per sq cm	Low	Low
Q4280	Xcell amnio matrix per sq cm	Low	Low

CY 2025 HCPCS Code	CY 2025 Short Descriptor	CY 2024 High/Low Cost Assignment	CY 2025 High/Low Cost Assignment
Q4281	Barrera slor dl per sq cm	Low	Low
Q4282	Cygnus dual per sq cm	High	High
Q4283	Biovance tri or 3l, sq cm	Low	Low
Q4284	Dermabind sl, per sq cm	Low	Low
Q4285	Nudyn dl or dl mesh pr sq cm	High	High*
Q4286	Nudyn sl or slw, per sq cm	High	High*
Q4287	Dermabind dl, per sq cm	Low	Low
Q4288	Dermabind ch, per sq cm	Low	Low
Q4289	Revoshield+ amnio, per sq cm	Low	Low
Q4290	Membrane wrap hydr per sq cm	Low	Low
Q4291	Lamellas xt, per sq cm	Low	Low
Q4292	Lamellas, per sq cm	Low	Low
Q4293	Acesso dl, per sq cm	Low	Low
Q4294	Amnio quad-core, per sq cm	Low	Low
Q4295	Amnio tri-core, per sq cm	Low	Low
Q4296	Rebound matrix, per sq cm	Low	Low
Q4297	Emerge matrix, per sq cm	Low	Low
Q4298	Amnicore pro, per sq cm	Low	Low
Q4299	Amnicore pro+, per sq cm	Low	Low
Q4300	Acesso tl, per sq cm	Low	Low
Q4301	Activate matrix, per sq cm	Low	Low
Q4302	Complete aca, per sq cm	Low	Low
Q4303	Complete aa, per sq cm	Low	Low
Q4304	Grafix plus, per sq cm	Low	Low
Q4305	Amer am ac tri-lay per sq cm	Low	Low
Q4306	Americ amnion ac per sq cm	Low	Low
Q4307	American amnion, per sq cm	Low	Low
Q4308	Sanopellis, per sq cm	Low	Low
Q4309	Via matrix, per sq cm	Low	Low
Q4311	Acesso, per sq cm	Low	Low
Q4312	Acesso ac, per sq cm	Low	Low
Q4313	Dermabind fm, per sq cm	Low	Low
Q4314	Reeva, per sq cm	Low	Low
Q4315	Regenelink amniotic mem allo	Low	Low
Q4316	Amchoplast, per sq cm	Low	Low
Q4317	Vitograft, per sq cm	Low	Low
Q4318	E-graft, per sq cm	Low	Low
Q4319	Sanograft, per sq cm	High	High*
Q4320	Pellograft, per sq cm	High	High*
Q4321	Renograft, per sq cm	Low	Low
Q4322	Caregraft, per sq cm	Low	Low

CY 2025 HCPCS Code	CY 2025 Short Descriptor	CY 2024 High/Low Cost Assignment	CY 2025 High/Low Cost Assignment
Q4323	Alloply, per sq cm	Low	Low
Q4324	Amniotx, per sq cm	Low	Low
Q4325	Acapatch, per sq cm	Low	Low
Q4326	Woundplus, per sq cm	Low	Low
Q4327	Duoamnion, per sq cm	Low	Low
Q4328	Most, per sq cm	Low	Low
Q4329	Singlay, per sq cm	Low	Low
Q4330	Total, per sq cm	Low	Low
Q4331	Axolotl graft, per sq cm	High	High*
Q4332	Axolotl dualgraft, per sq cm	High	High*
Q4333	Ardeograft, per sq cm	Low	Low
Q4334	Amnioplast 1, per sq cm	Low	Low
Q4335	Amnioplast 2, per sq cm	Low	Low
Q4336	Artecent c, per sq cm	Low	Low
Q4337	Artecent trident, per sq cm	Low	Low
Q4338	Artacent velos, per sq cm	Low	Low
Q4339	Artacent vericlen, per sq cm	Low	Low
Q4340	Simpligraft, per sq cm	Low	Low
Q4341	Simplimax, per sq cm	Low	Low
Q4342	Theramend, per sq cm	Low	Low
Q4343	Dermacyte ac matrx per sq cm	Low	Low
Q4344	Tri membrane wrap, per sq cm	Low	Low
Q4345	Matrix hd allogrft per sq cm	Low	Low

* These products do not exceed either the MUC or PDC threshold for CY 2025 but are assigned to the high-cost group because they were assigned to the high-cost group in CY 2024.

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8. Radioisotopes Derived From Non-Highly Enriched Uranium (non-HEU) Sources/Radioisotopes Derived From Domestically Produced Mo-99

Radioisotopes are widely used in modern medical imaging, particularly for cardiac imaging and predominantly for the Medicare population. Technetium-99m (Tc-99m), the radioisotope used in the majority of such diagnostic imaging services, is produced through the radioactive decay of molybdenum-99 (Mo-99). Historically, most of the Mo-99 used in the United States was produced in legacy reactors outside of the United States using highly enriched uranium (HEU).

The United States wanted to eliminate domestic reliance on these reactors and promoted the conversion of all medical radioisotope production to non-HEU sources. Alternative methods for producing Tc-99m without HEU are technologically and economically viable, but it was expected that this change in the supply source for the radioisotope used for modern medical imaging would introduce increased costs into the payment system that would not be fully accounted for in the historical claims data until all Tc-99m was produced from non-HEU sources.

Therefore, beginning in CY 2013, we finalized a policy to provide an additional payment of $10 for the marginal cost for radioisotopes produced by non-HEU sources (77 FR 68323). Under this policy, hospitals report HCPCS code Q9969 (Tc-99m from non-highly enriched uranium source, full cost recovery add-on per study dose) once per dose along with any diagnostic scan or scans furnished using Tc-99m as long as the Tc-99m doses used can be certified by the hospital to be at least 95 percent derived from non-HEU sources (77 FR 68323).

We stated in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68321) that our expectation was that this additional payment would be needed for the duration of the industry's conversion to alternative methods of producing Tc-99m without HEU. We also stated that we would reassess, and propose, if necessary, on an annual basis whether such an adjustment continued to be necessary and whether any changes to the adjustment were warranted (77 FR 68321). The Secretaries of Energy and Health and Human Services issued a certification regarding the supply of non-HEU-sourced Mo-99 effective January 2, 2022 (86 FR 73270). Mo-99 is the precursor material from which Tc-99m is sourced. The certification by the Secretary of Energy stated that there was a sufficient global supply of Mo-99 produced without the use of HEU available to meet the needs of patients in the United States. In the CY 2023 OPPS/ASC final rule with comment period, we stated that we believed the conversion to non-HEU sources of Tc-99m had reached a point where it was necessary to reassess our policy of providing an additional payment of $10 for the marginal cost for radioisotopes produced by non-HEU sources (87 FR 71987).

Historically, diagnostic radiopharmaceuticals have been packaged into the cost of the associated diagnostic imaging procedure no matter the per-day cost (we are adopting a policy beginning in CY 2025 to pay separately for higher cost diagnostic radiopharmaceuticals). The cost of the radiopharmaceutical, whether it is included as a part of the cost of the diagnostic imaging procedure or is separately paid, is reported through Medicare claims data. Medicare claims data used to set payment rates under the OPPS generally are from two years prior to the payment year.

As we explained in the CY 2023 OPPS/ASC final rule with comment period (87 FR 71987), the claims data we used to set payment rates for CY 2024 (generally CY 2022 claims data) contained claims for diagnostic radiopharmaceuticals that reflect both HEU-sourced Tc-99m and non-HEU-sourced Tc99m, rather than radiopharmaceuticals sourced solely from non-HEU Tc-99m. The cost of HEU-sourced Tc-99m is substantially lower than the cost of non-HEU-sourced Tc-99m. Therefore, we explained that providers who use radiopharmaceuticals in CY 2024 that contain only non-HEU-sourced Tc-99m might not receive a payment that is reflective of the radiopharmaceutical's current cost without the add-on payment. We believed that extending the additional $10 add-on payment described by HCPCS code Q9969 for non-HEU-sourced Tc-99m through the end of CY 2024 would ensure adequate payment for non-HEU-sourced Tc-99m. Starting in CY 2025, we believed the Medicare claims data utilized to set payment rates (likely CY 2023 claims data) would only include claims for diagnostic radiopharmaceuticals that utilized non-HEU-sourced Tc-99m, meaning the data would reflect the full cost of the Tc-99m diagnostic radiopharmaceuticals that would be used by providers in CY 2025. As a result, we believed there would no longer be a need for the additional $10 add-on payment for CY 2025 or future years.

The conversion of the last major global Mo-99 producer from HEU to Low Enriched Uranium (LEU) was previously expected to be completed by December 31, 2022, but the conversion did not occur until March 2023. As a result, it is possible that some claims for diagnostic radiopharmaceuticals in CY 2023 would report the cost of HEU-sourced Tc-99m. This means that in CY 2025, as in CY 2024, there is the possibility that the payment rate for procedures using diagnostic radiopharmaceuticals could be lower than the costs providers will incur for these procedures because providers will only have access to non-HEU-sourced Tc-99m. Therefore, we adopted a policy in the CY 2024 OPPS final rule with comment period (88 FR 81803) to extend the additional $10 add-on payment described by HCPCS code Q9969 for non-HEU-sourced Tc-99m through the end of CY 2025 to continue to ensure adequate payment for non-HEU-sourced Tc-99m.

Recently, the Department of Energy and other interested parties raised another issue affecting the domestic supply chain for Mo-99 and Tc-99 that, left unaddressed, could cause payment inequity among outpatient hospital providers. Foreign Mo-99 production has historically been subsidized by foreign governments, resulting in prices below the true cost of production. These artificially low, government-subsidized prices have created a disincentive for investments in Mo-99 production infrastructure, and they also created a barrier to entry for new producers, including U.S. companies. This in turn has resulted in unreliable production and periodic shortages. In response to the 2009–2010 shortages, Congress passed the American Medical Isotopes Production Act of 2012 (AMIPA), which directs the Secretary of Energy to provide financial and technical support to U.S. companies working to build new irradiation and manufacturing facilities to produce Mo-99 without HEU.

It was expected that the transition from HEU to LEU-based production would also involve the transition to a Full Cost Recovery pricing model; however, it does not appear that this transition has occurred in practice. Foreign producers continue to rely on multipurpose nuclear research reactors for Mo-99 production, and the global Mo-99 supply chain has not established a system of verifying that all of the costs attributable to Mo-99 production are being incorporated into the price of the product.

U.S. companies have made significant progress towards establishing the infrastructure needed for large-scale Mo-99 production. Unlike many foreign producers, U.S. companies must price their products high enough to cover the full cost of operating their production facilities. Based in part on the differences in pricing models, U.S. companies have experienced challenges in competing with foreign producers for customers. Currently, there is no domestic production of Mo-99.

Once U.S. companies initiate or resume Mo-99 production, the difference in pricing models will likely create a payment inequity, as hospitals purchasing Tc-99m derived from domestically produced Mo-99 would likely pay higher prices than those purchasing Tc-99m derived from imported Mo-99. We proposed to address the payment inequity resulting from the higher cost of domestically produced Tc-99m by establishing a new add-on payment of $10 per dose for radiopharmaceuticals that use Tc-99m derived from domestically produced Mo-99 starting on January 1, 2026, using our equitable adjustment authority under section 1833(t)(2)(E) of the Act. We stated that we believe the $10 add-on payment for domestically produced Tc-99m would ensure equitable payments by paying providers who use domestically produced Tc-99m radiopharmaceuticals when available an amount that reflects the anticipated higher cost of these products. We explained that the $10 add-on payment will help to ensure provider and beneficiary access to domestically produced Tc-99m radiopharmaceuticals by providing an additional payment amount that addresses the additional costs of domestically produced Tc-99m radiopharmaceuticals. The Department of Energy, National Nuclear Security Administration, (DOE/NNSA) would establish the criteria to certify whether the Tc-99m radiopharmaceutical dose is domestically produced and eligible for the add-on payment, which would be included in the CY 2026 OPPS/ASC proposed rule. The CY 2026 OPPS/ASC proposed rule would include additional details on how providers would bill for this add-on payment in CY 2026.

Comment: Multiple commenters supported our proposal to establish a new add-on payment of $10 per dose for radiopharmaceuticals that use Tc-99m derived from domestically produced Mo-99.

Response: We appreciate the support of the commenters for our proposal.

Comment: Multiple commenters expressed support for an add-on payment for domestically produced Tc-99m radiopharmaceuticals, but the commenters expressed several concerns about how the add-on payment policy would work. Some commenters believe the proposed payment amount for the add-on of $10 is too low and encouraged us to work with interested parties to determine a different payment amount that would adequately cover the cost difference between domestically produced Tc-99m radiopharmaceuticals and foreign produced Tc-99m radiopharmaceuticals. One commenter asked us to provide additional analysis to support the payment amount for the add-on payment.

Commenters had concerns about the effectiveness of the policy based on their experiences with the current add-on payment for Tc-99m radiopharmaceuticals produced from non-HEU sources. Commenters do not believe the add-on payment for Tc-99m radiopharmaceuticals produced from non-HEU sources has substantially influenced the types of Tc-99m radiopharmaceuticals purchased by outpatient hospitals or remedied cost differences between HEU and non-HEU Tc-99m for the companies who supply Tc-99m radiopharmaceuticals to hospitals. Commenters encouraged us to work with DOE/NNSA and other government agencies to ensure that domestic Mo-99 producers and Tc-99m generator manufacturers receive assistance to handle the higher costs of their products.

Commenters were also concerned about how a Tc-99m radiopharmaceutical will be defined as a domestically produced product. They asked that CMS and other government agencies show flexibility when coming up with a definition of domestically produced Tc-99m radiopharmaceuticals to avoid increasing production costs. Commenters noted that Tc-99m generators often mix Mo-99 from several sources, which may make it challenging for suppliers to adhere to strict domestic Tc-99m content requirements. Commenters want to ensure that the tracking and documentation requirements for outpatient hospital providers to prove the Tc-99m radiopharmaceuticals they use are domestically produced are easy to understand and use, and do not add an additional burden to hospitals.

Response: We will continue to monitor the differences in cost between domestically produced Tc-99m and foreign produced Tc-99m for future rulemaking. Using available information from the Organization for Economic Co-operation and Development, Nuclear Energy Agency (OECD/NEA), the methodology for a $10 add-on payment accounts for the per-dose cost of implementing full-cost recovery pricing. As such, DOE/NNSA recommends maintaining the $10 value as the add-on payment transitions from a non-HEU payment to a domestically sourced Tc-99m payment. We believe $10 is an appropriate amount for an add-on payment for domestically produced Tc-99m radiopharmaceuticals to address this expected cost difference.

We understand commenters' concerns about the ability of the add-on payment to change the purchasing behavior of providers. However, the $10 add-on payment is intended to address the expected additional cost of domestically-produced Tc-99m radiopharmaceuticals if providers choose to utilize these radiopharmaceuticals in the future. If commenters have data showing that the price differential between domestically produced and foreign produced Mo-99 will be significantly more or less than $10, they may provide that data to CMS so we can consider it for CY 2026 OPPS rulemaking.

We appreciate commenters' suggestions for how to establish requirements to determine that a Tc-99m radiopharmaceutical is domestically produced. As we stated in the CY 2025 OPPS/ASC proposed rule (89 FR 59378), DOE/NNSA is establishing the criteria to certify whether the Tc-99m radiopharmaceutical dose is domestically produced and eligible for the add-on payment, and those criteria will be included in the CY 2026 OPPS/ASC proposed rule. We will consider in CY 2026 rulemaking any additional requirements for Medicare providers to document that the Tc-99m radiopharmaceutical used in a procedure was domestically produced and can qualify to receive the add-on payment based on the criteria developed by DOE/NNSA.

Comment: One commenter was opposed to the $10 add-on payment for domestically produced Tc-99m radiopharmaceuticals. According to the commenter, the central challenge for the proposal is that the Mo-99 used to create the Tc-99m generators will come from both domestic and foreign sources, and suppliers would need to assess each generator individually to determine its domestic Tc-99 content and whether the Tc-99 meets the standard to be considered domestically produced. The Tc-99m generator suppliers would need to communicate the domestic production status of each generator to the provider receiving the generator. The provider would then have to track the Tc-99m generators and link them to the Tc-99m radiopharmaceutical administered to a patient to be able to claim the add-on payment for domestically produced Tc-99m radiopharmaceuticals. The commenter believes most providers will not be able to track or document information on the production source of the Tc-99m generators they purchase.

The commenter also does not believe that if a domestic company starts to produce Mo-99, it will price it higher than Mo-99 from foreign sources because the domestic producer will need to charge the same price for Mo-99 to stay competitive with foreign producers. Per the commenter, this would mean when the Tc-99m radiopharmaceuticals are purchased by outpatient hospital providers at the point where the add-on payment may have a policy impact, there will be no price difference between the domestically produced product and the foreign produced product, and no purpose for the add-on payment. The commenter also expressed concern that the add-on payment policy will not help the pharmacies, Tc-99m generator manufacturers, or the Mo-99 producers who supply Tc-99m radiopharmaceuticals to outpatient hospitals, and those suppliers will end up paying for the higher cost of domestically produced Tc-99m, not hospitals. The commenter asked that we not finalize our proposal or at least wait until CY 2027 before implementing it. The commenter believes that it will take until at least 2027 before a domestic producer can start producing Mo-99 for Tc-99m generators.

Response: We appreciate the concerns of the commenter. As stated in the previous comment, DOE/NNSA will be establishing the criteria to certify whether the Tc-99m radiopharmaceutical dose is domestically produced and eligible for the add-on payment, and those criteria will be included in the CY 2026 OPPS/ASC proposed rule. Regarding the challenges providers may face identifying a Tc-99m radiopharmaceutical as a domestically produced product, once requirements are established defining a domestically produced Tc-99m radiopharmaceutical, we will consider in future rulemaking any requirements for providers to document that the Tc-99m radiopharmaceutical used in a procedure was domestically produced and can qualify to receive the add-on payment. We understand commenters' concerns regarding the cost of domestically-produced Tc-99m radiopharmaceuticals for entities other than outpatient hospital departments, but note that this policy is only intended to address the additional cost to hospital outpatient departments of utilizing domestically-produced Tc-99m radiopharmaceuticals.

The commenter noted that currently there are no producers of domestically sourced Mo-99 and Tc-99, and the earliest that domestic production of Mo-99 and Tc-99 could begin is in 2027. While there may not be domestic production of Mo-99 and Tc-99in CY 2026, we believe it is better to have a regulatory framework for this policy in place when domestic production of Tc-99m radiopharmaceuticals begins. With

a regulatory framework already in place, providers will be knowledgeable about the availability of additional payments for domestically sourced Tc-99m radiopharmaceuticals. Likewise, producers of domestic Mo-99m will have certainty that the Medicare OPPS payment policy takes into account the additional costs of domestic production of Mo-99.

After consideration of the public comments we received, we are finalizing our proposal without modification to establish a new add-on payment of $10 per dose for radiopharmaceuticals that use Tc-99m derived from domestically produced Mo-99 starting on January 1, 2026. As established in the CY 2024 OPPS/ASC final rule with comment period, CY 2025 will be the final year of the $10 add-on payment for TC–99m derived from non-HEU sources.

VI. Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices

A. Amount of Additional Payment and Limit on Aggregate Annual Adjustment

Section 1833(t)(6)(E) of the Act limits the total projected amount of transitional pass-through payment for drugs, biologicals, and categories of devices for a given year to an ''applicable percentage,'' currently not to exceed 2.0 percent of total program payments estimated to be made for all covered services under the OPPS furnished for that year. If we estimate before the beginning of the calendar year that the total amount of pass-through payments in that year would exceed the applicable percentage, section 1833(t)(6)(E)(iii) of the Act requires a uniform prospective reduction in the amount of each of the transitional pass-through payments made in that year to ensure that the limit is not exceeded. We estimate the pass-through spending to determine whether payments exceed the applicable percentage and the appropriate pro rata reduction to the conversion factor for the projected level of pass-through spending in the following year to ensure that total estimated pass-through spending for the prospective payment year is budget neutral, as required by section 1833(t)(6)(E) of the Act.

For devices, developing a proposed estimate of pass-through spending in CY 2025 entails estimating spending for two groups of items. The first group of items consists of device categories that are currently eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2025. The CY 2008 OPPS/ASC final rule with comment period (72 FR 66778) describes the methodology we have used in previous years to develop the pass-through spending estimate for known device categories continuing into the applicable update year. The second group of items consists of devices that we know are newly eligible, or project may be newly eligible, for device pass-through payment in the remaining quarters of CY 2024 or beginning in CY 2025. The sum of the proposed CY 2025 pass-through spending estimates for these two groups of device categories equals the proposed total CY 2025 pass-through spending estimate for device categories with pass-through payment status. We determined the device pass-through estimated payments for each device category based on the amount of payment as required by section 1833(t)(6)(D)(ii) of the Act, and as outlined in previous rules, including the CY 2014 OPPS/ASC final rule with comment period (78 FR 75034 through 75036). We note that, beginning in CY 2010, the pass-through evaluation process and pass-through payment methodology for implantable biologicals newly approved for pass-through payment beginning on or after January 1, 2010, that are surgically inserted or implanted (through a surgical incision or a natural orifice) use the device pass-through process and payment methodology (74 FR 60476). As has been our past practice (76 FR 74335), in the proposed rule, we proposed to include an estimate of any implantable biologicals eligible for pass-through payment in our estimate of pass-through spending for devices. Similarly, we finalized a policy in CY 2015 that applications for pass-through payment for skin substitutes and similar products be evaluated using the medical device pass-through process and payment methodology (76 FR 66885 through 66888). Therefore, as we did beginning in CY 2015, for CY 2025, we also proposed to include an estimate of any skin substitutes and similar products in our estimate of pass-through spending for devices.

For drugs and biologicals eligible for pass-through payment, section 1833(t)(6)(D)(i) of the Act establishes the pass-through payment amount as the amount by which the amount authorized under section 1842(o) of the Act (or, if the drug or biological is covered under a competitive acquisition contract under section 1847B of the Act, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary) exceeds the portion of the otherwise applicable fee schedule amount that the Secretary determines is associated with the drug or biological. Consistent with current policy, we proposed to apply a rate of ASP plus 6 percent to most drugs and biologicals for CY 2025, and therefore our estimate of drug and biological pass-through payment for CY 2025 for this group of items was $10.2 million.

Payment for certain drugs,[146] specifically contrast agents without pass-through payment status, is packaged into payment for the associated procedures, and these products are not separately paid. In addition, we policy-package non-pass-through drugs and biologicals that function as supplies when used in a diagnostic test or procedure unless a high-cost diagnostic radiopharmaceutical with a per day cost greater than $630 is used for the test or procedure. We policy-package all drugs and biologicals that function as supplies when used in a surgical procedure or for anesthesia, and other categories of drugs and biologicals, as discussed in section V.B.1.c of the CY 2025 OPPS/ASC proposed rule (89 FR 59364). Consistent with current policy, we propose that all of these policy-packaged drugs and biologicals with pass-through payment status will be paid at ASP+6 percent, like other pass-through drugs and biologicals, for CY 2025, less the policy-packaged drug APC offset amount described below. Our estimate of pass-through payment for policy-packaged drugs and biologicals with pass-through payment status approved prior to CY 2025 is not $0. This is because the pass-through payment amount and the fee schedule amount associated with the drug or biological will not be the same, unlike for separately payable drugs and biologicals. In the CY 2024 OPPS/ASC final rule with comment period (88 FR 81774 through 81776), we discussed our policy to determine if the costs of certain policy-packaged drugs or biologicals are already packaged into the existing APC structure. If we determine that a policy-packaged drug or biological approved for pass-through payment resembles predecessor drugs or biologicals already included in the costs of the APCs that are associated with the drug receiving pass-through payment, we proposed to offset the amount of pass-through payment for the policy-packaged drug or biological. For these

[146] Please see section II.A.3.c. for more information regarding the payment of diagnostic radiopharmaceuticals.

drugs or biologicals, the APC offset amount is the portion of the APC payment for the specific procedure performed with the pass-through drug or biological, which we refer to as the policy-packaged drug APC offset amount. Consistent with current policy, if we determine that an offset is appropriate for a specific policy-packaged drug or biological receiving pass-through payment, we proposed to reduce our estimate of pass-through payments for these drugs or biologicals by the APC offset amount.

Similar to pass-through spending estimates for devices, the first group of drugs and biologicals requiring a pass-through payment estimate consists of those products that were recently made eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2025. The second group contains drugs and biologicals that we know are newly eligible, or project will be newly eligible, in CY 2025. The sum of the CY 2025 pass-through spending estimates for these two groups of drugs and biologicals equals the total CY 2025 pass-through spending estimate for drugs and biologicals with pass-through payment status.

B. Final Estimate of Pass-Through Spending for CY 2025

For CY 2025, we proposed to set the applicable pass-through payment percentage limit at 2.0 percent of the total projected OPPS payments for CY 2025, consistent with section 1833(t)(6)(E)(ii)(II) of the Act and our OPPS policy from CY 2004 through CY 2024 (88 FR 81805). The pass-through payment percentage limit is calculated using pass-through spending estimates for devices and for drugs and biologicals.

For the first group of devices, consisting of device categories that are currently eligible for pass-through payment and will continue to be eligible for pass-through payment in CY 2025, there are 8 active categories for CY 2025. The active categories are described by HCPCS codes C1747, C1826, C1827, C1600, C1601, C1602, C1603 and C1604. Based on the information from the device manufacturers, we estimated that HCPCS code C1747 will cost $19.5 million in pass-through expenditures in CY 2025, HCPCS code C1826 will cost $151,991 in pass-through expenditures in CY 2025, HCPCS code C1827 will cost $364,793 in pass-through expenditures in CY 2025, HCPCS code C1600 will cost $21.9 million in pass-through expenditures in CY 2025, HCPCS code C1601 will cost $14.4 million in pass-through expenditures in CY 2025, HCPCS code C1602 will cost $8.2 million in pass-through expenditures in CY 2025, HCPCS code C1603 will cost $6.6 million in pass-through expenditures in CY 2025, and HCPCS code C1604 will cost $20.0 million in pass-through expenditures in CY 2025. Therefore, we proposed an estimate for the first group of devices of $91.1 million.

We did not receive any public comments on our proposed estimate. Using our methodology for this final rule with comment period, the final estimated pass through costs based on updated data for HCPCS code C1747 will cost $18.9 million in pass-through expenditures in CY 2025, HCPCS code C1826 will cost $176,594 in pass-through expenditures in CY 2025, HCPCS code C1827 will cost $844,031 in pass-through expenditures in CY 2025, HCPCS code C1600 will cost $21.9 million in pass-through expenditures in CY 2025, HCPCS code C1601 will cost $14.4 million in pass-through expenditures in CY 2025, HCPCS code C1602 will cost $8.2 million in pass-through expenditures in CY 2025, HCPCS code C1603 will cost $6.6 million in pass-through expenditures in CY 2025, and HCPCS code C1604 will cost $20.0 million in pass-through expenditures in CY 2025. Therefore, we have finalized the CY 2025 spending estimate for the first group of devices of approximately $91.0 million.

In estimating our proposed CY 2025 pass-through spending for device categories in the second group, we included the following: (1) device categories that we assumed at the time of the development of the proposed rule would be newly eligible for pass-through payment in CY 2025; (2) additional device categories that we estimated could be approved for pass-through status after the development of the CY 2025 OPPS/ASC proposed rule (89 FR 59379) and before January 1, 2025; and (3) contingent projections for new device categories established in the second through fourth quarters of CY 2025. For CY 2025, we proposed to use the general methodology described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66778), while also taking into account recent OPPS experience in approving new pass-through device categories. For the CY 2025 OPPS/ASC proposed rule (89 FR 59379), the proposed estimate of CY 2025 pass-through spending for this second group of device categories was $523.7 million.

We did not receive any public comments on the proposed estimate. As stated earlier in this final rule with comment period, we are approving eight devices for pass-through payment status in the CY 2025 rulemaking cycle: AGENT™ Paclitaxel-Coated Balloon Catheter, AVEIR™ DR Dual Chamber Leadless Pacemaker System (Aveir™ DR System), DETOUR™ System, the Ultrasound Disposable Kit—Diagnostic/Therapeutic (UDK–T) component of the EndoSound Vision System™ (EVS™), iFuse Bedrock Granite™ Implant System, Paradise® Ultrasound Renal Denervation (RDN) System, Precision GI and Symplicity Spyral™ Renal Denervation (RDN) System.[147] The manufacturers of these systems provided utilization and cost data that indicate the amount of spending for the devices would be approximately $36.0 million for AGENT™ Paclitaxel-Coated Balloon Catheter; $113.0 million for AVEIR™ DR Dual Chamber Leadless Pacemaker System; $280,000 for the UDK–T component of the EVS™; $25.3 million for iFuse Bedrock Granite™ Implant System; $32.8 million for Paradise® Ultrasound RDN System; $0.78 million for Precision GI; and $16.0 million for Symplicity Spyral™ RDN System. In addition, we note that HCPCS code C8000 was preliminarily approved as part of the device pass-through quarterly review process with an effective date of October 1, 2024.[148] For this final rule based on updated data, we estimate that HCPCS code C8000 will cost $2.9 million in pass-through expenditures in CY 2025. Therefore, we are finalizing an estimate of $227.1 million for this second group of devices for CY 2025.

The estimated amount of pass-through spending of $227.1 million in this final rule is substantially less that the estimated amount of pass-through spending in the CY 2025 OPPS/ASC proposed rule (89 FR 59379) of $523.7

[147] As discussed in section IV.A.2 of this final rule with comment period, the DETOUR™ System pass-through application was preliminarily approved for transitional pass-through payment under the alternative pathway effective January 1, 2024, and the Aveir™ DR System pass-through application and the UDK–T component of the EVS™ pass-through application were preliminarily approved for transitional pass-through payment under the alternative pathway effective July 1, 2024. We are finalizing the approvals for device pass-through payment status for the DETOUR™ System, the Aveir™ DR System and the UDK–T component of the EVS™ in this final rule with comment period. Due to the timing of the preliminary approvals, the CY 2025 spending estimate for the DETOUR™ System is included in the CY 2025 spending estimate for the first group of devices; and the CY 2025 spending estimate for the Aveir™ DR System and the UDK–T component of the EVS™ is included in the CY 2025 spending estimate for the second group of devices.

[148] The device application associated with HCPCS code C8000 will be included and discussed in the CY 2026 OPPS/ASC proposed and final rules.

million because, in the proposed rule we assumed that all of the devices with pending applications to receive pass-through status would receive approval. For the final rule, we have determined the some of these devices have received pass-through status, and some of these devices have been denied pass-through status, and we adjusted our device pass-through spending estimates accordingly.

To estimate proposed CY 2025 pass-through spending for drugs and biologicals in the first group, specifically those drugs and biologicals recently made eligible for pass-through payment and continuing on pass-through payment status for at least one quarter in CY 2025, we proposed to use the CY 2023 Medicare hospital outpatient claims data regarding their utilization, information provided in their respective pass-through applications, other historical hospital claims data, pharmaceutical industry information, and clinical information regarding these drugs and biologicals to project the CY 2025 OPPS utilization of the products.

For the known drugs and biologicals (excluding policy-packaged contrast agents, drugs, biologicals, radiopharmaceuticals with per-day costs at or below the packaging threshold that function as supplies when used in a diagnostic test or procedure, and drugs and biologicals that function as supplies when used in a surgical procedure) that will be continuing on pass-through payment status in CY 2025, we estimated the pass-through payment amount as the difference between the general payment rate of ASP+6 percent and the payment rate for non-pass-through drugs and biologicals that would be separately paid. Because we proposed to utilize a payment rate of ASP plus 6 percent for most separately payable drugs and biologicals in the proposed rule, the proposed payment rate difference between the pass-through payment amount and the non-pass-through payment amount was $0 for this group of drugs.

Because payment for policy-packaged drugs and biologicals is packaged if the product is not paid separately due to its pass-through payment status, we propose to include in the CY 2025 pass-through estimate the difference between payment for the policy-packaged drug or biological at ASP+6 percent (or WAC+6 percent, or 95 percent of AWP, if ASP or WAC information is not available) and the policy-packaged drug APC offset amount, if we determine that the policy-packaged drug or biological approved for pass-through payment resembles a predecessor drug or biological already included in the costs of the APCs that are associated with the drug receiving pass-through payment. Diagnostic radiopharmaceuticals that currently have pass-through status, but would be paid separately because of the policy we are adopting described in Section II.A.3.c. to separately pay for diagnostic radiopharmaceuticals with a per day cost over $630, are not considered to be policy-packaged and are not included in this group. For this first group of policy-packaged drugs and biologicals, we estimated a pass-through spending for CY 2025 of $200,000.

We did not receive any public comments on our proposed estimate. Using our methodology for this final rule with comment period, the CY 2025 spending estimate for this first group of drugs and biologicals is around $200,000.

To estimate proposed CY 2025 pass-through spending for drugs and biologicals in the second group (that is, drugs and biologicals that we knew at the time of development of the proposed rule were newly eligible or recently became eligible for pass-through payment in CY 2024, additional drugs and biologicals that we estimated could be approved for pass-through status subsequent to the development of the proposed rule and before January 1, 2025, and projections for new drugs and biologicals that could be initially eligible for pass-through payment in the second through fourth quarters of CY 2025), we proposed to use utilization estimates from pass-through applicants, pharmaceutical industry data, clinical information, recent trends in the per unit ASPs of hospital outpatient drugs, and projected annual changes in service volume and intensity as our basis for making the CY 2025 pass-through payment estimate. We also proposed to consider the most recent OPPS experience in approving new pass-through drugs and biologicals. Using our proposed methodology for estimating CY 2025 pass-through payments for this second group of drugs, we calculated a proposed spending estimate for this second group of drugs and biologicals of approximately $10 million.

We did not receive any public comments on our proposed estimate. Using our methodology for this final rule with comment period, we are finalizing our estimate of pass-through spending for the second group of drugs and biologicals to be $10 million.

We estimated for the CY 2025 OPPS/ASC proposed rule (89 FR 59380) that the amount of pass-through spending for the device categories and the drugs and biologicals that are continuing to receive pass-through payment in CY 2025 and the amount of pass-through spending for those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2025 would be approximately $625 million (approximately $614.8 million for device categories and approximately $10.2 million for drugs and biologicals), which represented 0.71 percent of total projected OPPS payments for CY 2025 (approximately $88.2 billion). Therefore, we estimated for the proposed rule that pass-through spending in CY 2025 would not amount to 2.0 percent of total projected OPPS CY 2025 program spending.

We estimate for this final rule with comment period that the amount of pass-through spending for the device categories and the drugs and biologicals that are continuing to receive pass-through payment in CY 2025 and the amount of pass-through spending for those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2025 would be approximately $328.3 million (approximately $318.1 million for device categories and approximately $10.2 million for drugs and biologicals), which represents only 0.37 percent of total projected OPPS payments for CY 2025 (approximately $87.7 billion). Therefore, we estimate that pass-through spending in CY 2025 will not exceed the 2.0 percent of total projected OPPS CY 2025 program spending limit provided for in section 1833(t)(6)(E) of the Act.

VII. OPPS Payment for Hospital Outpatient Visits and Critical Care Services

For CY 2025, we proposed to continue our current clinic and emergency department (ED) hospital outpatient visits payment policies. For a description of these policies, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70448). We also proposed to continue our payment policy for critical care services for CY 2025. For a description of this policy, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70449), and for the history of this payment policy, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75043).

As we stated in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63663), the volume control method for clinic visits furnished by non-excepted off-campus provider-based departments (PBDs) applies for CY 2022 and subsequent years. More specifically, we finalized a policy to continue to utilize a PFS-equivalent payment rate

for the hospital outpatient clinic visit service described by HCPCS code G0463 when it is furnished by these departments for CY 2022 and subsequent years. The PFS-equivalent rate for CY 2025 is 40 percent of the proposed OPPS payment. Under this policy, these departments will be paid approximately 40 percent of the OPPS rate for the clinic visit service in CY 2025.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 71748), we finalized a policy that excepted off-campus provider-based departments (PBDs) (departments that bill the modifier ''PO'' on claim lines) of rural Sole Community Hospitals (SCHs), as described under 42 CFR 412.92 and designated as rural for Medicare payment purposes, are exempt from the clinic visit payment policy that applies a PFS-equivalent payment rate for the clinic visit service, as described by HCPCS code G0463, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act. For the full discussion of this policy, we refer readers to the CY 2023 OPPS/ASC final rule with comment period (87 FR 72047 through 72051). For CY 2025, we proposed to continue to exempt excepted off-campus PBDs of rural SCHs from the clinic visit payment policy. We stated that we would continue to monitor the effect of this change in Medicare payment policy, including on the volume of these types of OPD services.

Comment: We received several comments on our overall clinic visit payment policy. Many commenters continued to express the belief that this policy undermines Congressional intent and exceeds the agency's legal authority. As they have in previous years, commenters stated that the policy is based on flawed assumptions and urged CMS to eliminate it altogether. One commenter suggested that we lack the statutory authority to implement this policy in a non-budget neutral manner. While acknowledging that *American Hospital Association* v. *Azar,* 964 F.3d 1230 (D.C. Cir. 2020), affirmed our authority to implement our policy under section 1833(t)(2)(F), the commenter stated that it has been overtaken by *Loper Bright* v. *Raimondo,* 144 S. Ct. 2244 (2024), and so should be disregarded. They requested that CMS reverse this payment adjustment or, at a minimum, budget neutralize its application consistent with statute.

Response: We continue to believe that section 1833(t)(2)(F) of the Act gives the Secretary authority to develop a method for controlling unnecessary increases in the volume of covered OPD services, including a method that controls unnecessary volume increases by removing a payment differential that is driving a site-of-service decision, and as a result, is unnecessarily increasing service volume.

As we noted in the CY 2019 OPPS/ASC proposed rule (83 FR 37138 through 37143), ''[a] large source of growth in spending on services furnished in hospital outpatient departments (HOPDs) appears to be the result of the shift of services from (lower cost) physician offices to (higher cost) HOPDs.'' We continue to believe that these shifts in the sites of service are unnecessary if the beneficiary can safely receive the same services in a lower cost setting but instead receives care in a higher cost setting due to payment incentives. In most cases, the difference in payment is leading to unnecessary increases in the volume of covered outpatient department services, and we remain concerned that this shift in care setting increases beneficiary cost-sharing liability because Medicare payment rates for the same or similar services are generally higher in hospital outpatient departments than in physician offices. We continue to believe that our method addresses the concerns described in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59005).

As we stated in the CY 2019 OPPS ASC final rule with comment period (83 FR 59013), we believe implementing a volume control method in a budget neutral manner would not appropriately reduce the overall unnecessary volume of covered OPD services, and instead would simply shift services within the OPPS system because of payment rather than medical necessity. We also outlined in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59013) that while section 1833(t)(9)(B) of the Act requires that certain changes made under the OPPS be made in a budget neutral manner, this section does not apply to the volume control method under section 1833(t)(2)(F) of the Act.

As noted, the D.C. Circuit previously held that our regulation was a reasonable interpretation of the statutory authority to adopt a method to control for unnecessary increases in the volume of the relevant service. *AHA* v. *Azar,* 964 F.3d at 1241–45, *Loper Bright* does not change the result. As an initial matter, while *Loper Bright* changed certain aspects of the interpretative framework the D.C. Circuit used, the Supreme Court cautioned that the ''holdings of those cases that specific agency actions are lawful . . . are still subject to statutory *stare decisis* despite our change in interpretive methodology.'' 144 S. Ct. at 2273. *AHA's* holding is therefore still good law. And even under the new *Loper Bright* framework, the Supreme Court clarified that Congress ''often'' enacts statutes that ''delegate[] discretionary authority to an agency.'' *Id.* at 2263. Section 1833(t)(2)(F) is just such a statute. By instructing the Secretary to ''develop a method for controlling unnecessary increases in the volume of covered OPD services'' without specifying the method, the statute delegates discretionary authority to the Secretary. Because, as the D.C. Circuit explained, our policy ''falls comfortably within the plain text of subparagraph (2)(F)'' and is further supported by its structure, 964 F.3d at 1241, it does not fall outside the ''outer statutory bounds'' of the delegation, as discussed in *Loper Bright.* That aspect of the D.C. Circuit's holding, coupled with the considerations of *stare decisis,* indicate that there is no reason to doubt the continued validity of our policy. 144 S. Ct. at 2268.

Comment: We received comments supporting CMS's efforts to continue implementing its method to control for unnecessary increases in the volume of outpatient services. These commenters asked that CMS continue to consider ways to expand the current site-neutral payment policies to other services and settings. Commenters reiterated their statements from previous years suggesting that CMS apply the site-neutral payment policy to a list of 57 APCs for which MedPAC determined it would be reasonable and appropriate to align the OPPS and ASC payment rates with those set in the physician fee schedule (PFS). Other commenters recommended that CMS consider expanding the site-neutral payment policy to all services provided by excepted, off-campus PBDs. Others suggested that the site-neutral policy be extended to on-campus PBDs, ASCs, and emergency departments.

Response: We appreciate the commenters' support and we will continue to monitor this policy and take commenters' suggestions into consideration for potential future rulemaking.

After consideration of the public comments, we are continuing the volume control method under which we utilize a PFS-equivalent payment rate for the hospital outpatient clinic visit service described by HCPCS code G0463 when it is furnished by excepted off-campus PBDs in CY 2025.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 71748), we finalized a policy that excepted off-campus provider-based departments (PBDs) (departments that bill the

modifier ''PO'' on claim lines) of rural Sole Community Hospitals (SCHs), as described under 42 CFR 412.92 and designated as rural for Medicare payment purposes, are exempt from the clinic visit payment policy that applies a Physician Fee Schedule-equivalent payment rate for the clinic visit service, as described by HCPCS code G0463, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act. For the full discussion of this policy, we refer readers to the CY 2023 OPPS/ASC final rule with comment period (87 FR 72047 through 72051). For CY 2025, we proposed to continue to exempt excepted off-campus PBDs of rural SCHs from the clinic visit payment policy. We stated that we will continue to monitor the effect of this change in Medicare payment policy, including on the volume of these types of OPD services.

The following is a summary of the comments we received and our responses to those comments.

Comment: Commenters continued to support our proposal to exempt excepted off-campus PBDs of rural SCHs from the clinic visit payment policy for CY 2025. Commenters stated that the continuation of the exemption is an important step in maintaining access to care for a segment of the population that is underserved.

Response: We thank the commenters for their support.

Comment: Several commenters reiterated their requests from previous proposed rules that CMS consider expanding the exemption to excepted off-campus PBDs of rural hospitals with fewer than 100 beds, Medicare Dependent Hospitals (MDHs), Urban SCHs, and low-volume hospitals in future rulemaking, arguing that the same reasoning that led CMS to propose to exempt SCHs also applies to these hospitals.

Response: In the CY 2006 OPPS final rule with comment period (70 FR 68556 through 68561) we uniquely identified rural SCHs as providers with demonstrated additional resource costs. We found that rural SCHs have significantly higher costs per unit than urban hospitals. We have continued to adjust payments for rural SCHs by 7.1 percent each year since 2006. Building upon that foundation, for CY 2018 we finalized a policy to exclude rural SCHs from our 340B drug payment policy and continued to do so until September 27, 2023, when the 340B drug payment policy ended and we resumed paying for 340B drugs and biologicals under the OPPS at the same rates we pay for non-340B drugs and biologicals (generally, ASP plus 6 percent)). We believe exempting rural SCHs, which have demonstrated additional resource costs, is appropriate to ensure these hospitals can remain open to serve the beneficiaries who rely on them for their care. We share commenters' concerns about the financial difficulties associated with maintaining access to care in medically vulnerable communities. However, in each of these cases, the Congress did not determine that any of these hospital types required additional payments for outpatient services. Section 1833(t)(13)(B) of the Act authorizes an appropriate adjustment for hospitals located in rural areas where the Secretary determines, based on a study, that the costs incurred by these hospitals by APC group exceed costs incurred by hospitals in urban areas. In the CY 2006 OPPS final rule with comment period (70 FR 68556 through 68561), we summarized our study of the cost of covered outpatient department services to hospitals in rural areas and found that rural SCHs were the only rural hospital type that had higher resource costs for covered outpatient department services. Rural SCHs demonstrated significantly higher cost per unit than urban hospitals after controlling for labor input prices, service-mix complexity, volume, facility size, and type of hospital. In the CY 2006 OPPS final rule with comment period (70 FR 68556 through 68561) we stated that we found no significant difference in cost between all small rural hospitals with 100 or fewer beds and urban hospitals. We found that there was insufficient evidence to conclude that rural hospitals with 100 or fewer beds have higher costs than urban hospitals. We proposed a narrow exception to our clinic visit policy largely based upon the historical treatment and documented additional resource costs of rural SCHs under the OPPS. We are only accepting rural SCHs because we continue to believe that the underlying principles of the clinic visit policy continue to justify application of the volume control method for clinic visits to the remaining hospital types, including most rural and safety-net providers. Where the difference in payment is leading to unnecessary increases in the volume of covered outpatient department services, we remain concerned that this shift in care setting increases beneficiary cost-sharing liability because Medicare payment rates for the same or similar services are generally higher in hospital outpatient departments than in physician offices. Further, we do not believe that commenters provided sufficient reasoning or data to show that the other provider types suggested (Medicare Dependent Hospitals, Urban SCHs, and low-volume hospitals) demonstrate the additional resource costs that rural SCHs do and should therefore also be exempted from this OPPS payment policy. We continue to share commenters' concerns about maintaining access to care in urban and rural settings and enhancing access to care in medically vulnerable communities. We also share commenters' concerns about profit margins. However, we must balance the concerns of providers with the concerns of beneficiaries regarding the affordability of their care. For hospitals subject to the clinic visit policy, the proposed PFS-equivalent rate for a clinic visit brings the approximate average copayment down from $26 to $10. We will continue to study access and cost to see if further exemptions to the clinic visit policy are appropriate.

Comment: One commenter noted that, while it is necessary to distinguish between urban and rural hospitals for a number of payment and policy mechanisms, they believe the Metropolitan Statistical Areas (MSAs) CMS uses to delineate between these areas are not the most precise tool. This commenter argued that CMS should extend this exemption to urban SCHs because using MSAs to determine urban and rural areas is imprecise and unfairly disadvantages urban SCHs that may be the sole source of hospital services in their communities.

Response: We acknowledge the commenters' points about the important role that urban SCHs serve in their communities. However, we have not found that urban SCHs have the additional resource costs for covered outpatient department services that rural SCHs have, and as such, we are only applying the clinic visit policy exemption to rural SCHs.

After consideration of the public comments we received, we are finalizing our proposal to continue to exempt excepted off-campus PBDs of rural SCHs from the clinic visit payment policy in CY 2025.

VIII. Payment for Partial Hospitalization and Intensive Outpatient Services

This section discusses payment for partial hospitalization services as well as intensive outpatient services. Since CY 2000, Medicare has paid for partial hospitalization services under the OPPS. Beginning in CY 2024, as authorized by section 4124 of the Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–328), Medicare began paying for intensive

outpatient services furnished by hospital outpatient departments, community mental health centers, federally qualified health centers, and rural health clinics in addition to opioid treatment programs. Additional background on the partial hospitalization and intensive outpatient benefits is included in the following paragraphs.

A. Background

1. Partial Hospitalization

A partial hospitalization program (PHP) is an intensive outpatient program of psychiatric services provided as an alternative to inpatient psychiatric care for individuals who have an acute mental illness, which includes, but is not limited to, conditions such as depression, schizophrenia, and substance use disorders (SUD). Section 1861(ff)(1) of the Act defines partial hospitalization services as the items and services described in paragraph (2) prescribed by a physician and provided under a program described in paragraph (3) under the supervision of a physician pursuant to an individualized, written plan of treatment established and periodically reviewed by a physician (in consultation with appropriate staff participating in such program), which sets forth the physician's diagnosis, the type, amount, frequency, and duration of the items and services provided under the plan, and the goals for treatment under the plan. Section 1861(ff)(2) of the Act describes the items and services included in partial hospitalization services. Section 1861(ff)(3)(A) of the Act specifies that a PHP is a program furnished by a hospital to its outpatients or by a community mental health center (CMHC), as a distinct and organized intensive ambulatory treatment service, offering less than 24-hour-daily care, in a location other than an individual's home or inpatient or residential setting. Section 1861(ff)(3)(B) of the Act defines a CMHC for purposes of this benefit. We refer readers to sections 1833(t)(1)(B)(i), 1833(t)(2)(B), 1833(t)(2)(C), and 1833(t)(9)(A) of the Act and 42 CFR 419.21, for additional information regarding PHP.

PHP policies and payment have been addressed under OPPS since CY 2000. In CY 2008, we began efforts to strengthen the PHP benefit through extensive data analysis, along with policy and payment changes, by implementing two refinements to the methodology for computing the PHP median. For a detailed discussion on these policies, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66670 through 66676). In CY 2009, we implemented several regulatory, policy, and payment changes. For a detailed discussion on these policies, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68688 through 68697). In CY 2010, we retained the two-tier payment approach for partial hospitalization services and used only hospital-based PHP data in computing the PHP APC per diem costs, upon which PHP APC per diem payment rates are based (74 FR 60556 through 60559). In CY 2011 (75 FR 71994), we established four separate PHP APC per diem payment rates: two for CMHCs (APC 0172 and APC 0173) and two for hospital-based PHPs (APC 0175 and APC 0176) and instituted a 2-year transition period for CMHCs to the CMHC APC per diem payment rates. For a detailed discussion, we refer readers to section X.B of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71991 through 71994). In CY 2012, we determined the relative payment weights for partial hospitalization services provided by CMHCs based on data derived solely from CMHCs and the relative payment weights for partial hospitalization services provided by hospital-based PHPs based exclusively on hospital data (76 FR 74348 through 74352). In the CY 2013 OPPS/ASC final rule with comment period, we finalized our proposal to base the relative payment weights that underpin the OPPS APCs, including the four PHP APCs (APCs 0172, 0173, 0175, and 0176), on geometric mean costs rather than on the median costs. For a detailed discussion on this policy, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68406 through 68412).

In the CY 2014 OPPS/ASC proposed rule (78 FR 43621 through 43622) and CY 2015 OPPS/ASC final rule with comment period (79 FR 66902 through 66908), we continued to apply our established policies to calculate the four PHP APC per diem payment rates based on geometric mean per diem costs using the most recent claims data for each provider type. For a detailed discussion on this policy, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75047 through 75050). In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70453 through 70467), we described our extensive analysis of the claims and cost data and ratesetting methodology, corrected a cost inversion that occurred in the final rule data with respect to hospital-based PHP providers, and renumbered the PHP APCs. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79687 through 79691), we continued to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs and finalized a policy to combine the Level 1 and Level 2 PHP APCs for CMHCs and for hospital-based PHPs. We also implemented an eight-percent outlier cap for CMHCs to mitigate potential outlier billing vulnerabilities. For a comprehensive description of PHP payment policy, including a detailed methodology for determining PHP per diem amounts, we refer readers to the CY 2016 and CY 2017 OPPS/ASC final rules with comment period (80 FR 70453 through 70455 and 81 FR 79678 through 79680, respectively).

In the CYs 2018 and 2019 OPPS/ASC final rules with comment period (82 FR 59373 through 59381 and 83 FR 58983 through 58998, respectively), we continued to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs, designated a portion of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHCs, and proposed updates to the PHP allowable HCPCS codes. We finalized these proposals in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61352).

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61339 through 61350), we finalized a proposal to use the calculated CY 2020 CMHC geometric mean per diem cost and the calculated CY 2020 hospital-based PHP geometric mean per diem cost, but with a cost floor equal to the CY 2019 final geometric mean per diem costs as the basis for developing the CY 2020 PHP APC per diem rates. Also, we continued to designate a portion of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS, excluding outlier payments.

In the April 30, 2020 interim final rule with comment (85 FR 27562 through 27566), effective as of March 1, 2020 and for the duration of the COVID–19 Public Health Emergency (PHE), hospital and CMHC staff were permitted to furnish certain outpatient therapy, counseling, and educational services (including certain PHP services), incident to a physician's services, to beneficiaries in temporary expansion locations, including the beneficiary's home, as long as the location met all conditions of participation to the extent not waived. A hospital or CMHC could furnish such services using

telecommunications technology to a beneficiary in a temporary expansion location if that beneficiary was registered as an outpatient. In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72247), we confirmed that these provisions applied only for the duration of the COVID–19 PHE. On May 11, 2023, the COVID–19 PHE ended, and accordingly, these flexibilities ended as well.

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86073 through 86080), we continued our current methodology to utilize cost floors, as needed. Since the final calculated geometric mean per diem costs for both CMHCs and hospital-based PHPs were significantly higher than each proposed cost floor, a floor was not necessary at the time, and we did not finalize the proposed cost floors in the CY 2021 OPPS/ASC final rule with comment period.

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63665 through 63666), we explained that we observed a number of changes, likely as a result of the COVID–19 PHE, in the CY 2020 OPPS claims that we would have ordinarily used for CY 2022 ratesetting, and this included changes in the claims for partial hospitalization. We explained that significant decreases in utilization and in the number of hospital-based PHP providers who submitted CY 2020 claims led us to believe that CY 2020 data were not the best overall approximation of expected PHP services in CY 2022. Therefore, we finalized our proposal to calculate the PHP per diem costs using the year of claims consistent with the calculations that would be used for other OPPS services, by using the CY 2019 claims and the cost reports that were used for CY 2021 final rulemaking to calculate the CY 2022 PHP per diem costs. In addition, for CY 2022 and subsequent years, we finalized our proposal to use cost and charge data from the Hospital Cost Report Information System (HCRIS) as the source for the CMHC cost-to-charge ratios (CCRs), instead of using the Outpatient Provider Specific File (OPSF) (86 FR 63666).

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 71995), we explained that we continued to observe a decrease in the number of hospital-based and CMHC PHP days in our trimmed dataset due to the continued effects of COVID–19; however, the Medicare outpatient service volumes appeared to be returning to more normal, pre-pandemic levels. Therefore, we finalized our proposal to use the latest available CY 2021 claims but use the cost information from prior to the COVID–19 PHE for calculating the CY 2023 CMHC and hospital-based PHP APC per diem costs. The application of the OPPS standard methodology, including the effect of budget neutralizing all other OPPS policy changes unique to CY 2023, resulted in the final calculated CMHC PHP APC payment rate being unexpectedly lower than the CY 2022 final CMHC PHP APC rate. Therefore, in the interest of accurately paying for CMHC PHP services, under the unique circumstances of budget neutralizing all other OPPS policy changes for CY 2023, and in keeping with our longstanding goal of protecting continued access to PHP services provided by CMHCs by ensuring that CMHCs remain a viable option as providers of mental health care in the beneficiary's own community, we finalized utilizing the equitable adjustment authority of section 1833(t)(2)(E) of the Act to appropriately pay for CMHC PHP services at the same payment rate as for CY 2022, that is, $142.70. In addition, we clarified the payment under the OPPS for new HCPCS codes that designate non-PHP services provided for the purposes of diagnosis, evaluation, or treatment of a mental health disorder and are furnished to beneficiaries in their homes by clinical staff of the hospital would not be recognized as PHP services; however, none of the PHP regulations would preclude a patient that is under a PHP plan of care from receiving other reasonable and medically necessary non-PHP services from a hospital (87 FR 72001 and 72002).

In the CY 2024 OPPS/ASC final rule with comment period (88 FR 81811), we revised the regulation at § 424.24(e)(1)(i) to require the physician certification for PHP services to include a certification that the patient requires such services for a minimum of 20 hours per week, as required by section 1861(ff)(1) of the Act, as amended by section 4124(a) of Division FF of the CAA, 2023. In addition, we modified the regulations for PHP at § 410.43 to include references to SUD. In the same CY 2024 OPPS/ASC final rule with comment period, we also established separate payment rates for PHP days with 3 services and days with 4 or more services. Accordingly, we established four separate PHP APC per diem payment rates: one for CMHCs for 3-service days and another for CMHCs for 4-service days (APC 5853 and APC 5854, respectively), and one for hospital-based PHPs for 3-service days and another for hospital-based PHPs for 4-service days (APC 5863 and APC 5864, respectively). We also finalized a policy to utilize the separate CMHC rates for 3-service and 4-service PHP days as the Medicare Physician Fee Schedule (MPFS) rates, depending upon whether a nonexcepted off-campus hospital outpatient department furnishes 3 or 4 PHP services in a day. Lastly, we finalized several changes beginning in CY 2024 to align coding, billing, and payment between PHPs and intensive outpatient programs.

2. Intensive Outpatient Program Services

Section 4124(b) of the CAA, 2023 established Medicare coverage for intensive outpatient services effective for items and services furnished on or after January 1, 2024. An intensive outpatient program (IOP) is a distinct and organized program of psychiatric services for individuals who have an acute mental illness, which includes, but is not limited to, conditions such as depression, schizophrenia, and SUD. Intensive outpatient services are not required to be provided in lieu of inpatient hospitalization. Section 1861(ff)(4) of the Act defines intensive outpatient services as the items and services described in paragraph (2) prescribed by a physician for an individual determined (not less frequently than every other month) by a physician to have a need for such services for a minimum of 9 hours per week and provided under a program described in paragraph (3) under the supervision of a physician pursuant to an individualized, written plan of treatment established and periodically reviewed by a physician (in consultation with appropriate staff participating in such program), which plan sets forth the physician's diagnosis, the type, amount, frequency, and duration of the items and services provided under the plan, and the goals for treatment under the plan. Section 1861(ff)(2) of the Act describes the items and services included in intensive outpatient services. Section 1861(ff)(4)(C) of the Act specifies that an IOP is a program furnished by a hospital to its outpatients, a CMHC, a Federally qualified health center (FQHC), or by a rural health clinic (RHC) as a distinct and organized intensive ambulatory treatment service, offering less than 24-hour-daily care, in a location other than an individual's home or inpatient or residential setting. Section 1861(ff)(3)(B) of the Act defines a CMHC for purposes of this benefit. We refer readers to sections 1833(t)(1)(B)(i), 1833(t)(2)(B), 1833(t)(2)(C), and 1833(t)(9)(A) of the Act and 42 CFR 419.21, for additional information regarding IOP.

In the CY 2024 OPPS/ASC final rule with comment period (88 FR 81812 through 81857), we established payment and program requirements for the IOP benefit furnished by a hospital to its outpatients, or by a CMHC, an FQHC, or an RHC. In addition, we established Medicare Part B coverage for IOP services provided by Opioid Treatment Programs (OTPs) for the treatment of opioid use disorder (OUD).

Consistent with the statutory definition of intensive outpatient services under section 1861(ff)(2) of the Act, we finalized regulations at 42 CFR 410.44 to set forth the conditions and exclusions applicable for intensive outpatient services, and at § 424.24 to set forth the content of the certification and plan of treatment requirements for intensive outpatient services. We also revised certain existing regulations at §§ 410.2, 410.3, 410.10, 410.27, 410.150, and 419.21 to add a regulatory definition of intensive outpatient services and to include intensive outpatient services in the regulations for medical and other health services paid for under Medicare Part B, and in the case of § 419.21, under the OPPS. Additionally, we created regulations at § 410.111 to establish the requirements for coverage of IOP services furnished in CMHCs, and at § 410.173 to establish conditions of payment for IOP services furnished in CMHCs. Lastly, we revised § 410.155 to exclude IOP services from the outpatient mental health treatment limitation, consistent with the statutory requirement of section 1833(c)(2) of the Act, as amended by section 4124(b)(3) of the CAA, 2023.

In addition, as discussed in greater detail in the following sections, we established coding, billing, and payment policies for IOP that align with the policies established for PHP provided in the same settings. Specifically, we established four separate IOP APC per diem payment rates at the same rates we proposed for the PHP APCs: one for CMHCs for 3-service days and another for CMHCs for 4-service days (APC 5851 and APC 5852, respectively), and one for hospital-based IOPs for 3-service days and another for hospital-based IOPs for 4-service days (APC 5861 and APC 5862, respectively). Similar to the policy finalized for PHP, we finalized a policy to utilize the CMHC rates for 3-service and 4-service IOP days as the MPFS rates, depending upon whether a nonexcepted hospital outpatient department furnishes 3 or 4 IOP services in a day.

We also established payment for IOP provided by an RHC or FQHC at the same rate as APC 5861, which is the 3-service hospital-based IOP rate (§ 405.2462(j)). Furthermore, we established a payment adjustment for IOP provided by an OTP based on 3 times the payment rate for APC 5861 beginning in CY 2024 (§ 410.67(d)(4)(i)(F)).

B. Coding and Billing for PHP and IOP Services Under the OPPS

In the CY 2024 OPPS/ASC final rule with comment period, we finalized a billing requirement that all providers use condition code 41 to indicate that a claim is for partial hospitalization services and use condition code 92 to identify intensive outpatient claims, effective January 1, 2024. Since the statutory definitions of both IOP and PHP generally include the same types of items and services covered, we stated in the CY 2024 OPPS/ASC final rule with comment period that we believe it is appropriate to align the programs using a consistent list of services, so that level of intensity would be the only differentiating factor between partial hospitalization services and intensive outpatient services. The use of condition codes 41 for PHP claims and 92 for IOP claims allows us to differentiate between these services for billing purposes.

We recognize that the level of intensity of mental health services that a patient requires may vary over time; therefore, we believe utilizing a consolidated list of HCPCS codes to identify services under both the IOP and PHP benefits supports a smooth transition for patients when a change in the intensity of their services is necessary to best meet their needs. For example, a patient receiving IOP services may experience an acute mental health need that necessitates more intense services through a PHP. Alternatively, an IOP patient that no longer requires the level of intensity provided by the IOP can access less intense mental health services, such as individual mental health services. The full list of HCPCs codes recognized under the PHP and IOP benefits can be found in the Medicare Claims Processing internet Only Manual, Chapter 4, sections 260.1 and 261.1, respectively, and their subsections, available at *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c04.pdf*.

To qualify for payment for the IOP APC (5851, 5852, 5861, or 5862) or the PHP APC (5853, 5854, 5863, or 5864), one service provided that day must be from the Partial Hospitalization and Intensive Outpatient Primary list. We refer readers to the CY 2024 OPPS final rule with comment period for further discussion regarding our expectation that at least one of the services on the PHP and IOP Primary list will be indicated per day for patients who need the level of care offered by a PHP or IOP program. The PHP and IOP Primary List can be found in the CY 2024 OPPS/ASC final rule with comment period at 88 FR 81821.

Beginning in CY 2024, we recognized caregiver training services and Principal Illness Navigation (PIN) services as PHP and IOP services. We explained that the reported costs associated with providing such services are included when we calculate the PHP and IOP payment rates; however, these services do not count toward the determination of whether a PHP or IOP day is paid at the 3-service or 4-service rate. We refer readers to the CY 2024 OPPS/ASC final rule with comment period for a detailed discussion of this policy (88 FR 81823 through 81825).

As finalized in the CY 2024 OPPS/ASC final rule with comment period, if new codes are established that represent the PHP and IOP services described under §§ 410.43(a)(4) and 410.44(a)(4), respectively, such codes are added to the list of codes recognized for payment for PHP or IOP through sub-regulatory guidance. We note that coding updates frequently occur outside of the standard rulemaking timeline. We adopted this sub-regulatory process in order to pay expeditiously when new codes are created that describe any of the services enumerated at §§ 410.43(a)(4) and 410.44(a)(4), which PHPs and IOPs, respectively, would provide. We explained that this policy applies to new codes that are cross walked to a previously included code, or whose code descriptor is substantially similar to a descriptor for a code on the list or describes a service on the list. We stated that any additional services not described at § 410.43(a)(4) or § 410.44(a)(4) would be added to the lists in regulation through notice and comment rulemaking. We note that for CY 2025, we did not propose to add any new services not described at § 410.43(a)(4) or § 410.44(a)(4) to the list of PHP and IOP services. However, we received comments regarding the addition of new services to the PHP and IOP benefits. A summary of these comments and our response is provided.

Comment: Several commenters advocated for caregiver training services and principal illness navigation (PIN) services to be included in the number of PHP or IOP services per day for payment. Commenters also strongly supported the inclusion of discharge support and peer services be adopted as applicable for PHP and IOP.

Response: We thank commenters for their feedback. As discussed in the CY 2024 OPPS/ASC final rule with comment period (88 FR 81825), PIN services are reported monthly and represent time spent throughout the month; therefore, we did not include these services in the evaluation of whether a particular PHP or IOP day receives the 3-service or 4-service day for payment. We intend to continue to analyze utilization and cost data for these services and consider any payment changes in future rulemaking to better recognize such costs. Additionally, as discussed in the CY 2024 PFS final rule with comment period (88 FR 78938 through 78949), CMS finalized to pay separately for PIN services to account for resources when clinicians involve certain types of health care support staff such as peer support specialists in furnishing medically necessary care. We believe that including these PIN HCPCS codes in the services recognized for PHP and IOP appropriately indicates that the services of peer support specialists are eligible services for inclusion in PHP and IOP.

Regarding the suggestion to count caregiver training services in the evaluation of whether a PHP or IOP day receives the 3-service or 4-service day for payment, we note that, as explained in the CY 2024 OPPS/ASC final rule with comment period (88 FR 81822), we believe it would be appropriate to exclude these services from the determination of the number of services provided per day, but we would include such services in the calculation of cost per day for determining the PHP and IOP payment rates. We recognize that caregiver training services are an integral part of many PHPs and IOPs; however, we believe that until we have actual utilization data for the provision of caregiver training services, it would be more appropriate to base the payment for a higher-intensity PHP or IOP day on the provision of therapeutic, diagnostic, and training services that have historically been recognized for PHP or OPPS payment.

We did not propose to include caregiver training services in the determination of whether a PHP or IOP day receives the 3-service or 4-service day for payment, and we are not finalizing any changes to this policy for CY 2025. We intend to continue analyzing utilization and cost data for these services to consider whether payment changes may be appropriate in the future.

Comment: One commenter suggested CMS include the treatment of postpartum depression as applicable for PHP and IOP.

Response: We thank the commenter for their suggestion, and note that currently, the ICD–10–CM code F53.0 (*Postpartum depression*) is included in the ICD–10–CM Codes that Support Medical Necessity list for PHP.[149] A patient may receive treatment of postpartum depression under a PHP as long as all other patient eligibility requirements are met, including that PHP patients are required to be certified by a physician as needing at least 20 hours of services per week, and the patient would require inpatient hospitalization if they did not receive PHP services.

In addition, we are clarifying in this CY 2025 OPPS/ASC final rule with comment period that ICD–10–CM code F53.0 (*Postpartum depression*) is included in the ICD–10–CM Codes that Support Medical Necessity list for IOP. A patient may receive treatment of postpartum depression under an IOP as long as all other patient eligibility requirements are met, including that IOP patients are required to be certified by a physician as needing at least 9 hours of services per week.

Comment: One commenter requested CMS clarify the expectation that PHP and IOP participants identified as needing medically necessary occupational therapy (OT) services should receive those services as part of the overall interdisciplinary plan of care. This commenter also requested that CMS clarify whether occupational therapists can bill for other PHP and IOP services, which the commenter stated are within the scope of practice for occupational therapists. The commenter included the following services in their letter:

- 97153 Adaptive behavior tx by tech
- 97154 Grp adapt bhv tx by tech
- 97155 Adapt behavior tx phys/qhp
- 97156 Fam adapt bhv tx gdn phy/qhp
- 97157 Mult fam adapt bhv tx gdn
- 97158 Grp adapt bhv tx by phy/qhp
- 96112 Devel tst phys/qhp 1st hr
- 96156 Hlth bhv assmt/reassessment
- 96158 Hlth bhv ivntj indiv 1st 30
- 96161 Admin of caregiver-focused hlth risk asst for ben of patient
- 96164 Hlth bhv ivntj grp 1st 30
- 96167 Hlth bhv ivntj fam 1st 30
- 97151 Bhv id assmt by phys/qhp
- 97152 Bhv id suprt assmt by 1 tech

Response: We thank the commenter for their feedback. We are clarifying in this CY 2025 OPPS/ASC final rule with comment period that occupational therapy services are an important part of PHPs and IOPs, specifically listed in the statute at section 1861(ff)(2)(B) and in the regulations at §§ 410.43(a)(4)(ii) and 410.44(a)(4). Currently, HCPCS code G0129 is the recognized code for OT services provided for PHP and IOP patients. However, occupational therapists working within their scope of practice as determined by state law can provide and bill for other services as part of a PHP or IOP, including the services mentioned by the commenter which are listed above. We note that because these codes are already included in the list of HCPCS applicable for PHP and IOP, which are identified in Table 98 in the CY 2024 OPPS/ASC final rule with comment period (88 FR 81827 through 81828), it is not necessary to make any changes to the list to permit them to be billed as part of a PHP or IOP. We are not adding any new HCPCS codes to the list at this time. However, we remind readers that we established a sub-regulatory process in the CY 2024 OPPS/ASC final rule with comment period (88 FR 81818 through 81822) to consider the inclusion of additional codes that represent the PHP and IOP services described under §§ 410.43(a)(4) and 410.44(a)(4), respectively. We periodically review these code lists and may add new codes to the list of codes applicable for PHP and IOP if they describe services included under the regulatory definitions of partial hospitalization services or intensive outpatient services.

Comment: A few commenters were concerned CMS did not propose to allow PHP and IOP services to be furnished remotely. Commenters noted that the availability of remote PHP services during the COVID–19 Public Health Emergency (PHE) increased access to these services, especially in rural areas. The commenters believed allowing PHP and IOP services to be furnished remotely to beneficiaries in their homes would also increase access to these benefits.

Response: As discussed in the March 31, 2020, interim final rule with comment entitled ''Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' (85 FR 19232), CMS announced the expansion of telehealth services on a temporary and emergency basis pursuant to waiver authority added under section 1135(b)(8) of the Act by the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (Pub. L. 116–123, March 6, 2020). In addition, in the April 30, 2020, interim final rule with comment entitled

[149] *https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=56850&ver=23&.*

''Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' (85 FR 27562 through 27566), we discussed that effective March 1, 2020, and for the duration of the COVID–19 PHE, a hospital or CMHC could furnish such services using telecommunications technology to a beneficiary in a temporary expansion location if that beneficiary is registered as an outpatient. The flexibility to provide PHP services remotely to a beneficiary in his or her home ended with the expiration of the PHE on May 11, 2023.

In terms of the request to allow IOP services to be furnished remotely to beneficiaries in their homes, we note that section 1861(ff) of the Act, as amended by section 4124(b)(2)(B) of the CAA, 2023 adopts much of the statutory definition of PHP for IOP. Section 1861(ff)(3)(A) provides, in part, that a PHP (and through the cross-reference in section 1861(ff)(4), an IOP) is a distinct and organized intensive ambulatory treatment offering less than 24-hour-daily care other than in an individual's home or in an inpatient or residential setting. Thus, neither PHP nor IOP services can be furnished remotely to beneficiaries in their homes.

However, we clarified in the CY 2023 OPPS/ASC final rule with comment period (87 FR 72001) that none of the PHP regulations would preclude a patient that is under a PHP plan of care from receiving other reasonable and medically necessary non-PHP services from a hospital. This means that patients in a PHP are not precluded from receiving remote mental health services provided outside of the PHP by the same or another hospital when such services are reasonable and medically necessary.

Likewise, none of the IOP regulations would preclude a patient that is under an IOP plan of care from receiving other reasonable and medically necessary non-IOP services from a hospital. Additionally, we are reiterating in this final rule with comment period that we would expect that a physician would update the patient's PHP or IOP plan of care to appropriately reflect any change to the type, amount, duration, or frequency of the therapeutic services planned for that patient in circumstances when a PHP or IOP patient receives non-PHP/IOP remote mental health services from a hospital outpatient department. We also note that the medical documentation should continue to support the patient's eligibility for participation in a PHP or IOP.

Final Decision: After consideration of the public comments we received, we are maintaining our coding and billing policies for PHP and IOP as established in the CY 2024 OPPS/ASC final rule with comment period.

C. CY 2025 Payment Rates for PHP and IOP

1. Background

Beginning in CY 2024, we established four separate PHP APC per diem payment rates: one for CMHCs for 3-service days and another for CMHCs for 4-service days (APC 5853 and APC 5854, respectively), and one for hospital-based PHPs for 3-service days and another for hospital-based PHPs for 4-service days (APC 5863 and APC 5864, respectively). In addition, for hospital-based PHPs, we finalized a policy to calculate payment rates using the broader OPPS data set, instead of using hospital-based PHP data only. We explained that using the broader OPPS data set allows CMS to capture data from claims not identified as PHP, but that also include the service codes and intensity required for a PHP day. Because we established consistent coding and payment between the PHP and IOP benefits, we considered all OPPS data for PHP days and non-PHP days that include 3 or more of the same service codes. We established four separate IOP APC per diem payment rates at the same rates we proposed for the PHP APCs: one for CMHCs for 3-service days and another for CMHCs for 4-service days (APC 5851 and APC 5852, respectively), and one for hospital-based IOPs for 3-service days and another for hospital-based IOPs for 4-service days (APC 5861 and APC 5862, respectively).

In the CY 2024 OPPS/ASC final rule with comment period, we noted that the standard PHP day is typically four services or more per day. We explained that we have historically provided payment for three services a day for extenuating circumstances when a beneficiary would be unable to complete a full day of PHP treatment. As we stated in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66672), it was never our intention that days with only three units of service should represent the number of services provided in a typical PHP day. Our intention was to cover days that consisted of three units of service only in certain limited circumstances. For example, as we noted in the CY 2009 OPPS/ASC proposed rule (73 FR 41513), we believe 3-service days may be appropriate when a patient is transitioning towards discharge (or days when a patient is at the beginning of his or her PHP stay). Another example of when it may be appropriate for a program to provide only three units of service in a day is when a patient is required to leave the PHP early for the day due to an unexpected medical appointment.

We also explained that prior to CY 2024, we historically prepared the data by first applying PHP-specific trims and data exclusions and assessing CCRs. We direct the reader to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465) for a more complete discussion of these trims, data exclusions, and CCR adjustments. In prior rules, we have typically included a discussion of PHP-specific data trims, exclusions, and CCR adjustments; we did not include that discussion in the CY 2024 OPPS/ASC proposed rule or final rule with comment period. We stated that these PHP-specific data trims and exclusions addressed limitations as well as anomalies in the PHP data. However, as noted earlier, we finalized a methodology for CY 2024 to calculate hospital-based PHP payment rates for 3 services per day and 4 services per day based on cost per day using the broader OPPS data set. Accordingly, we did not apply PHP-specific trims and data exclusions, but rather we applied the same trims and data exclusions consistent with the OPPS.

We stated in the CY 2024 OPPS/ASC final rule with comment period (88 FR 81830) that while no IOP benefit existed prior to the CAA, 2023, the types of items and services included in IOP had been, and were, paid for by Medicare either as part of the PHP benefit or under the OPPS more generally. Additionally, we stated that prior to the CAA, 2023, CMS had begun gathering information from interested parties on IOP under Medicare. In the CY 2023 OPPS/ASC proposed rule (87 FR 44679), we issued a comment solicitation on intensive outpatient mental health treatment, including SUD treatment furnished by IOPs, to collect information regarding whether there are any gaps in coding that may be limiting access to needed levels of care for treatment of mental health disorders or SUDs for Medicare beneficiaries, and specific information about IOP services, such as the settings of care in which these programs typically furnish services, the range of services typically offered, and the range of practitioner types that typically furnish these services.

We explained that along with the requirements for IOP mandated by the CAA, 2023, we took into consideration information we received from the comment solicitation to construct an appropriate data set to develop

proposed rates for IOP. Since IOPs furnish the same types of services as PHP, just at a lower intensity, we stated that we believe it was appropriate to use the same data and methodology for calculating payment rates for both PHP and IOP for CY 2024. We explained that although PHP claims can be specifically identified, there was no specific identifier or billing code to indicate IOP services that may have been provided before CY 2024. However, we noted that hospitals have been permitted to furnish and bill for many of these services as outpatient services under the OPPS. Thus, we analyzed a broader set of data that included both PHP and non-PHP days with 3 or more services in order to calculate proposed payment for PHP services. In order to establish consistent payment between PHP and IOP, we set IOP payment rates at the same rates as PHP. We stated that the primary goal in developing the payment rate methodology for IOP and PHP services was to pay providers an appropriate amount relative to the patients' needs, and to avoid cost inversion in future years. We stated that setting the IOP payment rates equal to the PHP payment rates was appropriate because IOP was a newly established benefit, and we did not have definitive data on utilization. However, we explained that both programs utilize the same services, but furnish them at different levels of intensity, with different numbers of services furnished per day and per week, depending on the program. Therefore, we stated that we expect it would be appropriate to pay the same per diem rates for IOP and PHP services unless future data analysis supports calculating rates independently.

2. CY 2025 Payment Rate Methodology for PHP and IOP

For CY 2025, we proposed to use the latest available cost information, from cost reports beginning three fiscal years prior to the year that is the subject of the rulemaking, and CY 2023 OPPS claims to update the payment rates for the four PHP APCs and the four IOP APCs finalized in the CY 2024 OPPS/ASC final rule with comment period. The proposal is consistent with the overall proposed use of cost data for the OPPS, which is discussed in section II.A.1.a of this final rule with comment period. In accordance with the methodology finalized in the CY 2024 OPPS/ASC final rule with comment period, we proposed to base the payment rate for each PHP APC on the geometric mean per diem cost for days with three services and four or more services, calculated separately for CMHCs and hospital outpatient departments. We proposed to use the broader set of OPPS data to calculate the geometric mean costs for hospital outpatient departments, and we proposed to apply the same trims and exclusions consistent with the OPPS. We also proposed to set the payment rates for the four IOP APCs based on the geometric mean per diem cost for PHP days with three services and four or more services, calculated separately for CMHCs and hospital outpatient departments. Lastly, we proposed that if more recent data subsequently became available after the publication of the CY 2025 OPPS/ASC proposed rule, we would use such updated data, if appropriate, to determine the CY 2025 payment rates for the four PHP APCs and the four IOP APCs finalized in the CY 2024 OPPS/ASC final rule with comment period.

For beneficiaries in a PHP or IOP, we proposed to apply the four-service payment rate (that is, payment for PHP APCs 5854 for CMHCs and 5864 for hospitals, and IOP APCs 5852 for CMHCs and 5862 for hospitals) for days with 4 or more services. For days with three or fewer services, we proposed to apply the three-service payment rate (that is, payment for PHP APCs 5853 for CMHCs and 5863 for hospitals, and IOP APCs 5851 for CMHCs and 5861 for hospitals), which is consistent with the policy we established in the CY 2024 OPPS/ASC final rule with comment period (88 FR 81833). As we noted in the CY 2024 OPPS/ASC final rule with comment period, we expect days with fewer than three services would be very infrequent, and we intend to monitor the provision of these days among providers and individual patients.

Comment: We received five comments from providers, hospital associations, and national organizations expressing concerns about the proposed PHP and IOP per diem rates. Commenters expressed that the proposed rates would not be sufficient to ensure the sustainability of PHP and IOP programs and could negatively affect access to PHP services. Some commenters noted that the proposed payment rates for PHP and IOP APCs published in Addendum A were lower than the geometric mean per diem cost figures published in the proposed rule. The commenters requested that CMS reconsider its approach to rate structures for IOPs and PHPs so that rates sufficiently cover the cost of these programs.

Response: We understand the concerns that commenters raised regarding the proposed PHP and IOP rates for CY 2025. We proposed to calculate the PHP payment rates based on our longstanding methodology, in accordance with the statutorily required relative payment weight calculations under the OPPS. Under the longstanding OPPS ratesetting methodology, CMS establishes APC payment rates by annually reviewing and revising the APC groups and relative payment weights for APCs in accordance with sections 1833(t)(2) and 1833(t)(9)(A) of the Act, as further described in section II.A.4 of this final rule with comment period. We further note that the OPPS is subject to budget neutral adjustments to the weight scaler as described in section II.A.4 of this final rule with comment period and APC payment rates are calculated using the OPPS conversion factor described in section II.B. of this final rule with comment period. As a result of the OPPS budget neutrality adjustments, the proposed and final APC payment rates may be higher or lower than their estimated APC geometric mean costs. We believe these per diem costs are in line with 2024 per diem costs and appropriately use hospital and CMHC cost data. The final payment rates for the PHP and IOP APCs can be found in Addendum A of this CY 2025 OPPS/ASC final rule with comment period.

After consideration of the public comments we received, we are finalizing the payment rate methodology for CY 2025 as proposed. Table 136 below shows the final APCs and the calculated geometric mean per diem costs for this CY 2025 OPPS/ASC final rule with comment period. Additional information about the data trims, data exclusions, and CCR adjustments applicable to the data used for this final rule can be found online at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*).[150]

[150] Click on the link labeled ''CY 2025 OPPS/ASC Notice of Proposed Rulemaking'', which can be found under the heading ''Hospital Outpatient Prospective Payment System Rulemaking'' and open the claims accounting document link at the bottom of the page, which is labeled ''2025 NPRM OPPS Claims Accounting (PDF)''.

TABLE 136: CY 2025 PHP AND IOP APC GEOMETRIC MEAN PER DIEM COSTS

CY 2025 APC	Group Title	PHP and IOP APC Geometric Mean Per Diem Costs
5851	Intensive Outpatient (3 services per day) for CMHCs	$112.59
5852	Intensive Outpatient (4 or more services per day) for CMHCs	$170.37
5853	Partial Hospitalization (3 services per day) for CMHCs	$112.59
5854	Partial Hospitalization (4 or more services per day) for CMHCs	$170.37
5861	Intensive Outpatient (3 services per day) for hospital-based IOPs	$272.46
5862	Intensive Outpatient (4 or more services per day) for hospital-based IOPs	$413.50
5863	Partial Hospitalization (3 services per day) for hospital-based PHPs	$272.46
5864	Partial Hospitalization (4 or more services per day) for hospital-based PHPs	$413.50

D. Outlier Policy for CMHCs

For CY 2025, we proposed to maintain the calculations of the CMHC outlier percentage, cutoff point and percentage payment amount, outlier reconciliation, outlier payment cap, and fixed dollar threshold according to previously established policies to include PHP and IOP services. We refer readers to the CY 2024 OPPS/ASC final rule with comment period (88 FR 81834 through 81836) for more details on CMHC outlier policies, and to section II.G.1 of this final rule with comment period for our general policies for hospital outpatient outlier payments.

1. Background

As discussed in the CY 2004 OPPS final rule with comment period (68 FR 63469 through 63470), we created a separate outlier policy specific to the estimated costs and OPPS payments provided to CMHCs. We designated a portion of the estimated OPPS outlier threshold specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS each year, excluding outlier payments, and established a separate outlier threshold for CMHCs.

2. CMHC Outlier Percentage

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59267 through 59268), we described the current outlier policy for hospital outpatient payments and CMHCs. We note that we also discussed our outlier policy for CMHCs in more detail in section VIII.C of that same final rule (82 FR 59381). We set our projected target for all OPPS aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS (82 FR 59267). This same policy was also reiterated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58996), the CY 2020 OPPS/ASC final rule with comment period (84 FR 61350), and the CY 2021 OPPS/ASC final rule with comment period (85 FR 86082). We did not propose any changes to the CMHC outlier percentage policy for CY 2025.

3. Cutoff Point and Percentage Payment Amount

Also described in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59381), our policy has been to pay CMHCs for outliers if the estimated cost of the day exceeds a cutoff point. In CY 2006, we set the cutoff point for outlier payments at 3.4 times the highest CMHC PHP APC payment rate implemented for that calendar year (70 FR 68551). For CY 2018, the highest CMHC PHP APC payment rate was the payment rate for CMHC PHP APC 5853. In addition, in CY 2002, the final OPPS outlier payment percentage for costs above the multiplier threshold was set at 50 percent (66 FR 59889). In CY 2018, we continued to apply the same 50 percent outlier payment percentage that applies to hospitals to CMHCs and continued to use the existing cutoff point (82 FR 59381). Therefore, for CY 2018, we continued to pay for partial hospitalization services that exceeded 3.4 times the CMHC PHP APC payment rate at 50 percent of the amount of CMHC PHP APC geometric mean per diem costs over the cutoff point. This same policy was also reiterated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58996 through 58997), the CY 2020 OPPS/ASC final rule with comment period (84 FR 61351), the CY 2021 OPPS/ASC final rule with comment period (85 FR 86082 through 86083), the CY 2022 OPPS/ASC final rule with comment period (86 FR 63670), the CY 2023 OPPS/ASC final rule with comment period (87 FR 72004), and the CY 2024 OPPS/ASC final rule with comment period (88 FR 81835). For CY 2024, we extended this policy to intensive outpatient services. We did not propose any changes to the cutoff point and payment amount policy for CY 2025.

4. Outlier Reconciliation

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599), we established an outlier reconciliation policy to address charging aberrations related to OPPS outlier payments. We addressed vulnerabilities in the OPPS outlier payment system that led to differences between billed charges and charges included in the overall CCR, which are used to estimate cost and would apply to all hospitals and CMHCs paid under the OPPS. We initiated steps to ensure that outlier payments appropriately account for the financial risk when providing an extraordinarily costly and complex service but are only being made for services that legitimately qualify for the additional payment.

For a comprehensive description of outlier reconciliation, we refer readers to the CY 2023 OPPS/ASC and CY 2019 OPPS/ASC final rules with comment period (83 FR 58874 through 58875 and 81 FR 79678 through 79680, respectively). We did not propose any changes to the outlier reconciliation policy for CY 2025.

5. Outlier Payment Cap

In the CY 2017 OPPS/ASC final rule with comment period, we implemented a CMHC outlier payment cap to be applied at the provider level, such that in any given year, an individual CMHC will receive no more than a set percentage of its CMHC total per diem payments in outlier payments (81 FR 79692 through 79695). Our analysis of

CY 2014 claims data found that CMHC outlier payments began to increase similarly to the way they had prior to CY 2004. This was due to inflated cost from three CMHCs that accounted for 98 percent of all CMHC outlier payments that year and received outlier payments that ranged from 104 percent to 713 percent of their total per diem payments. To balance our concern about disadvantaging CMHCs with our interest in protecting the benefit from excessive outlier payments and to mitigate potential inappropriate outlier billing vulnerabilities, we finalized the CMHC outlier payment cap at 8 percent of the CMHC's total per diem payments (81 FR 79694 through 79695) to limit the impact of inflated CMHC charges on outlier payments. This outlier payment cap only affects CMHCs; it does not affect other provider types (that is, hospital-based PHPs), and is in addition to and separate from the current outlier policy and reconciliation policy in effect. We did not propose any changes to the outlier payment cap for CY 2025. We received comments on the outlier payment cap for CMHCs, which are summarized below and include our responses.

Comment: Several commenters urged CMS to implement a site-neutral payment for CMHCs and hospital-based providers for PHP and IOP services, stating CMS policy creates arbitrary incentives for PHP and IOP services in settings other than CMHCs; a few of these commenters went on to state that a site-neutral payment would eliminate the need for a separate outlier policy for CMHCs.

Response: We disagree with commenters who believe CMS policy creates an incentive for PHP and IOP services in settings other than CMHCs and that a site-neutral payment would eliminate the need for a separate outlier policy for CMHCs. Current data for partial hospitalization reflect significant cost structure differences between hospitals and CMHCs, and our longstanding payment policies reflect those differences as well. We have no factual basis at this time on which to assume, as many commenters suggest, that the stark difference between hospital and CMHC payment rates for PHP services indicate that such services do not reflect the actual cost structure differences between facility types. As discussed in the CY 2004 OPPS final rule with comment period (68 FR 63469 and 63470), we noted the use of historical cost-to-charge ratios applied to current charges resulted in an excessive amount of outlier payments being made to CMHCs. As a result of more in-depth analysis of the 2001 data files that were used to compute the CY 2003 PHP per diem amount, we discovered a significant difference in the amount of outlier payments made to hospitals and CMHCs for PHP. Therefore, we finalized a policy to designate a portion of the estimated 2.0 percent outlier target amount specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS in CY 2004, excluding outlier payments. Given the difference in PHP charges between hospitals and CMHCs, we did not believe it was appropriate to make outlier payments to CMHCs using the outlier percentage target amount and threshold established for hospitals. Therefore, beginning in CY 2004, we created a separate outlier policy specific to the estimated costs and OPPS payments provided to CMHCs. We designated a portion of the estimated OPPS outlier threshold specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS each year, excluding outlier payments, and established a separate outlier threshold for CMHCs. Furthermore, to balance our concern about disadvantaging CMHCs with our interest in protecting the benefit from excessive outlier payments and to mitigate potential inappropriate outlier billing vulnerabilities, we finalized the CMHC outlier payment cap at 8 percent of the CMHC's total per diem payments (81 FR 79694 and 79695) to limit the impact of inflated CMHC charges on outlier payments. In conclusion, CMS does not believe our payment methodology has any effect on outlier policy.

Final Decision: After consideration of the public comments we received, we are maintaining our existing policy to apply a cap on outlier payments as we finalized in the CY 2017 OPPS/ASC final rule with comment period,

6. Fixed-Dollar Threshold

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59267 through 59268), for the hospital outpatient outlier payment policy, we set a fixed-dollar threshold in addition to an APC multiplier threshold. Fixed-dollar thresholds are typically used to drive outlier payments for very costly items or services, such as cardiac pacemaker insertions. Currently, for CY 2024, CMHC PHP APCs (5853 or 5854) and IOP APCs (5851 or 5852) are the only APCs for which CMHCs may receive payment under the OPPS, and these APCs are for providing a defined set of services that are relatively low cost when compared to other OPPS services. Because of the relatively low cost of CMHC services that are used to comprise the structure of CMHC PHP APCs (5853 or 5854) and IOP APCs (5851 or 5852), it is not necessary to also impose a fixed-dollar threshold on CMHCs. Therefore, in the CY 2018 OPPS/ASC final rule with comment period, we did not set a fixed-dollar threshold for CMHC outlier payments (82 FR 59381). This same policy was also reiterated in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61351), the CY 2021 OPPS/ASC final rule with comment period (85 FR 86083), the CY 2022 OPPS/ASC final rule with comment period (86 FR 63508), the CY 2023 OPPS/ASC final rule with comment period (87 FR 72004), and the CY 2024 OPPS/ASC final rule with comment period (88 FR 81836). We did not propose any changes to the fixed-dollar threshold policy for CY 2025, which will continue in CY 2025.

IX. Services That Will Be Paid Only as Inpatient Services

A. Background

Established in rulemaking as part of the initial implementation of the OPPS, the inpatient only (IPO) list identifies services for which Medicare will only make payment when the services are furnished in the inpatient hospital setting because of the invasive nature of the procedure, the underlying physical condition of the patient, or the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged (70 FR 68695). The IPO list was created based on the premise (rooted in the practice of medicine at that time), that Medicare should not pay for procedures furnished as outpatient services that are performed on an inpatient basis virtually all of the time for the Medicare population, for the reasons described above, because performing these procedures on an outpatient basis would not be safe or appropriate, and therefore not reasonable and necessary under Medicare rules (63 FR 47571). Services included on the IPO list were those determined to require inpatient care, such as those that are highly invasive, result in major blood loss or temporary deficits of organ systems (such as neurological impairment or respiratory insufficiency), or otherwise require intensive or extensive postoperative care (65 FR 67826). There are some services designated as inpatient only that, given their clinical intensity, would not be expected to be performed in the hospital outpatient setting. For example, we have traditionally considered certain surgically invasive

procedures on the brain, heart, and abdomen, such as craniotomies, coronary-artery bypass grafting, and laparotomies, to require inpatient care (65 FR 18456). Designation of a service as inpatient only does not preclude the service from being furnished in a hospital outpatient setting but rather means that Medicare will not make payment for the service if it is furnished to a Medicare beneficiary in the hospital outpatient setting (65 FR 18443). Conversely, the fact that a procedure is not on the IPO list should not be interpreted to mean the procedure is only appropriately performed in the hospital outpatient setting (70 FR 68696).

As part of the annual update process, we have historically worked with interested parties, including professional societies, hospitals, surgeons, hospital associations, and beneficiary advocacy groups, to evaluate the IPO list and to determine whether services should be added to or removed from the list. Interested parties are encouraged to request reviews for a particular code or group of codes; and we have asked that their requests include evidence that demonstrates that the procedure was performed on an outpatient basis in a safe and appropriate manner in a variety of different types of hospitals—including but not limited to—operative reports of actual cases, peer-reviewed medical literature, community medical standards and practice, physician comments, outcome data, and post-procedure care data (67 FR 66740).

We traditionally have used five longstanding criteria to determine whether a procedure should be removed from the IPO list. As noted in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74353), we assess whether a procedure or service meets these criteria to determine whether it should be removed from the IPO list and assigned to an APC group for payment under the OPPS when provided in the hospital outpatient setting. We have explained that while we only require a service to meet one criterion to be considered for removal, satisfying only one criterion does not guarantee that the service will be removed; instead, the case for removal is strengthened with the more criteria the service meets. The criteria for assessing procedures for removal from the IPO list are as follows:

- Most outpatient departments are equipped to provide the services to the Medicare population.
- The simplest procedure described by the code may be furnished in most outpatient departments.
- The procedure is related to codes that we have already removed from the IPO list.
- A determination is made that the procedure is being furnished in numerous hospitals on an outpatient basis.
- A determination is made that the procedure can be appropriately and safely furnished in an ASC and is on the list of approved ASC services or has been proposed by us for addition to the ASC covered procedures list.

In the past, we have requested that interested parties submit corresponding evidence in support of their claims that a code or group of codes meet the longstanding criteria for removal from the IPO list and are safe to perform on the Medicare population in the hospital outpatient setting—including, but not limited to case reports, operative reports of actual cases, peer-reviewed medical literature, medical professional analysis, clinical criteria sets, and patient selection protocols. Our clinicians then thoroughly review all information submitted within the context of the established criteria and if, following this review, we determine that there is sufficient evidence to confirm that the code could be safely and appropriately performed on an outpatient basis, we assign the service to an APC and include it as a payable procedure under the OPPS (67 FR 66740). We determine the APC assignment for services removed from the IPO list by evaluating the clinical similarity and resource costs of the service compared to other services paid under the OPPS and by reviewing the Medicare Severity Diagnosis Related Groups (MS–DRG) rate for the service under the IPPS, though we note we would generally expect the cost to provide a service in the outpatient setting to be less than the cost to provide the service in the inpatient setting.

We stated in prior rulemaking that, over time, given advances in technology and surgical technique, we would continue to evaluate services to determine whether they should be removed from the IPO list. Our goal is to ensure that inpatient only designations are consistent with the current standards of practice. We have asserted in prior rulemaking that, insofar as advances in medical practice mitigate concerns about these procedures being performed on an outpatient basis, we would be prepared to remove procedures from the IPO list and provide payment for them under the OPPS (65 FR 18443). Further, CMS has at times had to reclassify codes as inpatient only services with the emergence of new information.

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74352 through 74353) for a full discussion of our historic policies for identifying services that are typically provided only in an inpatient setting and that, therefore, will not be paid by Medicare under the OPPS, as well as the criteria we have used to review the IPO list to determine whether any services should be removed.

B. Changes to the Inpatient Only (IPO) List

As stated above, we encourage interested parties to request reviews for a particular code or group of codes for removal from the IPO list. For the CY 2025, we received requests from interested parties recommending that certain services be removed from the IPO list. Following our clinical review using the five criteria listed above, we did not find sufficient evidence that any of those services meet the criteria to be removed from the IPO list for CY 2025. Therefore, we did not propose to remove any services from the IPO list for CY 2025.

We proposed to add three services for which codes were newly created by the AMA CPT Editorial Panel for CY 2025 to the IPO list. These new services are described by CPT codes 0894T, 0895T, and 0896T, which will be effective on January 1, 2025. After clinical review of these services, we found that they require a hospital inpatient admission or stay and are not appropriate for payment under the OPPS. We proposed to assign these services to status indicator ''C'' (Inpatient Procedures) for CY 2025. The CPT codes, long descriptors, and the proposed CY 2025 payment indicators are displayed in Table 137.

Table 137 contains the proposed changes to the IPO list for CY 2025. The complete list of codes describing services that we proposed to designate as inpatient only services beginning in CY 2025 is also included as Addendum E to the CY 2025 proposed rule, which is available via the internet on the CMS website.

TABLE 137: PROPOSED CHANGES TO THE INPATIENT ONLY (IPO) LIST FOR CY 2025

CY 2025 CPT Code	CY 2025 Long Descriptor	Action	CY 2025 Proposed Status Indicator
0894T	Cannulation of the liver allograft in preparation for connection to the normothermic perfusion device and decannulation of the liver allograft following normothermic perfusion	Add to the IPO list	C
0895T	Connection of liver allograft to normothermic machine perfusion device, hemostasis control; initial 4 hours of monitoring time, including hourly physiological and laboratory assessments (eg, perfusate temperature, perfusate pH, hemodynamic parameters, bile production, bile pH, bile glucose, biliary)	Add to the IPO list	C
0896T	Connection of liver allograft to normothermic machine perfusion device, hemostasis control; each additional hour, including physiological and laboratory assessments (eg, perfusate temperature, perfusate pH, hemodynamic parameters, bile production, bile pH, bile glucose, biliary bicarbonate, lactate levels, macroscopic assessment) (List separately in addition to code for primary procedure)	Add to the IPO list	C

Comment: We received several comments in support of our proposal to add CPT codes 0894T, 0895T, and 0896T to the IPO list for CY 2025.

Response: We thank the commenters for their support.

Comment: We received one comment requesting that we remove CPT code 22848 (Pelvic fixation (attachment of caudal end of instrumentation to pelvic bony structures) other than sacrum (List separately in addition to code for primary procedure)) from the IPO list. Additionally, the commenter presented at the 2024 Hospital Outpatient Panel (HOP) on August 26, 2024, with the Panel recommending CMS remove the service from the IPO list.

The commenter stated that the service described by CPT code 22848 met the following criteria for removal: (1) most outpatient departments are equipped to provide the services to the Medicare population; (2) the simplest procedure described by the code may be furnished in most outpatient departments; (3) the procedure is related to codes that we have already removed from the IPO list; and (4) a determination is made that the procedure is being furnished in numerous hospitals on an outpatient basis.

Response: We thank the commenter for their feedback. After further in-depth review of the evidence provided, we agree with the commenter that this service meets criteria 1, 2, 3, and 4 in our regulation text at § 419.23(b)(1) through (4). For criteria 1 and 2, we found that most outpatient departments are equipped to provide this service to the Medicare population and the simplest procedure described by CPT code 22848 may be furnished in most outpatient departments. For criterion 3, the procedure is related to codes that we have already removed from the IPO list. Our review found that this procedure is the related to CPT codes 22612 (Arthrodesis, posterior or posterolateral technique, single interspace; lumbar (with lateral transverse technique, when performed)) and 22614 (Arthrodesis, posterior or posterolateral technique, single interspace; each additional interspace (list separately in addition to code for primary procedure)). Finally, for criterion 4, we found that this procedure is being furnished in numerous hospitals on an outpatient basis. Since CPT code 22848 is an add-on code and will always be packaged, we are reassigning this code to status indicator ''N'' (Items and Services Packaged into APC Rates).

Comment: We received one comment requesting that we add CPT code 31647 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, when performed, assessment of air leak, airway sizing, and insertion of bronchial valve(s), initial lobe) to the IPO list. The commenter cited that the standard of care for this procedure required a stay of 3 to5 days for this procedure. The commenter was also concerned that, while a procedure on the IPO list can be performed as either outpatient or inpatient, outside payors who depend on the IPO list may refuse to approve inpatient admissions for surgeries not on the IPO list that require inpatient stays over two midnights.

Response: We thank the commenter for their feedback. CPT code 31647 was created in 2013 and is currently assigned to APC 5155 (Level 5 Airway Endoscopy) and status indicator ''J1'' (Hospital Part B Services Paid Through a Comprehensive APC). While our review found that the mean length of stay from the OPPS claims for CY 2020–2024 ranged from 2.10 to 3.02 days, showing that this procedure does require an overnight hospital stay for some patients, our review also found that a portion of patients are receiving

this service in the hospital outpatient setting. Because a portion of beneficiaries have been receiving this procedure in the hospital outpatient setting, we believe that it is appropriate for CPT code 31647 to remain off the IPO list and assigned to a clinical APC. As stated above, the fact that a procedure is not on the IPO list should not be interpreted to mean the procedure is only appropriately performed in the hospital outpatient setting.

Comment: We received four comments requesting that we assign services newly removed from the IPO list to New Technology APCs until sufficient data is collected to assign these services to clinical APCs.

Response: We thank the commenters for their input. As we previously stated in the CY 2021 OPPS/ASC final rule with comment period (85 FR 86093), consistent with our regulation at 42 CFR 419.31(a)(1), we classify outpatient services and procedures that are comparable clinically and in terms of resource use into APC groups. As we stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74224), the OPPS is a prospective payment system that provides payment for groups of services that share clinical and resource use characteristics. It should be noted that for all codes newly paid under the OPPS, including codes removed from the IPO list, our policy has been to assign the service or procedure to an APC based on feedback from a variety of sources, including but not limited to, review of the clinical similarity of the service to existing procedures; advice from CMS medical advisors; information from interested specialty societies; and review of all other information available to us, including information provided to us by the public, whether through meetings with stakeholders or additional information that is mailed or otherwise communicated to us (84 FR 61229). Therefore, we believe assigning procedures removed from the IPO list to existing clinical APCs that are similar in clinical characteristics and resource costs is appropriate. We note that procedures assigned to New Technology APCs cannot be placed in clinical APCs due to insufficient clinical and cost data, unlike the procedures transitioning from the IPO list.

Comment: One commenter was concerned about the transparency of CMS's review of requests to remove or add services to the IPO list and asked that CMS publish a list of these requests in the OPPS/ASC proposed rules.

Response: We thank the commenter for their input and will consider it for future rulemaking. As stated above, we review the IPO list on a yearly basis and encourage interested parties to request reviews for a particular code or group of codes for removal or addition to the IPO list, after which our clinicians thoroughly review all information submitted within the context of the established criteria. While we have not historically published pre-proposed rule recommendations for which we did not propose any changes, we do address all codes that are recommended during the public comment period in the OPPS/ASC final rule.

Comment: We received one comment requesting that CMS preserve the treating physician's autonomy and create a formal review panel of physicians to evaluate changes to the IPO list. Another commenter also stated that the determination of the appropriate surgical site of service should be left to the judgment of surgeons.

Response: We thank the commenters for their feedback. In the CY 2022 OPPS/ASC final rule with comment period, we explained that we recognized that while physicians are able to make safety determinations for a specific beneficiary, CMS is in the position to make safety determinations for the broader population of Medicare beneficiaries. Furthermore, we explained that we want to afford physicians and hospitals the maximum flexibility in choosing the most clinically appropriate site of service for the procedure, as long as the characteristics of the procedure are consistent with the criteria listed above (86 FR 63673). While we are open to suggestions from interested parties on improving the IPO list review process, we reiterate that recommendations and changes to the IPO list are thoroughly reviewed by our clinicians.

In summary, after consideration of the public comments we received, we are finalizing our proposal with modification to add CPT codes 0894T, 0895T, and 0896T to the IPO list and assign them to status indicator ''C'' (Inpatient Procedures). We are also removing CPT code 22848 from the IPO list and reassigning it to status indicator ''N'' (Items and Services Packaged into APC Rates). Table 138 below contains the changes to the IPO list for CY 2025. The complete list of codes that are designated as inpatient only services beginning in CY 2025 is also included as Addendum E to this final rule with comment period, which is available via the internet on the CMS website.

TABLE 138: FINAL CHANGES TO THE INPATIENT ONLY (IPO) LIST FOR CY 2025

CY 2025 CPT Code	CY 2025 Long Descriptor	Action	CY 2025 Final Status Indicator
0894T	Cannulation of the liver allograft in preparation for connection to the normothermic perfusion device and decannulation of the liver allograft following normothermic perfusion	Add to the IPO list	C
0895T	Connection of liver allograft to normothermic machine perfusion device, hemostasis control; initial 4 hours of monitoring time, including hourly physiological and laboratory assessments (eg, perfusate temperature, perfusate pH, hemodynamic parameters, bile production, bile pH, bile glucose, biliary)	Add to the IPO list	C
0896T	Connection of liver allograft to normothermic machine perfusion device, hemostasis control; each additional hour, including physiological and laboratory assessments (eg, perfusate temperature, perfusate pH, hemodynamic parameters, bile production, bile pH, bile glucose, biliary bicarbonate, lactate levels, macroscopic assessment) (List separately in addition to code for primary procedure)	Add to the IPO list	C
22848	Pelvic fixation (attachment of caudal end of instrumentation to pelvic bony structures) other than sacrum (List separately in addition to code for primary procedure)	Remove from the IPO list	N

X. Nonrecurring Policy Changes

A. Remote Services

1. Payment for Outpatient Therapy Services, Diabetes Self-Management Training, and Medical Nutrition Therapy When Furnished by Institutional Staff to Beneficiaries in Their Homes Through Communications Technology

Section 1861(p) of the Act establishes the benefit category for outpatient PT, SLP and OT services (expressly for PT services and, through section 1861(ll)(2) of the Act, for outpatient SLP services and, through section 1861(g) of the Act, for outpatient OT services).

Section 1861(p) of the Act defines outpatient therapy services in the three disciplines as those furnished by a provider of services, a clinic, rehabilitation agency, or a public health agency, or by others under an arrangement with, and under the supervision of, such provider, clinic, rehabilitation agency, or public health agency to an individual as an outpatient; and those furnished by a therapist not under arrangements with a provider of services, clinic, rehabilitation agency, or a public health agency. As such, section 1861(p) of the Act defines outpatient therapy services very broadly to include those furnished by providers and other institutional settings, as well as those furnished in office settings. Section 1834(k)(3) of the Act requires payment for outpatient therapy services to be made based on the PFS (via section 1848 of the Act), for all institutional providers listed at sections 1833(a)(8) and (9) of the Act. These providers include clinics, rehabilitation agencies, public health agencies, comprehensive outpatient rehabilitation agencies (CORFs), SNFs, home health agencies (HHAs) (to individuals who are not homebound), hospitals to outpatients or hospital inpatients who are entitled to benefits under Part A but have exhausted benefits for inpatient hospital services during a spell of illness or are not so entitled to benefits under Part A, and all other CORF services.

Section 1861(qq) of the Act defines Diabetes Self-Management Training (DSMT) services and authorizes CMS to regulate Medicare DSMT outpatient services. A ''certified provider'' of DSMT is further defined in section 1861(qq)(2)(A) of the Act as a physician or other individual or entity designated by the Secretary who meets certain quality requirements described in section 1861(qq)(2)(B) of the Act. In CY 2000, we finalized a standalone rule titled ''Medicare Program; Expanded Coverage for Outpatient Diabetes Self-Management Training and Diabetes Outcome Measurements.'' In that rule, we finalized that payment for outpatient DSMT would be made under the PFS (65 FR 83132). We further established that, in the case of payments made to other approved entities, such as hospital outpatient departments, ESRD facilities, and durable medical equipment suppliers, the payment would be equal to the amounts established under the PFS and made under the appropriate payment systems (65 FR 83142).

Section 1861(s)(2)(V) of the Act authorizes Medicare Part B coverage of medical nutrition therapy services (MNT) for certain beneficiaries who have diabetes or a renal disease. In the CY 2002 PFS final rule, we established that payment for MNT services furnished in the institutional setting, including hospital outpatient departments (HOPDs), would be made under the PFS, not under the hospital Outpatient Prospective Payment System (OPPS) (66 FR 55279). Telehealth services may be paid under the PFS only when the services are furnished to a beneficiary at an originating site (defined at § 410.78), which prior to the PHE was not typically defined to include a beneficiary's home.

During the PHE for COVID–19, outpatient therapy services, DSMT, and MNT could be furnished via a telecommunications system to beneficiaries in their homes, and bills for these services were submitted and paid either separately or as part of a bundled payment, when either personally provided by the billing practitioner or provided by institutional staff and billed for by institutions, such as HOPDs, SNFs, and HHAs. For professionals, CMS used waiver authority provided under section 1135 of the Act to expand the range of practitioners that could serve as distant site practitioners for Medicare telehealth services as described in section 1834(m)(4)(E) of the Act and 42 CFR 410.78(b)(2), as well as to waive the originating site requirements for Medicare telehealth services described in section 1834(m)(4)(C) of the Act. This allowed for outpatient therapy services to be furnished and billed by therapists (PTs, OTs and SLPs) in private practice, and for DSMT and MNT to be furnished via Medicare telehealth to beneficiaries in urban areas, as well as rural areas, including to beneficiaries located in their homes.[151]

When CMS expanded the types of practitioners who may bill for their services when furnished as Medicare telehealth services from a distant site to include therapists using section 1135 waiver authority during the PHE for COVID–19, CMS generally took the position for services furnished in HOPDs that separate waiver authority was needed to allow hospitals to bill for services furnished by hospital staff through communication technology to beneficiaries in their homes. CMS implemented the Hospitals Without Walls (HWW) policy that relied on waiver authority, which allowed hospitals to reclassify patients' homes as part of the hospital. HWW allowed hospitals to bill two different kinds of fees for services furnished remotely to patients in their homes: (1) hospital facility payment in association with professional services billed under the PFS; and (2) single payment for a limited number of practitioner services, when statute or other applicable rules only allow the hospital to bill for services personally provided by their staff. These services are either billed by hospitals or by professionals, there would not be separate facility and professional billing. This latter category includes outpatient therapy services, DSMT, and MNT. However, while CMS relied upon PHE-specific waiver authority to allow hospital billing for these services, CMS also issued guidance instructing HOPDs to bill using modifiers consistent with those used for Medicare telehealth services. For further background, we refer readers to *https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf*. In the same referenced document, CMS also issued specific guidance for other institutional providers of therapy services to use modifier 95 (indicating a Medicare telehealth service), along with the specific bill types for outpatient therapy services furnished by their staff.

The Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–328) extended many of the flexibilities that were available for Medicare telehealth services during the PHE for COVID–19 under emergency waiver authorities, including adding PTs, OTs and SLPs as distant site practitioners through the end of CY 2024. In developing post-PHE guidance, CMS initially took the position that institutions billing for services furnished remotely by their employed practitioners (where the practitioners do not bill for their own services), would end with the PHE for COVID–19 along with the HWW waivers.[152] However, after reviewing input from interested parties, as well as relevant guidance, including applicable billing instructions, we considered whether certain institutions, as the furnishing providers, can bill for certain remotely furnished services personally performed by employed practitioners.

In the CY 2024 PFS final rule, we stated that, while we considered how we might address this topic in future rulemaking, in the interests of maintaining access to outpatient therapy, DSMT, and MNT services furnished remotely by institutional staff to beneficiaries in their homes consistent with the accessibility of these services when furnished by professionals via Medicare telehealth, we finalized that we would continue to allow institutional providers to bill for these services when furnished remotely in the same manner they have during the PHE for COVID–19 through the end of CY 2024. We sought comment on current practice for these services when billed, including how and to what degree they continue to be provided remotely to beneficiaries in their homes. We sought comment as to whether these services may fall within the scope of Medicare telehealth at section 1834(m) of the Act or if there are other relevant authorities CMS might consider in future rulemaking. For further information on this comment solicitation, please see the discussion in the CY 2024 PFS final rule (88 FR 78886 through 78888).

For DSMT specifically, we stated that the clinical staff personally delivering the service may be a type of practitioner authorized to furnish Medicare telehealth services under section 1834(m) of the Act; but we also understood that DSMT may be provided by other types of staff. Accordingly, we noted in an FAQ that we were exercising enforcement discretion in reviewing the telehealth eligibility status of the practitioner personally providing any part of a remotely furnished DSMT service, so long as the persons were otherwise qualified to provide the service until the end of 2024. For more background we refer readers to *https://www.cms.gov/files/document/frequently-asked-questionscms-waivers-flexibilities-and-end-covid19-public-health-emergency.pdf.*

While the amendments made by section 4113 of the CAA, 2023 to section 1834(m) of the Act have continued to expand the range of practitioners eligible to furnish telehealth services through CY 2024, without subsequent legislation these practitioners will no longer be able to bill for Medicare telehealth services beginning January 1, 2025.

In the CY 2024 PFS final rule, we articulated the importance of maintaining access to outpatient therapy, DSMT, and MNT services furnished remotely by institutional staff to beneficiaries in their homes consistent with the availability of these services when furnished by professionals via Medicare telehealth as part of our rationale for allowing institutional providers to bill for these services when furnished remotely in the

[151] *https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf.*

[152] *https://www.cms.gov/files/document/frequently-asked-questions-cms-waivers-flexibilities-and-end-covid-19-public-health-emergency.pdf.*

same manner they have during the PHE for COVID–19 through the end of CY 2024.

We recognize that for the past several years, through the PHE for COVID–19 and several legislative extensions of PHE-related flexibilities for Medicare telehealth services under section 1834(m) of the Act, we have generally aligned payment policies for outpatient therapy, DSMT, and MNT services furnished remotely by hospital staff to beneficiaries in their homes with policies for Medicare telehealth services. We noted in the CY 2025 OPPS/ASC proposed rule that, to the extent that therapists and DSMT and MNT practitioners continue to be distant site practitioners for purposes of Medicare telehealth services, we anticipated aligning our policy for these services with policies under the PFS and continuing to make payment to the hospital for these services when furnished by hospital staff.

Comment: Commenters supported our clarification that we would continue to align our policies for outpatient therapy, DSMT, and MNT services when furnished by hospital staff with the Medicare telehealth policies that apply when these services are billed by the same clinicians but in private practice. Commenters stated that aligning these policies would ensure clarity and consistency for providers and beneficiaries. Other commenters, while supportive, requested that CMS provide additional guidance for how outpatient therapy, DSMT, and MNT services should be billed when provided by hospitals staff versus how these services should be billed when furnished by practitioners in private practice. A few commenters suggested that CMS permanently allow payment for remote or virtual services under the OPPS.

Response: We thank commenters for their support for our clarification. Section 4113 of the CAA, 2023 expanded the range of practitioners eligible to furnish telehealth services only through CY 2024, which included PTs, OTs, and SLPs. Beginning January 1, 2025, these practitioners will no longer be able to bill for Medicare telehealth services. Consequently, beginning January 1, 2025, we likewise will no longer pay for outpatient therapy, DSMT, and MNT services when furnished remotely by hospital staff to beneficiaries in their homes. As we have stated before, and as noted by other commenters, continuing to align our policies for outpatient therapy, DSMT, and MNT services when furnished by hospital staff with the Medicare telehealth policies that apply when these services are billed by the same clinicians but in private practice ensures clarity and consistency for providers and beneficiaries.

We may consider refinements to our policies in future rulemaking.

2. Periodic In-Person Visits for Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries in Their Homes

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72017), we finalized a requirement that payment for mental health services furnished remotely to beneficiaries in their homes using telecommunications technology may only be made if the beneficiary receives an in-person service within 6 months prior to the first time the hospital clinical staff provides the mental health services remotely; and that there must be an in-person service without the use of telecommunications technology within 12 months of each mental health service furnished remotely by the hospital clinical staff. We also finalized that we would permit exceptions to the requirement that there be an in-person service without the use of communications technology within 12 months of each remotely furnished mental health service when the hospital clinical staff member and beneficiary agree that the risks and burdens of an in-person service outweigh the benefits. We stated that exceptions to the in-person visit requirement should involve a clear justification documented in the beneficiary's medical record, including the clinician's professional judgement that the patient is clinically stable and/or that an in-person visit has the risk of worsening the person's condition, creating undue hardship on the person or their family, or would otherwise result in disengaging with care that has been effective in managing the person's illness. We also finalized that hospitals must document that the patient has a regular source of general medical care and has the ability to obtain any needed point of care testing, including vital sign monitoring and laboratory studies. We finalized that these requirements would not go into effect until the 152nd day after the PHE for COVID–19 ends to maintain consistency with similar policies implemented for professional services paid under the PFS, and for RHCs/FQHCs (87 FR 72018).

Section 4113(d) of the CAA, 2023, extended the delay in implementing the in-person visit requirements until January 1, 2025, for both professionals billing for mental health services via Medicare telehealth and for RHCs/FQHCs furnishing remote mental health visits. In the CY 2024 OPPS final rule with comment period, we reiterated that we believe it is important to maintain consistent requirements for these policies across payment systems; therefore, we finalized delaying the in-person visit requirements for mental health services furnished remotely by hospital staff to beneficiaries in their homes until January 1, 2025. As such, these in-person visit requirements are currently set to take effect for services furnished on or after January 1, 2025 (88 FR 81874).

However, we noted in the CY 2025 OPPS/ASC proposed rule that, to the extent that these in-person visit requirements are delayed in the future for professionals billing for mental health telehealth services under the PFS, we anticipate that we would align the requirements for mental health services furnished remotely to beneficiaries in their homes through communications technology with mental health services furnished via Medicare telehealth in future rulemaking.

Comment: Commenters supported our clarification that we would continue to align our policies for in person visit requirements for mental health services furnished remotely to beneficiaries in their homes through communications technology with similar policies for mental health services furnished via Medicare telehealth. Of these supportive comments, many recommended that CMS permanently remove the in-person visit requirements for these services.

Response: We appreciate the supportive comments but note that the in-person visit requirement for professionals billing for mental health services via Medicare telehealth applies again beginning January 1, 2025. We continue to believe in the principle of aligning payment policy for remotely furnished mental health services across the OPPS and PFS payment systems, and accordingly, the in-person visit requirements will also apply for mental health services furnished remotely by hospital staff to beneficiaries in their homes through communications technology beginning January 1, 2025. We may consider refinements to our policy through future rulemaking.

3. HOPD Payment for Telemedicine Evaluation and Management Services

The CPT Editorial Panel created 17 new codes describing audio/video and audio-only telemedicine E/M services. For further discussion of these 17 new codes and CMS' related proposals, please see section II.E.4.18 of the CY 2025 PFS proposed rule.

In 2014, CMS established HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of

a patient) to describe the service associated with a hospital outpatient clinic visit for assessment and management of a patient. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75042), we stated that the code is applicable for hospital use only representing any clinic visit under the OPPS. We further stated that HCPCS code G0463 replaces evaluation and management (E/M) CPT codes 99201–99205 (new patient) and 99211–99215 (established patient), thereby eliminating the distinction between new and established clinic visits.

Given the similarities between the new telemedicine E/M code set and the office/outpatient E/M code set, we believe that the telemedicine E/M codes fall within the scope of the hospital outpatient clinic visit policy because the predecessor codes (the office/outpatient E/M code set) would be reported by hospitals using HCPCS code G0463. Under the hospital outpatient clinic visit policy, the CPT codes describing office/outpatient E/M visits are not recognized under the OPPS and instead hospitals report HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient) when billing for the facility costs associated with an outpatient E/M visit. Therefore, we proposed to not recognize the telemedicine E/M code set under OPPS. We invited comment on the hospital resources associated with the telemedicine E/M services, particularly any resource costs that would not be included in the payment for HCPCS code G0463. We also invited comment, should CMS finalize separate payment for these telemedicine E/M codes under the PFS, on the resource costs that would be associated with these services for hospitals and whether we should develop separate coding to describe the resource costs associated with a telemedicine E/M service.

We received public comments on the proposal. The following is a summary of the comments we received and our responses.

Comment: Some commenters supported our proposal to maintain our policy of not recognizing office/outpatient E/M visits, including those furnished via telemedicine, as payable under the OPPS and instead using HCPCS code G0463 to capture the associated facility costs. Other commenters recommended that CMS allow HCPCS code G0463 to be reported when the beneficiary is not physically in the hospital, while others encouraged CMS to provide separate payment for the telemedicine E/Ms, including recommending clinical APC assignments.

Response: We thank commenters for the additional information and may consider this issue, including any refinements to our clinic visit policy, for future rulemaking. As we are not finalizing payment for the telemedicine E/M CPT codes under the PFS, we do not believe there is a programmatic need to recognize these codes for payment under the OPPS.

After consideration of the public comments we received, we are finalizing our proposal not to recognize the telemedicine E/M code set under the OPPS as proposed.

B. Virtual Direct Supervision of Cardiac Rehabilitation (CR), Intensive Cardiac Rehabilitation (ICR), Pulmonary Rehabilitation (PR) Services and Diagnostic Services Furnished to Hospital Outpatients

1. Background

a. Virtual Direct Supervision of CR, ICR and PR Services Furnished to Hospital Outpatients (42 CFR 410.27(a)(1)(B)(*1*))

In the interim final rule with comment period titled ''Policy and Regulatory Provisions in Response to the COVID–19 Public Health Emergency,'' published on April 6, 2020 (the April 6th COVID–19 IFC) (85 FR 19230, 19246, 19286), we changed the regulation at 42 CFR 410.27(a)(1)(iv)(D) [153] to provide that, during a Public Health Emergency as defined in 42 CFR 400.200, the presence of the physician for purposes of the direct supervision requirement for PR, CR, and ICR services includes virtual presence through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider. Specifically, the required direct physician supervision can be provided through virtual presence using audio/video real-time communications technology (excluding audio-only) subject to the clinical judgment of the supervising practitioner. We further amended § 410.27(a)(1)(iv)(B) [154] in the CY 2021 OPPS/ASC final rule with comment period to provide that this flexibility continues until the later of the end of the calendar year in which the PHE as defined in § 400.200 ends or December 31, 2021 (85 FR 86113 and 86299). In the CY 2021 OPPS/ASC final rule with comment period we also clarified that this flexibility excluded the presence of the supervising practitioner via audio-only telecommunications technology (85 FR 86113).

In the CY 2023 OPPS/ASC final rule with comment period, we finalized a policy to extend the revised definition of direct supervision of CR, ICR, and PR to include the presence of the supervising practitioner through two-way, audio/video telecommunications technology until December 31, 2023 (87 FR 72019 and 72020). In the CY 2024 OPPS/ASC final rule with comment period, we finalized a policy to further revise § 410.27(a)(1)(iv)(B)(*1*) [155] to allow for the direct supervision requirement for CR, ICR, and PR to include the virtual presence of the physician through audio-video real-time communications technology (excluding audio-only) through December 31, 2024, and to extend this policy to the nonphysician practitioners, that is NPs, PAs, and CNSs, who were eligible to supervise these services beginning in CY 2024 (88 FR 81863 through 81867).

b. Virtual Direct Supervision of Diagnostic Services Furnished to Hospital Outpatients (42 CFR 410.28(e)(2)(iii))

In the April 6th COVID–19 IFC, for consistency with the revisions made to 42 CFR 410.27(a)(1)(iv)(D) [156] and 410.32(b)(3)(ii), we changed the regulation at 42 CFR 410.28(e) to provide that, during a Public Health Emergency as defined in 42 CFR 400.200, the presence of the physician for purposes of the direct supervision requirement for diagnostic services includes virtual presence through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider (85 FR 19245 and 19246).

In the CY 2023 OPPS/ASC final rule with comment period, to ensure consistency with additional revisions made to 42 CFR 410.27(a)(1)(iv)(B)(*1*) and 410.32(b)(3)(ii) extending the end date of the flexibility allowing for the virtual supervision of the services governed by those regulations, we revised § 410.28(e) to extend the end date of the flexibility allowing for the virtual supervision of outpatient diagnostic services through audio/video real-time communications technology (excluding audio-only) from the end of the PHE to the end of the calendar year

[153] In the CY 2023 OPPS/ASC final rule with comment period, we removed § 410.27(a)(1)(iv)(D) in its entirety and added its language regarding pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services and the virtual presence of a physician through audio/video real-time communications technology during the PHE to the newly designated § 410.27(a)(1)(iv)(B)(*1*) (87 FR 72024).

[154] Ibid.

[155] Ibid.

[156] Ibid.

in which the PHE ends (87 FR 72024 through 72026).

In the CY 2024 final OPPS rule with comment period, to again ensure consistency with further revisions made to 42 CFR 410.27(a)(1)(iv)(B)(*1*) and 410.32(b)(3)(ii) extending the end date of the flexibility allowing for the virtual supervision of the services governed by those regulations, we revised § 410.28(e) to extend the end date of the flexibility allowing for the virtual supervision of outpatient diagnostic services through audio/video real-time communications technology (excluding audio-only) through December 31, 2024 (88 FR 81866 and 81867).

2. Extension of Virtual Direct Supervision of CR, ICR, PR Services and Diagnostic Services Furnished to Hospital Outpatients Through December 31, 2025.

In the CY 2025 PFS proposed rule, we proposed to revise the definition of direct supervision at § 410.32(b)(3)(ii) to extend the availability of virtual direct supervision of therapeutic and diagnostic services under the PFS through December 31, 2025. As described in that proposed rule, we proposed this extension based on our concern that an immediate reversion to the pre-PHE definition of direct supervision would prohibit virtual direct supervision, which may present a barrier to access to many services that have been facilitated by our PHE-related policy over the past several years; and that physicians and other practitioners need time to reorganize their practice patterns established during the PHE to reimplement the pre-PHE approach to direct supervision without the use of audio/video technology.

As we explained in the CY 2025 OPPS/ASC proposed rule, in addition to desiring uniformity under the PFS and OPPS in how regulations are applied to similarly situated providers, the beneficiary access and provider preparedness concerns that motivated us to propose extending the availability of virtual direct supervision of therapeutic and diagnostic services under the PFS through December 31, 2025, were also concerns with respect to the direct supervision of CR, ICR, PR and diagnostic services under the OPPS. Consequently, in the CY 2025 OPPS/ASC proposed rule, we proposed to revise §§ 410.27(a)(1)(iv)(B)(*1*) and 410.28(e)(2)(iii) to allow for the direct supervision of CR, ICR, PR services and diagnostic services via audio-video real-time communications technology (excluding audio-only) through December 31, 2025.

The following is a summary of the comments we received on the proposal and our responses to those comments.

Comment: All commenters supported our proposal to make conforming revisions to §§ 410.27 and 410.28 to allow for the direct supervision of CR, ICR, PR services and diagnostic services via audio-video real-time communications technology (excluding audio-only) through December 31, 2025. These commenters indicated that this extension would reduce burden on providers, ensure the continuity of ongoing services, allow more time for providers to reorganize and readjust policies to meet pre-PHE requirements, improve patient access to historically underutilized services and be of particular value in rural and other underserved areas where workforce shortages remain acute.

Response: We thank commenters for their support.

Comment: Many commenters additionally requested that the availability of virtual direct supervision of these services be made permanent, arguing that virtual supervision has been in place long enough for its safety to have been established and any serious problems identified. One commenter expressed concern that if virtual supervision was not made permanent it would be more difficult to recruit and retain non-physician staff with the necessary training and experience to safely deliver services under virtual supervision and to recruit and retain physicians who can effectively provide virtual supervision because those staff and physicians would be concerned that the policy enabling remote supervision is temporary and could be revoked within a year. One commenter requested that once the virtual supervision of these services is made permanent that CMS retire the requirement for a service-level modifier to identify when direct supervision is provided via appropriate telehealth technology.

Response: We appreciate the commenters' suggestions to make the virtual direct supervision of CR, ICR, PR and diagnostic services permanent and will take them under consideration for future rulemaking as we continue to evaluate safety, quality of care, and other considerations related to virtual direct supervision.

Comment: One commenter, while supporting the proposed extension, specifically requested that the extension not be made permanent. The commenter opined that permanently allowing for the virtual direct supervision of CR, ICR, PR and diagnostic services would be undesirable because it would increase the amount of physician ''incident to'' billing (a Medicare billing provision that applies in the office or clinic setting and allows medical services to be performed by auxiliary personnel as an incident to the services of the billing practitioner and under their supervision) for services provided by PAs and NPs, which would obscure the extent to which PAs and NPs are actually performing the services.

Response: We appreciate the commenter's input regarding the appropriate attribution of services performed by PAs and NPs when those services are billed ''incident to'' a physician's service and we look forward to reviewing the information provided as we consider the most appropriate way to balance patient safety concerns with the interest of supporting access that we may address in future rulemaking. We reiterate that we did not propose to extend the availability of the direct supervision of CR, ICR, PR services and diagnostic services via audio-video real-time communications technology (excluding audio-only) beyond December 31, 2025.

Comment: One commenter requested that audio-only virtual supervision of CR, ICR and PR be allowed during system downtimes or situations where patients may not be comfortable or willing to participate in the video portion of the supervision of their CR, ICR, and PR. The commenter also contended that allowing this flexibility would reduce barriers to care for patients with disabilities or mobility issues who might have trouble getting into a physical location.

Response: We appreciate the commenter's suggestion that we allow for the virtual supervision of CR, ICR, and PR to be provided via audio-only, however, under the applicable definition of direct supervision, the physician/practitioner is required to be available using both audio and video. As a reminder, direct supervision means that the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. We have traditionally defined ''immediately available'' to require the physical presence of the supervising practitioner, given the importance of certain services being furnished under direct supervision to ensuring quality of care and patient safety, and in particular the ability of the supervising practitioner to intervene if complications arise. As we continue to evaluate safety, quality of care, and other considerations related to virtual direct supervision and the role of virtual direct supervision after the COVID–19

PHE, we proposed to temporarily extend the availability of virtual direct supervision of therapeutic and diagnostic services only through December 31, 2025. To ensure quality of care and patient safety, any direct supervision furnished remotely will continue to require the use of real-time audio and visual interactive telecommunications technology. We note that does not necessarily mean that any interaction between the patient and the physician/practitioner supervising the service would require a video component.

Comment: One commenter questioned whether patient access to care is fully addressed by the virtual supervision of CR services in the absence of nationally available free or low-income access to broadband quality technology and telecommunications services. The commenter requested that CMS simultaneously adjust the facility and non-facility policies and prices under the Physician Fee Schedule (PFS) for outpatient CR services (HCPCS codes 93797 or 93798) so that Medicare pays hospital outpatient departments the PFS non-facility price at higher than current rates to allow facilities to subsidize the cost of supplying patients with broadband internet technologies for the duration of their enrollment in cardiac rehabilitation sessions.

Response: We appreciate the commenter's suggestion, but we note this comment is out of scope for this final rule.

Comment: One commenter encouraged CMS to consider additional services that could be safely supervised virtually in future years.

Response: We thank the commenter for their input and will consider taking it under consideration in future rulemaking.

Comment: Two commenters requested that CMS allow for CR and ICR to be provided virtually to patients in their homes, contending that CMS has the authority to do so under existing statute. These commenters stated that CMS has the authority under section 1861(eee) of the Act to (1) designate a patient's home as a setting for delivery of CR and ICR services and (2) allow CR and ICR services to be delivered virtually.

Response: We appreciate commenters' suggestion that section 1861(eee) of the Act provides the authority to furnish virtual CR and ICR services to outpatients in their homes and we will take their interpretation under consideration in future rulemaking.

After consideration of the public comments we received, we are finalizing, without modification, our proposal to revise §§ 410.27(a)(1)(iv)(B)(*1*) and 410.28(e)(2)(iii) to allow for the direct supervision of CR, ICR, PR services and diagnostic services via audio-video real-time communications technology (excluding audio-only) through December 31, 2025.

C. All-Inclusive Rate (AIR) Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities

1. Background

In the CY 2000 OPPS final rule (65 FR 18434), CMS implemented the PPS for hospital outpatient services furnished to Medicare beneficiaries, as set forth in section 1833(t) of the Act. In this final rule, we noted that the OPPS applies to covered hospital outpatient services furnished by all hospitals participating in the Medicare program with a few exceptions. We identified one of these exceptions as ''outpatient services provided by hospitals of the Indian Health Service (IHS).'' We stated that these services would ''continue to be paid under separately established rates which are published annually in the **Federal Register**'' and, in the CY 2002 OPPS/ASC final rule (66 FR 59856), we finalized a revision to § 419.20 (Hospitals subject to the hospital outpatient prospective payment system) by adding paragraph (b)(4), which specifies that hospitals of the IHS are excluded from the OPPS.

In the intervening years, IHS and tribal facilities have been paid under the separately established All-Inclusive Rate (AIR). On an annual basis, the IHS calculates and publishes, in the **Federal Register**, calendar year reimbursement rates.[157] Due to the higher cost of living in Alaska, separate rates are calculated for Alaska and the lower 48 States. For CY 2024, the Medicare Outpatient per Visit Rate is $667 for the lower 48 states and $961 for Alaska.[158]

IHS and tribal facilities have continued to expand the breadth of services that they provide to their communities. Increasingly, this has meant providing higher-cost drugs and biologics (hereinafter referred to as ''drugs'') along with more complex and expensive services. While the majority of IHS and tribal facilities appear to be well served by the AIR, some IHS and tribal facilities provide specialized services for which the AIR might not adequately represent Medicare's share of costs. If providing a drug or service costs IHS and tribal facilities thousands of dollars more than the payment they receive through the AIR, it is likely not financially feasible for these facilities to routinely provide that drug or service. For example, the cost of providing a frequently used cancer drug such as Opdualag (HCPCS code 00003–7125), which has a per day cost of $28,975, greatly exceeds the $667 payment an IHS or tribal facility receives through the AIR. We are concerned that, if payments under the AIR are inadequate for high-cost drugs, this could potentially threaten the viability of the few IHS and tribal hospital outpatient specialty programs currently in operation and provide less incentive to IHS hospitals and tribal facilities not currently offering specialty services to begin doing so. This constitutes a significant equity and beneficiary access concern if IHS and tribal hospitals are not able to provide oncology services or other services that require high-cost drugs because the hospital would always receive payment for those services that is far below what it would have to pay to acquire those high-cost drugs.

Consequently, in the CY 2024 OPPS/ASC proposed rule, we sought comment on whether Medicare should pay separately for certain high-cost drugs provided by IHS and tribal facilities and, if so, how we might do so. Among other topics, we specifically requested input on which drugs it would be appropriate to pay separately for (high-cost oncology drugs or all high-cost drugs), how we might define high-cost drugs (for example, a list of named drugs versus any drugs exceeding a certain cost threshold), and what the appropriate payment amount for the separately paid drugs should be (ASP plus 6 percent, which is what hospitals are generally paid under the OPPS for separately payable drugs, or the Federal Supply Schedule (FSS), which is where IHS and tribal hospitals acquire the majority of their drugs at rates significantly lower than ASP plus 6 percent). For a full discussion of the comment solicitation, we refer readers to the CY 2024 OPPS/ASC proposed rule (88 FR 49741 through 49742).

Commenters, including a tribal facility, the CMS Tribal Technical Advisory Group (TTAG), organizations representing tribal healthcare providers, pharmaceutical companies, and other interested parties, expressed universal support for establishing a policy that would allow IHS and tribal healthcare facilities to receive separate payment outside of the AIR for high-cost drugs. The preferred approach of those

[157] *https://www.ihs.gov/BusinessOffice/reimbursement-rates/.*

[158] 88 FR 87789 (December 19, 2023); *https://www.federalregister.gov/documents/2023/12/19/2023-27815/reimbursement-rates-for-calendar-year-2024.*

commenters who provided input on how to define a high-cost drug eligible for separate payment was to treat the amount of the Medicare Outpatient per Visit Rate for the lower 48 States' AIR (hereinafter referred to as ''the lower 48 AIR'') as a payment threshold. Under this approach, if the cost of a particular drug is less than or equal to the lower 48 AIR, the provider would not receive a separate payment for the drug and if the cost of the drug was more than the lower 48 AIR, then the provider would receive a separate payment for the drug. Commenters noted that this payment approach is currently being used for all drugs (oncology and otherwise) receiving payment through Arizona Medicaid (AHCCCS) for IHS and tribal facilities located in Arizona. With respect to the payment amount, several commenters requested that separately payable drugs furnished by IHS and tribal facilities be paid at a rate of ASP plus 6 percent rather than the FSS rate. These commenters argued that the IHS is chronically underfunded and that paying ASP plus 6 percent for high-cost drugs could help with remedying those funding issues. For a full discussion of the comments we received as a result of our comment solicitation and our responses to those comments, we refer readers to the CY 2024 OPPS/ASC final rule with comment period (88 FR 81896 through 81897).

2. AIR Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities

In light of the equity and beneficiary access concerns that prompted our CY 2024 comment solicitation and the input received in response to that solicitation, in the CY 2025 OPPS/ASC proposed rule we proposed, starting January 1, 2025, to separately pay IHS and tribal hospitals [159] for high-cost drugs furnished in hospital outpatient departments through an add-on payment in addition to the AIR using the authority under which the annual AIR is calculated.[160] We emphasized that the amount of the proposed add-on payment would *not* be carved out of the annual AIR payment amount calculation. In other words, we proposed that the add-on payment would have no effect on the calculation of the annual AIR payment amount. We invited comment on separately paying IHS and tribal hospitals for high-cost drugs furnished in hospital outpatient departments through the establishment of an add-on payment to the AIR using the authority under which the annual AIR is calculated.

Comment: All commenters on the proposed policy supported separately paying IHS and tribal hospitals for high-cost drugs furnished in hospital outpatient departments through the establishment of an add-on payment to the AIR using the authority under which the annual AIR is calculated. These commenters cited as the basis for their support the need to address beneficiary equity and access concerns resulting from the current payment policy for high-cost drugs under the AIR, historic and ongoing health disparities of American Indian and Alaska Native people compared to other Americans, including lower life expectancy, disproportionate disease burden and higher rates of colorectal, kidney, liver, lung, and stomach cancers, ensuring the continued viability of IHS and tribal hospital outpatient specialty programs currently in operation and enabling IHS and tribal facilities not currently offering specialty services to begin doing so. Several of these commenters additionally expressed support for the exclusion of the add-on payment from the calculation of the annual AIR payment, stating that it was a critically important component of the proposal because it would ensure that the add-on payment would have no effect on IHS and tribal facilities that do not seek reimbursement for high-cost drugs.

Response: We thank the commenters for their support.

After consideration of the public comments we received on the proposed policy to separately pay IHS and tribal hospitals for high-cost drugs furnished in hospital outpatient departments through the establishment of an add-on payment to the AIR using the authority under which the annual AIR is calculated and to exclude the add-on payment from the calculation of the annual AIR payment, we are finalizing the policy as proposed.

In the CY 2025 OPPS/ASC proposed rule, we proposed that the drugs to which the add-on payment would apply would not be limited to high-cost oncology drugs but would include all high-cost drugs furnished in hospital outpatient departments of IHS and tribal hospitals to the extent those drugs were covered under Medicare Part B and would be paid for under the OPPS if furnished by a hospital paid under that system. In determining which drugs would be eligible for the add-on payment, we considered limiting the add-on payment to high-cost oncology drugs. However, as we discussed in the CY 2025 OPPS/ASC proposed rule, we determined that it would be appropriate to apply the add-on payment to all high-cost drugs for several reasons. First, the same equity and access concerns that supported utilizing an add-on payment for oncology drugs also supported utilizing an add-on for high-cost drugs used in other care specialties. Although this issue arose in the context of removing barriers to beneficiaries' access to high-cost oncology drugs, we concluded that there were presumably similar barriers to other specialties that used high-cost drugs that would be addressed through a broader application of the add-on payment. Second, we determined that applying the add-on payment to all high-cost drugs would eliminate the possibility of unintentionally excluding an oncology drug from separate payment due to the inherent challenge of defining a class of drugs. Third, the proposal would parallel how drugs are being paid for under Arizona Medicaid (AHCCCS) for IHS and tribal facilities. In the CY 2025 OPPS/ASC proposed rule we invited comment on applying the add-on payment to all high-cost drugs furnished in hospital outpatient departments of IHS and tribal hospitals to the extent those drugs were covered under Medicare Part B and would be paid for under the OPPS if furnished by a hospital paid under that system.

Comment: Several commenters supported applying the add-on payment to all high-cost drugs furnished in hospital outpatient departments of IHS and tribal hospitals to the extent those drugs are covered under Medicare Part B and would be paid for under the OPPS if furnished by a hospital paid under that system. These commenters observed that there are many other types of high-cost drugs that can be administered in an outpatient hospital setting that are unrelated to oncology and that the same equity and access concerns that support an add-on payment for high-cost oncology drugs applies to other high-cost drugs.

Response: We thank the commenters for their support.

After consideration of the public comments we received on the proposed policy to apply the add-on payment to all high-cost drugs furnished in hospital outpatient departments of IHS and tribal hospitals to the extent those drugs are covered under Medicare Part B and would be paid for under the OPPS if furnished by a hospital paid under that

[159] IHS Critical Access Hospitals (CAHs) are paid for covered outpatient services based on 101 percent of an all-inclusive facility specific rate rather than the national AIR rate. Consequently, they are excluded from the proposed separate payment policy.

[160] Sections 321(a) and 322(b) of the Public Health Service Act (42 U.S.C. 248), Public Law 83–568 (42 U.S.C. 2001(a)), and the Indian Health Care Improvement Act (25 U.S.C. 1601 *et seq.*).

system, we are finalizing the policy as proposed.

As to what constitutes a high-cost drug, we proposed in the CY 2025 OPPS/ASC proposed rule to define high-cost drugs for the purpose of the policy as all drugs covered under Medicare Part B and for which payment would otherwise be made under the OPPS whose per day cost exceeds two times the lower 48 AIR ($1,334 in CY 2024). We proposed a threshold greater than the lower 48 AIR to account for the fact that IHS and tribal hospitals would continue to receive the lower 48 AIR payment, in addition to the add-on payment, for encounters that include a high-cost drug. While we acknowledged that it was true that under the Arizona Medicaid program, IHS and tribal hospitals are paid the lower 48 AIR payment in addition to an add-on payment for drugs whose costs exceed the lower 48 AIR, we were concerned that providing separate payment for drugs whose costs only slightly exceed the lower 48 AIR could result in excessive payment for those drugs. For example, we pointed out that for a drug costing $700, using the CY 2024 lower 48 AIR as the threshold for our proposal would result in a payment of at least $1,367 (the $667 lower 48 AIR encounter payment plus an add-on payment for the high-cost drug as calculated under the payment methodology we proposed in the CY 2025 OPPS/ASC proposed rule) for the provision of a drug whose cost exceeds the lower 48 AIR by only $33.00. We concluded that such an outcome would be at odds with the objective of the proposed policy, which was to provide adequate payment for drugs that are high cost in relation to the lower 48 AIR. Consequently, in the CY 2025 OPPS/ASC proposed rule, we proposed two times the lower 48 AIR as the threshold triggering the add-on payment because that amount would ensure that the add-on payment would apply only to drugs whose costs significantly exceed the lower 48 AIR. The proposed cost-multiplier approach was also consistent with how CMS has implemented thresholds relating to payments to hospitals under other payment systems. For example, the OPPS outlier policy [161] requires that the cost of a service exceed 1.75 times the payment amount for the service to qualify for an additional payment. Similarly, the OPPS two-times rule requires that the highest calculated cost of an individual procedure categorized to any given Ambulatory Payment Classification (APC) not exceed two times the calculated cost of the lowest cost procedure categorized to that same APC.

In the CY 2025 OPPS/ASC proposed rule, we stated that an alternative to our proposal to set the threshold at two times the lower 48 AIR would be to set the threshold at the lower 48 AIR despite our concerns about excessive payment. We also stated that another alternative would be to set the threshold at 1.75 times the lower 48 AIR ($1,167.25 in CY 2024) to align it with the multiplier used to calculate the threshold triggering outlier payments under the OPPS. In the CY 2025 OPPS/ASC proposed rule, we invited comment on the alternatives of using the lower 48 AIR or 1.75 times the lower 48 AIR as the threshold amount for triggering the add-on payment for high-cost drugs.

Comment: Three commenters provided input on setting the threshold at the lower 48 AIR, agreeing with CMS that providing a separate payment for drugs whose costs only slightly exceed the lower 48 AIR could result in excessive payment because the facility would be receiving the lower 48 AIR payment plus the add-on payment for the drug.

Response: We thank commenters for their feedback.

Comment: Four commenters suggested that we set the threshold at 1.75 times the lower 48 AIR. Three of these commenters argued that the threshold be set at 1.75 times the lower 48 AIR because (1) doing so would align it with the multiplier used to calculate the threshold triggering outlier payments under the OPPS and (2) there were, based on the proposed rule data and example threshold of $1,334, three high-use drugs (Bendeka [Bendamustine HCL], Xembify [immune globulin] and Neulasta On-Pro [Pegfilgrastim]) that would not qualify for the add-on payment if the threshold was two times the lower 48 AIR but would qualify for the add-on payment if the threshold was 1.75 times the lower 48 AIR and one high-use drug (Vivitrol [Naltrexone]) that would qualify for the add-on payment if the threshold was two times the lower 48 AIR but was sufficiently close to the threshold that it could easily fall below the threshold and not qualify for separate payment in the future.

Response: We appreciate the commenters' preference for using 1.75 times the lower 48 AIR, but our view is that two times the lower 48 AIR is the most appropriate threshold to use as it would best ensure that only those drugs whose costs significantly exceed the amount of the annual lower 48 AIR payment would qualify for the add-on payment. It is also consistent with the two-times rule the OPPS uses to determine Ambulatory Payment Classification (APC) levels and the calculation of the diagnostic radiopharmaceutical packaging threshold that that we are finalizing in section II.A.3.c.(2) of this rule. With respect to the four high-use drugs referenced by the commenters, using final rule data, Bendeka and Xembify have per day costs that are well above $1,334 and thus qualify for the add-on payment under two times the lower 48 AIR threshold. Neulasta has a per day cost significantly below the lower 48 AIR of $667 and thus would not qualify for the add-on payment under any threshold that we are considering. Vivitrol has a per day cost that is slightly above $1,334 and therefore qualifies for the add-on payment under two times the lower 48 AIR threshold. While we acknowledge that this closeness to the threshold could cause Vivitrol to fluctuate from qualifying for separate payment to not qualifying for separate payment on an annual basis, there will always be drugs for which this is true when using any threshold-based payment criterion.

Comment: Two commenters suggested that we use non-AIR thresholds to calculate the list of drugs for which the add-on payment would be made. One of these commenters suggested that we use the standard drug packaging threshold of $140 to better recognize the costs for IHS and tribal facilities that furnish expensive drug treatment services to Native Americans with cancer. The other commenter, expressing concern that the proposed threshold was too high and might exclude some drugs that are clinically necessary and significantly costly for IHS and tribal hospitals, suggested that CMS establish a threshold based on CMS' specialty tier cost threshold criteria under Medicare Part D.[162]

Response: We appreciate the commenters' suggested alternatives to using a multiple of the AIR as the threshold; however, we do not think that these thresholds would achieve the objective of providing a separate add-on payment only for drugs that greatly exceed the lower 48 AIR.

[161] The OPPS provides outlier payments to hospitals to help mitigate the financial risk associated with high-cost and complex procedures, where a very costly service could present a hospital with significant financial loss. Outlier payments are provided on a service basis when the cost of a service exceeds the APC payment amount multiplier threshold (the APC payment amount multiplied by 1.75) as well as the APC payment amount plus a fixed-dollar amount threshold (the APC payment plus a certain dollar amount).

[162] 42 CFR 423.104(d)(2)(iv).

Comment: One commenter suggested that, regardless of which approach CMS selects to determine the high-cost threshold, that CMS ''categorically apply separate payment'' for biosimilar [163] products when administered in IHS and tribal facilities. The commenter observes that American Indians and Alaska Natives experience disparities in healthcare access and outcomes and argues that by ensuring that biosimilar products are financially accessible in IHS and tribal facilities, CMS would be taking a step toward reducing these disparities and promoting health equity. The commenter also stated that a ''separate payment system'' for biosimilar products could also incentivize their use over more expensive reference products, fostering a competitive market that may, in turn, lead to further reductions in prescription drug costs over time.

Response: It isn't entirely clear what the commenter means by ''categorically apply separate payment'' for biosimilar products or a ''separate payment system'' for biosimilar products, but it appears that the commenter is suggesting that all biosimilars be paid for separately when furnished by an IHS or tribal hospital outpatient department regardless of the payment threshold. We appreciate the commenter's suggestion; however, we do not think that paying separately for all biosimilars would achieve the objective of providing a separate add-on payment only for drugs and biologicals that greatly exceed the lower 48 AIR.

After consideration of the public comments we received on the proposed policy to define high-cost drugs as all drugs covered under Medicare Part B and for which payment would otherwise be made under the OPPS whose per day cost exceeds two times the lower 48 AIR ($1,334 in CY 2024), we are finalizing the policy as proposed.

We also sought comment in the CY 2025 OPPS/ASC proposed rule on whether we should adopt an exception to whichever AIR-based threshold we adopted that would parallel the drug packaging threshold exception for biosimilars under the OPPS. As we explained in the CY 2025 OPPS/ASC proposed rule, under the OPPS, if a drug's per-day cost is less than or equal to the drug packaging threshold, then payment for the drug is packaged. Conversely, if a drug's per-day cost exceeds the drug packaging threshold, then it is paid for separately (unless it is policy packaged). For a more detailed discussion of the drug packaging threshold, we referred readers to the CY 2024 OPPS/ASC final rule with comment period (88 FR 81776 through 81778). In CY 2024, we established an exception to this threshold for biosimilars when the biosimilar's per-day cost does not exceed the threshold, but its reference product's per-day cost does. In other words, if the biosimilar's reference product is paid separately (because its per-day cost exceeds the threshold), then we also pay separately for the biosimilar even if its per-day cost does not exceed the threshold. This exception was based on our concern that packaging biosimilars when the reference product or other marketed biosimilars are separately paid might create financial incentives for providers to select more expensive, but clinically similar, products. For a more detailed discussion of the exception for biosimilars to the drug packaging threshold, we referred readers to the CY 2024 OPPS/ASC final rule with comment period (88 FR 81783 through 81786). Because we proposed to use a threshold to trigger application of the add-on payment for high-cost drugs to IHS and tribal hospitals, we stated that we had the same concerns about financial incentives that motivated us to establish the exception for biosimilars to the drug packaging threshold. Consequently, in the CY 2025 OPPS/ASC proposed rule, we sought comment on whether we should pay the add-on payment to IHS and tribal hospitals for biosimilars whose per-day costs do not exceed the threshold but whose reference products per-day costs do exceed the threshold.

Comment: We received several comments on whether we should pay the add-on payment to IHS and tribal hospitals for biosimilars whose per-day costs do not exceed the threshold but whose reference products do exceed the threshold. All commenters supported doing so, indicating that they shared CMS' concerns that packaging biosimilars when the reference product is separately paid might create financial incentives for providers to select more expensive but clinically similar products.

Response: We thank the commenters for their feedback and, based on this feedback, we will adopt a drug packaging threshold exception for biosimilars in which we will pay the add-on payment to IHS and tribal hospitals for biosimilars whose per-day costs do not exceed the threshold of two times the lower 48 AIR but whose reference products do exceed the threshold.

In the CY 2025 OPPS/ASC proposed rule, we also proposed that the amount of the add-on payment for a high-cost drug would be the average sales price (ASP) for the drug with no additional payment (*i.e.,* ASP). We explained that this payment amount would be consistent with what hospitals receive as payment for most drugs under the OPPS (ASP plus 6 percent) but would exclude the 6 percent additional payment in recognition of the fact that IHS and tribal facilities, unlike hospitals paid under the OPPS, primarily obtain their drugs through the FSS, whose rates are significantly lower than ASP. We also emphasized that this approach would be consistent with our existing policies of paying ASP without any additional payment for certain Opioid Treatment Program drugs under 42 CFR 410.67(d)(2)(i)(A) and (B). In the event ASP pricing information was not available for a particular drug, we proposed to pay the Wholesale Acquisition Cost (WAC) plus 0 percent and if WAC pricing information was not available, we proposed to pay 89.6 percent of Average Wholesale Price (AWP).

In the CY 2025 OPPS/ASC proposed rule, we sought comment on an alternative policy of paying ASP plus 6 percent instead of ASP plus 0 percent. We also proposed that if we were to adopt this alternative policy and pricing information was not available for a particular drug, we would pay WAC plus 6 percent and if WAC pricing information was not available, we would pay 95 percent of AWP. We sought comment on our proposal to pay an add-on of ASP plus 0 percent in addition to the lower 48 AIR for drugs administered by IHS and tribal facilities with costs that exceed two times the lower 48 AIR. We also sought comment on our proposed pricing hierarchy for drugs for which ASP pricing information was not available.

Comment: Three tribal commenters supported paying ASP with no additional payment. In their view this would adequately compensate IHS and tribal hospital outpatient departments for their costs because the facilities would be receiving both the add-on payment for the drug and the lower 48 AIR encounter payment.

Response: We thank commenters for their support.

Comment: Multiple commenters suggested that the payment amount for the add-on payment should be ASP plus 6 percent. One of these commenters additionally requested that CMS pay ASP plus 8 percent for certain

[163] A biosimilar is a biologic medication. It is highly similar to a biologic medication already approved by FDA—the original biologic (also called the reference product).

qualifying biosimilar products. Many of these commenters argued that paying ASP plus 6 percent is necessary to ensure access to high-cost drugs because only ASP plus 6 percent adequately reflects the true acquisition and administration costs of high-cost drugs. Some of these commenters, while acknowledging that IHS and tribal facilities primarily obtain their drugs through the FSS, argued that not all IHS and tribal facilities might have access to the FSS and that not all drugs are necessarily available through the FSS. One commenter expressed concern that providers might perceive reimbursement without the 6 percent add-on as a ''penalty'' for furnishing higher-cost drugs in these settings. Finally, some of these commenters argued that CMS should pay ASP plus 6 percent for consistency with how separately payable Part B drugs are reimbursed in the OPPS setting.

Response: We thank the commenters for their input and share their concerns that the payment amount for separately paid for drugs reflect the acquisition and administration costs of those drugs and that IHS and tribal hospital outpatient departments be paid consistently with how outpatient hospital departments are paid for drugs under the OPPS. However, it is our view that paying ASP plus 0 percent would achieve these goals. We believe that ASP with no add-on payment captures the acquisition and administration costs of the drugs given that (1) IHS and tribal facilities acquire most of their drugs through the FSS at rates significantly lower than ASP plus 6 percent; and (2) IHS and tribal facilities will continue to receive the lower 48 AIR payment for the encounter in addition to the add-on payment for the drug. Given these two factors, we believe that an add-on payment equal to ASP is sufficient.

With respect to paying IHS and tribal hospital outpatient departments consistently with how we pay hospital outpatient departments under the OPPS, our view is that paying IHS and tribal hospital outpatient departments ASP with no additional add-on is consistent with how we pay hospital outpatient departments under the OPPS given the differences in how hospitals under the two payment systems primarily acquire their drugs. As we stated in our proposed rule, our rationale for paying ASP was to pay IHS and tribal hospitals the same rate we pay hospital outpatient departments under the OPPS for separately payable drugs, while excluding the 6 percent add-on in recognition of the fact that IHS and tribal hospitals, unlike hospitals under the OPPS, primarily acquire their drugs through the FSS at a significantly lower rate than hospitals under the OPPS.

Comment: Three commenters expressed support for our proposed pricing hierarchy for drugs for which ASP pricing information is not available. These commenters indicated that there may be many times when new drugs are available for which an ASP has not yet been set and the proposed hierarchy would allow IHS and tribal facilities to be reimbursed for those high-cost drugs at these other rates until an ASP is set. Without such a hierarchy in place, these commenters warned, many new drugs would not be eligible for the add-on payment.

Response: We thank commenters for their support.

After consideration of the public comments we received on the proposed policy to set the amount of the add-on payment for a high-cost drug at ASP with no additional payment (ASP plus zero percent) and the proposed pricing hierarchy for drugs for which ASP pricing information was not available, we are finalizing the policies as proposed.

To implement this policy, in the CY 2025 OPPS/ASC proposed rule we proposed that, starting with IHS's annual announcement in the **Federal Register** in December 2024 of the lower 48 AIR amount for CY 2025, we would multiply the lower 48 AIR amount for the payment year by two and then compare the result to the estimated per day costs of all drugs covered under Part B for which payment would otherwise be made under the OPPS. To determine the calculated per day cost for each drug and biological HCPCS code, we proposed to follow a methodology similar to our longstanding methodology used to calculate the per day cost of drugs and biologicals for OPPS payment purposes as discussed in section V.B.1.b of this final rule with comment period. Specifically, to calculate the per day cost, we proposed to use an estimated payment rate based on the ASP methodology payment rate, which for purposes of the proposal was generally ASP plus 0 percent (which is the payment rate we proposed for separately payable IHS drugs and biologicals) for CY 2025. We used the manufacturer-submitted ASP data from the fourth quarter of CY 2023 to determine the proposed rule per day cost. For drugs and biologicals that did not have either an ASP-based payment rate or a payment rate based on WAC, we used mean unit cost of the items derived from the CY 2023 hospital claims data to determine their per day cost.

In the CY 2025 OPPS/ASC proposed rule, we proposed that a list of drugs whose costs exceeded two times the lower 48 AIR would be generated using the above-described methodology and then communicated to IHS and tribal hospitals prior to January 1, 2025. During CY 2025, IHS and tribal hospitals would submit claims for drugs included on this list. The list of drugs would be updated on a quarterly basis using existing drug compendia and CMS ASP quarterly reporting only to account for newly introduced drugs. The payment rates for drugs on the list would be updated quarterly as well based on changes in drug prices. We proposed to then repeat this process on an annual basis each December when the lower 48 AIR amount for the following calendar year was announced by IHS. As an example, we included in our proposed rule a list of the drugs for which the add-on payment would have been made (drugs with a per day cost exceeding two times the CY 2024 lower 48 AIR) had our proposed policy been in place for CY 2024. We sought comment on our proposed implementation plan.

Comment: We received three comments specifically supporting our proposed implementation plan with one requested alteration. These commenters requested that when we annually create the list of drugs that qualify for the add-on payment that we use the lower 48 AIR in effect at the time of the release of the CY OPPS/ASC final rule with comment period to calculate the threshold for creating the list rather than waiting for IHS's release of the lower 48 AIR for the payment year (typically released in December). For example, to create the drug list for CY 2025, CMS would use the lower 48 AIR for 2024 rather than waiting for the release of the lower 48 AIR for 2025. These commenters indicated that while IHS has issued the lower 48 AIR in December in recent years, that has not always been the case and that in some years the lower 48 AIR was not released until months into the payment year. If that were to occur in future years, the commenters were concerned that it would delay the release of the drug list until after January 1 of the payment year. Accordingly, the commenters suggested that CMS use the lower 48 AIR in effect at the time the final OPPS rule is released and then update the list in the first quarterly update during the payment year using the new lower 48 AIR amount once it has been released by IHS.

Response: We share the commenters' concern about the release of the list being delayed beyond January 1 of the

payment year. Adopting the commenters' suggestion would allow the final list of covered drugs to be included in the OPPS/ASC final rule which must be released by November 1 of each year. In addition to ensuring that the list would not be delayed beyond January 1 of the payment year, this would also have the advantage of avoiding the operational complexity of having to finalize and release a covered drug list separately from the final OPPS rule. It would also give CMS more time to communicate the drug list to IHS and tribal hospitals and would provide those hospitals with more time to familiarize themselves with the list. With respect to the commenter's suggestion that we update the list in the next quarterly update using the new lower 48 AIR once it's released by IHS, we should explain that, as we stated in the proposed rule, the quarterly updates consist solely of adding newly introduced drugs to the list and updating the ASP for listed drugs. In other words, we will only use the lower 48 AIR once, annually, to establish the list of qualifying drugs for the payment year and we will not update that list again using the AIR during the payment year. The only quarterly updates will be to add new-to-market drugs with per-day costs that exceed two times the lower 48 AIR and to update qualifying drugs' ASPs, not to add to/change the list of qualifying drugs.

For both operational simplicity and to ensure that the list of separately paid drugs is released prior to January 1 of each year, we are finalizing using the lower 48 AIR in effect at the time of the release of the CY OPPS/ASC final rule with comment period to annually create the list of drugs qualifying for the add-on payment for the following calendar year.

Comment: Two commenters commented on CMS' proposed process to create the list of drugs qualifying for the add-on payment. One suggested that CMS clearly communicate to IHS facilities the final process to develop the list and the results of the quarterly and annual updates to that list. The other recommended that CMS maintain a transparent process that would allow manufacturers to validate the results and establish a process whereby manufacturers could seek to correct any identified errors.

Response: We agree with the commenters on the importance of employing a transparent process to develop the list of high-cost drugs for which separate payment will be made and clearly communicating that process and its results to IHS and tribal facilities on an annual and quarterly basis. The process we are using to create the list of drugs qualifying for the add-on payment is described in detail earlier in this section. The results of that process are contained in Addendum Q to this final rule, which is the list of drugs qualifying for the add-on payment for CY 2025. Quarterly updates to the list will be posted on the CMS website [164] as they occur during CY 2025. Additionally, links to Addendum Q and the quarterly updates to the list during the calendar year will be posted on the IHS website [165] and IHS will be sending ''Dear Tribal Leader Letters'' [166] to tribal officials informing them of the new policy and where the list can be found. With respect to allowing for the validation of the results of the process, we direct commenters to the cost statistics files [167] which can be used to validate the results of the per day cost calculations.

Comment: Another commenter encouraged CMS to monitor whether adoption of the separate payment policy will adequately facilitate equitable patient access to drugs administered in hospital outpatient facilities in tribal communities. The commenter also suggested that CMS consider reporting on access to drugs within American Indian/Alaskan Native and other racial and ethnic communities within Health and Human Services Dashboards, such as those produced by the IHS.

Response: Given the health equity and beneficiary access concerns motivating our separate payment policy, we agree with the commenter on the importance of monitoring the effects of the separate payment policy on equitable patient access to drugs administered in hospital outpatient facilities in tribal communities and we plan on assessing the impact of our separate payment policy following its implementation. We will take the commenter's suggestion to report the outcome of such monitoring within Health and Human Services Dashboards under consideration for future rulemaking.

Comment: We received a comment supporting the policy and requesting that we consider expanding the scope of the add-on payments to include other high-cost services beyond drugs, such as radiology services.

Response: We appreciate the commenter's suggestion to expand the scope of the add-on payments to include other high-cost services beyond drugs and may consider this in future rulemaking.

Comment: We received two comments supporting the policy and requesting that it be expanded to include Urban Indian Organization (UIOs) clinics. These commenters emphasized that UIOs are severely underfunded and the same equity and access concerns that support providing IHS and tribal facilities with the proposed AIR add-on payment for high-cost drugs are also relevant to the needs of UIOs.

Response: We appreciate the commenters' suggestion; however, UIO clinics are not paid the outpatient AIR for hospital outpatient services furnished to Medicare beneficiaries and therefore are outside of the scope of the AIR add-on payment policy that we are finalizing in this rule.

Finally, we proposed to implement this policy on a permanent basis but may revisit it in the future if we have any concerns about its impact once it has been implemented.

Comment: We received two comments supporting our proposal to implement the policy on a permanent basis.

Response: We thank the commenters for their input.

After consideration of the public comments we received on our proposed plan to implement the separate payment policy, we are finalizing the policy as proposed except we will use the lower 48 AIR in effect at the time of the release of the CY OPPS/ASC final rule with comment period (rather than the lower 48 AIR for the payment year) to annually create the list of drugs qualifying for the add-on payment for the following calendar year.

As discussed in the preceding sections, after consideration of the public comments we received, we are finalizing the policy to separately pay IHS and tribal hospitals for high-cost drugs furnished in hospital outpatient departments as proposed with modifications to (1) use the lower 48 AIR amount in effect at the time of the release of the CY OPPS/ASC final rule with comment period to calculate the threshold for the list of drugs qualifying for the add-on payment for the following calendar year and (2) adopt a drug packaging threshold exception for biosimilars that parallels the drug packaging threshold exception for biosimilars under the OPPS.

[164] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/addendum-a-b-updates.*

[165] *https://www.ihs.gov/businessoffice/reimbursement-rates/.*

[166] *https://www.ihs.gov/newsroom/triballeaderletters/.*

[167] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

D. Request for Information—Paying All IHS and Tribally Operated Clinics the IHS Medicare Outpatient All Inclusive Rate (AIR)

CMS established a Tribal Technical Advisory Group (TTAG) in 2004 to provide advice and input to CMS on policy and program issues impacting American Indians and Alaska Natives (AI/AN) populations served by CMS programs. Although not a substitute for formal consultation with tribal leaders, the TTAG enhances the government-to-government relationship between HHS and federally recognized tribes and improves understanding between CMS and tribes. The TTAG has subject specific subcommittees that meet on a regular basis in order to be more effective and perform in-depth analysis of Medicare, Medicaid, Children's Health Insurance Program (CHIP), and Health Insurance Marketplace® [168] policies that may have tribal implications. The TTAG is composed of 17 representatives. It has historically included an elected tribal leader or an appointed representative from each of the 12 geographic areas of the Indian Health Service (IHS) delivery system and a representative from each of the national Indian organizations headquartered in Washington, DC—the National Indian Health Board, the National Congress of American Indians, and the Tribal Self-Governance Advisory Group. Section 5006(e)(1) of the American Recovery and Reinvestment Act of 2009, which became effective July 1, 2009, mandates that TTAG shall be maintained within CMS and added two new representatives: a representative from a national urban Indian health organization; and a representative from the IHS.

In June 2020, the TTAG suggested that CMS amend its Medicare regulations to make all IHS and tribally operated outpatient facilities eligible for Medicare payment at the IHS Medicare outpatient per visit rate/AIR. The TTAG explained that outpatient clinics, which are otherwise similar to grandfathered tribal Federally Qualified Health Centers (FQHCs), are paid at different rates depending upon whether they meet the requirements as a provider-based facility, a grandfathered tribal FQHC, a non-grandfathered tribal FQHC, or none of the above. TTAG's position is that the rates vary based on Medicare regulatory definitions, rather than the actual costs of the outpatient clinic.[169] There are varying payment differentials among Medicare enrolled providers and suppliers under the authorities of the Social Security Administration (SSA). For example, Ambulatory Surgical Centers (ASCs) are paid differently than Hospital Outpatient Departments (HOPDs); which are paid differently depending on whether they are located in a critical access hospital.

In the CY 2022 PFS proposed rule (86 FR 39240), we acknowledged that the TTAG is concerned about ensuring appropriate Medicare payments for similar services and is also concerned about the impact on tribal Medicare beneficiaries and on ensuring equitable access to healthcare. We take these concerns seriously but noted in the CY 2022 PFS proposed rule that we had insufficient information to evaluate the costs and benefits of potential changes to these policies. Therefore, we solicited comments on the TTAG's request for CMS to amend its Medicare regulations to make all IHS- and tribally operated outpatient facilities/clinics eligible for payment at the Medicare outpatient per visit rate/AIR, regardless of whether they were owned, operated, or leased by IHS. In response to the solicitation, we did not receive specific information on costs or specific types of clinics; however, in the CY 2022 PFS final rule (86 FR 65211 through 65214), we stated we would like to continue these discussions to evaluate the impact of the commenters' proposed changes to the current Medicare payment policies and will consider these recommendations for future rulemaking. Thus, to continue these discussions, we requested this information again in the CY 2025 proposed rule (89 FR 59394).

Additionally, beginning in the Fall of 2023, CMS began participating in a workgroup related to the TTAG's Medicare priority to make the IHS Medicare outpatient AIR available to all IHS and tribally operated outpatient facilities that request it. Although we have received some information through the workgroup, we requested additional information consistent with our previous comment solicitation in the CY 2022 PFS proposed rule (86 FR 39238).

We requested information on the kinds of and number of facilities or clinics to which the Medicare outpatient IHS AIR could apply; It was unclear whether TTAG anticipated that these facilities enroll in Medicare as FQHCs going forward, or whether they are referring to FQHCs that are currently paid under the FQHC Prospective Payment System (PPS). Moreover, we requested information on whether the facilities in question were freestanding or provider-based. We asked commenters to confirm or clarify whether the clinics are physician offices, or whether they are recommending establishment of a new provider type. We solicited information regarding the relative operating costs of tribally operated outpatient clinics, as well as feedback and supporting evidence to address whether or why payment set at the IHS AIR would be more appropriate than payment rates under the FQHC PPS, the physician fee schedule, or other some other Medicare payment system. Further, we solicited comment on how the Medicare outpatient AIR, which is based upon a limited number of hospital cost reports, related to costs in tribal clinics and the kinds of services that the clinics furnish. Finally, we solicited comment on the concerns that the AI/AN community may have regarding access to or inequity of care in situations where a payment differential exists (86 FR 39240).

We noted in the CY 2025 RFI that we have information on historically excepted FQHCs, the outpatient provider-based clinics to the hospital, and some general information about the composition of IHS and tribal facilities and clinics. However, we stated there are still gaps in the data and therefore we requested responses to the following questions: If the clinic or facilities in question are not enrolled in Medicare as an FQHC or provider-based to a hospital, are they physician practices? How are these facilities organized and related? (89 FR 59394.)

Because paying the Medicare outpatient AIR to additional IHS and tribally operated facilities that are currently paid under another Medicare payment methodology or not yet enrolled in Medicare as all would potentially increase expenditures, we also solicited information on how tribally operated facilities participate in Medicare currently, which would assist us with estimating the impacts of such a policy change.

We received a few comments in response to the information we requested. Below, we provide a summary of the comments we received and our responses.

Comment: Commenters support CMS' continuing efforts to better understand the request to make all IHS and tribally operated outpatient facilities eligible for Medicare payment at the IHS Medicare outpatient per visit rate/AIR as it would provide financial stability and improve

[168] Health Insurance Marketplace® is a registered service mark of the U.S. Department of Health & Human Services.

[169] *https://www.nihb.org/tribalhealthreform/wp-content/uploads/2020/06/TTAG-letter-to-CMS-requesting-IHS-rate-for-all-tribal-clinics-06.10.2020.pdf.*

comprehensive care delivery for tribal communities. Some of the commenters believe the current Medicare payment rates for outpatient Indian health providers are inequitable, increasingly illogical and contrary to National Indian policies, as the requested change would increase Medicare expenditures only a negligible amount. One commenter believes the most efficient, expeditious, reliable and appropriate way for CMS to gather the requested information is through the TTAG, not a Request for Information (RFI), but they provided information on the known or likely enrollment status of potentially affected programs, discussed why many small Indian Health Programs currently bill Medicare (if at all) under the Physician Fee Schedule (PFS), explained why neither the PFS nor the FQHC PPS rates come close to covering their costs, discussed why the AIR is the most appropriate payment option for all Outpatient Indian Programs, and provided some illustrative examples. Another commenter would like CMS to consider using the IHS Medicare outpatient per visit rate/AIR to pay for hospital outpatient services furnished by Urban Indian Organizations (UIOs) to Medicare beneficiaries.

Response: CMS acknowledges comments received on this important issue, and, commits to continuing close collaboration with TTAG to evaluate IHS and Tribally Operated Clinics without IHS Medicare outpatient AIR payments to identify opportunities for improving financial stability and equitable healthcare delivery in these communities, including determining whether these clinics would receive a net benefit from being paid the IHS Medicare Outpatient AIR.

D. Coverage Changes for Colorectal Cancer (CRC) Screening Services

Medicare coverage for colorectal cancer (CRC) screening tests under Part B is described in statutes (sections 1861(s)(2)(R), 1861(pp), 1862(a)(1)(H) and 1834(d) of the Social Security Act (the Act)), regulation (42 CFR 410.37), and a National Coverage Determination (NCD) (Section 210.3 of the Medicare National Coverage Determinations Manual). Section 1861(pp)(1)(D) of the Act includes in its definition of colorectal cancer screening test ''[s]uch other tests or procedures, and modifications to the tests and procedures described under this subsection, with such frequency and payment limits, as the Secretary determines appropriate, in consultation with appropriate organizations.''

The regulations at 42 CFR 410.37 list and define the tests and procedures covered by Medicare as colorectal cancer screening tests. Specifically, the following tests and procedures furnished to an individual for the purpose of early detection of colorectal cancer are covered by Medicare:

- Screening fecal-occult blood tests.
- Screening flexible sigmoidoscopies.
- Screening colonoscopies, including anesthesia furnished in conjunction with the service.
- Screening barium enemas.
- Other tests or procedures established by a national coverage determination, and modifications to tests under this paragraph, with such frequency and payment limits as CMS determines appropriate, in consultation with appropriate organizations.

In recent years we have received recommendations from the public to remove Medicare coverage for the barium enema test since the test no longer meets modern clinical standards and is no longer recommended in clinical guidelines. As a replacement to the barium enema test, organizations have suggested the use of CT colonography, which is a more effective test for colorectal cancer screening. For a more extensive discussion on the background and proposal to revise the Medicare coverage for colorectal cancer screening services, we refer readers to the CY 2025 Physician Fee Schedule (PFS) proposed rule.

For CY 2025, based on public input and consultation with specialty societies, and as discussed in the CY 2025 PFS proposed rule, we proposed to exercise our authority under section 1861(pp)(1)(D) of the Act to update and expand coverage for CRC screening. As discussed in the CY 2025 PFS proposed rule, we proposed to make the following revisions to § 410.37:

- Remove coverage for the barium enema procedure.
- Add coverage for the computed tomography colonography (CTC) procedure.
- Expand the existing definition of a ''complete colorectal cancer screening'' to include a follow-on screening colonoscopy after a Medicare covered blood-based biomarker CRC screening test (described and authorized in NCD 210.3).

The above screening tests are currently described by existing HCPCS codes. These HCPCS codes are listed in Table 139 along with their long descriptors.

TABLE 139: SCREENING HCPCS CODES FOR BARIUM ENEMA, COMPUTED TOMOGRAPHY COLONOGRAPHY, AND BLOOD-BASED BIOMARKER TESTS

Colorectal Cancer (CRC) Screening Test	HCPCS Code	Long Descriptor
Barium enema	G0106	Colorectal cancer screening; alternative to g0104, screening sigmoidoscopy, barium enema
Barium enema	G0120	Colorectal cancer screening; alternative to g0105, screening colonoscopy, barium enema
Computed tomography colonography (CTC)/Virtual colonoscopy	74263	Computed tomographic (ct) colonography, screening, including image postprocessing
Blood-based biomarker	G0327	Colorectal cancer screening; blood-based biomarker

Based on the proposed coverage changes for CRC screening, we proposed to make the following changes under the OPPS for CY 2025:

- HCPCS codes G0106 and G0120 (screening barium enema): These codes were established by CMS effective January 1, 1998, to implement Medicare coverage for barium enema as a test for colorectal cancer screening. Since we proposed to remove Medicare coverage for barium enema colorectal cancer screening effective January 1, 2025, and we no longer need to keep these codes active, we proposed to delete them on December 31, 2024. Therefore, we proposed to revise the status indicator for the HCPCS codes from status indicator ''S'' (Procedure or Service, Not Discounted When Multiple. Paid under OPPS; separate APC payment.) to ''D'' (Discontinued code) to indicate that HCPCS codes G0106 and G0120 will be deleted on December 31, 2024. In addition to the deletion of these codes, we also proposed to delete HCPCS code G0122 (Colorectal cancer screening; barium enema), which is already non-covered by Medicare, on December 31, 2024.
- CPT code 74263 (screening computed tomography colonography (CTC)/virtual colonoscopy): We proposed to reassign this code from status indicator ''E1'' (not covered/not payable) to status indicator ''S'' and APC 5522 (Level 2 Imaging Without Contrast) to indicate that the code is separately payable. Based on our review, we noted that we believed the time and resources associated with performing a screening virtual colonoscopy was similar to a diagnostic virtual colonoscopy, which is described by CPT code 74261 (Computed tomographic (ct) colonography, diagnostic, including image postprocessing; without contrast material). Consequently, the proposed APC assignment for CPT code 74263 was based on its clinical and resource homogeneity to CPT code 74261, which was assigned to APC 5522.
- HCPCS code G0327 (screening blood-based biomarker): This HCPCS code is currently assigned to status indicator ''A'' to indicate that the test is paid separately under a different Medicare payment system than the OPPS. Since HCPCS G0327 is currently separately payable under the Clinical Laboratory Fee Schedule (CLFS), we did not propose to revise the status indicator. Specifically, with the expanded coverage to include blood-based biomarker as a screening test to detect colorectal cancer, we proposed to continue to assign HCPCS code G0327 to status indicator ''A'' for CY 2025.

In summary, based on the proposed coverage changes for colorectal cancer screening services, we proposed to revise the OPPS status indicator for certain HCPCS codes for CY 2025. Table 140 shows the long descriptors, current CY 2024 OPPS status indicators, and proposed CY 2025 OPPS status indicators for HCPCS codes G0106, G0120, G0122, 74263, and G0327. The proposed CY 2025 OPPS payment rates, where applicable, for these HCPCS codes can be found in Addendum B to the proposed rule. In addition, for the complete list of the proposed status indicators and their definitions, refer to Addendum D1 of the CY 2025 OPPS/ASC proposed rule.

TABLE 140: PROPOSED CY 2025 OPPS STATUS INDICATOR AND APC ASSIGNMENT FOR HCPCS CODES G0106, G0120, G0122, 74263, AND G0327

HCPCS Code	Long Descriptor	CY 2024 OPPS SI	CY 2024 OPPS APC	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
G0106	Colorectal cancer screening; alternative to g0104, screening sigmoidoscopy, barium enema	S	5571	D	
G0120	Colorectal cancer screening; alternative to g0105, screening colonoscopy, barium enema	S	5572	D	
G0122	Colorectal cancer screening; barium enema (Non-covered)	E1		D	
74263	Computed tomographic (ct) colonography, screening, including image postprocessing	E1		S	5522
G0327	Colorectal cancer screening; blood-based biomarker	A		A	

Comment: Overall, commenters supported our proposals of the following Colorectal Cancer (CRC) Screening Services changes:

- Deleting HCPCS codes G0106 and G0120 (screening barium enema) effective December 31, 2024, and deleting HCPCS code G0122 (Colorectal cancer screening; barium enema), which is already non-covered by Medicare, on December 31, 2024.
- Reassigning the status indicator of CPT code 74263 (screening computed tomography colonography (CTC)/virtual colonoscopy) from status indicator ''E1'' (not covered/not payable) to status indicator ''S'' to indicate that the code is separately payable and assigning CPT code 74263 to APC 5522 (Level 2 Imaging Without Contrast).
- Maintaining the status indicator of HCPCS code G0327 (screening blood-based biomarker) as status indicator ''A'' to indicate that the test is paid separately under a different Medicare payment system than the OPPS.

Response: We thank commenters for supporting our proposals related to § 410.37 and NCD 210.3 on Colorectal Cancer (CRC) Screening Services.

Comment: A commenter requested that CMS exercise our authority in section 1861(pp)(1)(D) of the Act to expand our approach to a ''complete CRC screening'' to add CTC along with the Medicare covered blood-based biomarker CRC screening test and the Medicare covered non-invasive stool-based CRC screening test within the definition of a ''complete colorectal cancer screening.''

Response: We disagree with commenters that requested a further expansion of a complete colorectal cancer screening to include CTC. CTC is a visualization procedure along with colonoscopy and flexible sigmoidoscopy whereas stool-based and blood-based CRC screening tests are non-visualization tests. CTC provides visualization of the contours of the whole colon and demonstrates mucosal surface abnormalities consistent with polyps and tumors. CTC tests are unlike noninvasive modalities such as stool-based and blood-based CRC screening, which present a binary positive/negative result with variable specificity and may result (in the case of a positive test) in the need for a visualization study to confirm the derived suspicion of adenoma or cancer. The follow-on colonoscopy in cases of stool-based or blood-based CRC screenings represents an extension of screening in a patient who has converted from average risk to increased risk as a result of the positive test. In the case of CTC, however, visualization of the colonic mucosal contour, as well as the remainder of the colonic wall and surrounding structures, has already been achieved and the determination of a suspicious finding has already been made. Polyps over the size threshold prompt a referral for diagnostic/therapeutic colonoscopy for the purpose of polypectomy. A follow-up colonoscopy after an abnormal finding from a CTC would be considered a diagnostic colonoscopy to biopsy or remove visualized polyps and/or cancer.

After consideration of the public comments we received, we are finalizing the proposals made in the CY 2025 OPPS/ASC proposed rule affecting Colorectal Cancer (CRC) Screening Services with one modification. Specifically, we are finalizing the deletion of HCPCS codes G0106 and G0120 (screening barium enema) effective December 31, 2024. We are finalizing the reassignment of CPT code 74263's status indicator as proposed from status indicator ''E1'' (not covered/not payable) to ''S'' to indicate that the code is separately payable. However, we are reassigning CPT code 74263 to APC 5523 (Level 3 Imaging Without Contrast) in this final rule. We refer readers to section III.E of this final rule with comment period for a detailed discussion of CPT code 74263's APC assignment. We are maintaining the status indicator of HCPCS code G0327 (screening blood-based biomarker) as status indicator ''A'' to indicate that the test is paid separately under a different Medicare payment system than the OPPS.

Table 141 shows the long descriptors proposed and final CY 2025 OPPS status indicators for HCPCS codes G0106, G0120, G0122, 74263, and G0327. The finalize CY 2025 OPPS payment rates, where applicable, for these HCPCS codes can be found in Addendum B to

this final rule. In addition, for the complete list of the final status indicators and their definitions, refer to Addendum D1 of this final rule with comment period.

TABLE 141: PROPOSED AND FINAL CY 2025 OPPS STATUS INDICATOR AND APC ASSIGNMENT FOR HCPCS CODES G0106, G0120, G0122, 74263, AND G0327

HCPCS Code	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC	Final CY 2025 OPPS SI	Final CY 2025 OPPS APC
G0106	Colorectal cancer screening; alternative to g0104, screening sigmoidoscopy, barium enema	D		D	
G0120	Colorectal cancer screening; alternative to g0105, screening colonoscopy, barium enema	D		D	
G0122	Colorectal cancer screening; barium enema (Non-covered)	D		D	
74263	Computed tomographic (ct) colonography, screening, including image postprocessing	S	5522	S	5523
G0327	Colorectal cancer screening; blood-based biomarker	A		A	

E. Request for Comment on Payment Adjustments Under the IPPS and OPPS for Domestic Personal Protective Equipment

1. General Background

As discussed in the FY 2023 IPPS/LTCH PPS and CY 2023 OPPS/ASC rules, President Biden issued Executive Order (E.O.) 13987, ''Organizing and Mobilizing the United States Government To Provide a Unified and Effective Response To Combat COVID–19 and To Provide United States Leadership on Global Health and Security,'' on January 20, 2021 (86 FR 7019). This order launched a whole-of-government effort to combat the coronavirus disease 2019 (COVID–19) and prepare for future biological and pandemic threats. As the COVID–19 pandemic eased, work has continued to prepare for future pandemics. As the COVID–19 pandemic demonstrated, sufficient availability of personal protective equipment (PPE) in the health care sector is a critical component of preparedness.

The CY 2023 OPPS/ASC final rule with comment period implemented payment adjustments under the OPPS and IPPS to support a resilient and reliable supply of surgical N95 respirators—a specific type of filtering facepiece respirator that is a subset of N95 masks used in some clinical settings under conditions requiring respiratory protection from airborne pathogens and splash protection from exposure to fluids. Early on in the COVID–19 pandemic, ''just-in-time'' supply chains, minimal stockpiling, and overreliance on foreign imports left U.S. hospitals unable to obtain enough N95 respirators to protect health care workers. Prices for surgical N95s soared from an estimated $0.25–$0.40/unit to $5.75/unit (and up to $12.00/unit in some reported cases). Unable to obtain surgical N95s regulated by NIOSH, hospitals had to turn to KN95s—a Chinese standard respirator—and other non-NIOSH-approved respirators under Emergency Use Authorization (EUA). Skyrocketing demand during the COVID–19 pandemic also raised counterfeit respirator concerns.

Currently available payment adjustments offset the marginal costs that hospitals face in procuring domestically made NIOSH-approved and FDA-certified surgical N95 respirators. These marginal costs are due to higher per-unit acquisition prices that stem from higher costs of inputs and labor in the U.S., as compared to international suppliers, where many N95 and other respirators are made, as well as a demonstrated record of more consistent high quality for domestically made products.[170] These payment adjustments offset the additional marginal costs of hospitals that purchase domestically made NIOSH-approved surgical N95 respirators to help sustain demand for—and thus domestic production of—high-quality domestically made respirators in order to ensure quality PPE is available to health care personnel when needed.

The policy goal to maintain a baseline domestic production capacity of high-quality PPE in order to ensure that quality PPE is readily available to health care personnel when needed is emphasized in the National Strategy for a Resilient Public Health Supply Chain, published in July 2021 as directed by President Biden's Executive Order 14001 on ''A Sustainable Public Health Supply Chain.'' The U.S. Government has committed to purchase wholly domestically-made PPE in line with section 70953 of the Infrastructure Investment and Jobs Act (Pub. L. 117–58).

[170] *https://www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSHresults.html.*

2. Potential Modifications to Payment Adjustments for Domestic NIOSH-Approved Surgical N95 Respirators

Although the payment adjustments for domestic NIOSH-approved surgical N95 respirators under the OPPS and IPPS have applied to cost reporting periods beginning on or after January 1, 2023, use of the payment adjustments has been limited. Furthermore, market data suggests that a majority of surgical N95 respirators purchased by hospitals are not wholly domestically made. In the CY 2023 OPPS/ASC final rule with comment period, we stated that as we gain more experience with this policy and the data collected, we may also consider modifications to the reasonable cost-based payment approach we were finalizing. HHS has conducted stakeholder outreach to better understand barriers to awareness and uptake and seek feedback on potential modifications that could increase effectiveness, and continues to engage hospitals and other manufacturers on these payment adjustments. Furthermore, as discussed in more detail below, in the CY 2025 OPPS/ASC proposed rule (89 FR 59396 through 59399), we solicited feedback and comments on potential modifications to the payment adjustment in order to reduce reporting burden and achieve the policy goal to maintain a baseline domestic production capacity of PPE in order to ensure that quality PPE is readily available to health care personnel when needed.

Payment adjustment methodology: In the CY 2023 OPPS/ASC final rule with comment period, we finalized to initially base the payment adjustments on the IPPS and OPPS shares of the estimated difference in the reasonable costs. We created a new supplemental cost reporting form to enable calculation of a hospital-specific unit cost differential between domestic and non-domestic NIOSH-approved surgical N95 respirators. We noted that, based on available data, our best estimate of the difference in the average unit cost of domestic and non-domestic NIOSH-approved surgical N95 respirators was $0.20. In the CY 2023 OPPS/ASC final rule with comment period, we also noted that MedPAC, while not supportive of the proposed payment adjustments, stated that CMS should set the unit cost differential between domestic and non-domestic NIOSH-approved surgical N95 respirators at a national level (rather than on a hospital-by-hospital basis). MedPAC believed this would reduce the administrative burden on hospitals, encourage hospitals to purchase the most economical domestically made product, and reduce the ability of hospitals to increase their payments by artificially inflating reported N95 costs. In the CY 2025 OPPS/ASC proposed rule, we solicited comment on the following questions:

- Should we consider modifying the payment adjustment methodology calculation to provide a national standard unit cost differential between domestic and non-domestic NIOSH-approved surgical N95 respirators (rather than on a hospital-by-hospital basis)?
- If so, how should we calculate that standard unit cost differential between domestic and non-domestic NIOSH-approved surgical N95 respirators, and what should the current unit cost differential be?
- If we modified the payment adjustment methodology calculation to provide a national standard unit cost differential, would it be appropriate to calculate the payment adjustment by multiplying the unit cost differential by the total quantity of domestic NIOSH-approved surgical N95 respirators used by the hospital, and then multiplying by the Medicare Part A hospital inpatient cost share (to calculate the IPPS payment adjustment) or the Medicare Part B hospital outpatient cost share (to calculate the OPPS payment adjustment)?
- Do hospitals need additional support to purchase domestic-made surgical N95 respirators as opposed to non-domestic surgical N95 respirators? If so, how much support is needed, and in what form?

Comment: We received several comments supporting a modification to the payment adjustment methodology calculation that would provide a national standard unit cost differential between domestic and non-domestic NIOSH-approved surgical N95 respirators. Several commenters emphasized that this modification would minimize reporting burden for hospitals and ensure payments to hospitals are equitable. One commenter stated that CMS should provide hospitals the option of calculating their payment adjustment utilizing a national standard unit cost differential or a hospital-specific unit cost differential. A commenter stated that the national differential should be set at $0.50. Other commenters encouraged CMS to collaborate with external partners and use external resources to determine the national standard unit cost differential. Commenters suggested regularly collaborating with reliable benchmarking services, distributors, and group purchasing organizations to establish and recalibrate, if necessary, an accurate national standard unit cost differential.

Several commenters provided suggestions on additional support for hospitals to purchase domestic-made surgical N95 respirators as opposed to non-domestic surgical N95 respirators. Several commenters requested that CMS work with Congress to give CMS authority to apply this payment policy in a non-budget neutral manner under the OPPS. Other commenters requested that CMS work with Congress to give CMS authority to offset all the marginal costs incurred by the hospital in procuring domestically made surgical N95 respirators rather than just the Medicare-share of these costs. One commenter stated that CMS should pay the full cost of procuring domestically made surgical N95 respirators rather than the marginal costs of procuring domestically made surgical N95 respirators over non-domestically made surgical N95 respirators. A couple of commenters stated that CMS should reimburse hospitals 5 times the differential between the acquisition cost of domestic surgical N95 respirators and non-domestic surgical N95 respirators. One commenter stated that CMS should create a HCPCS code for surgical N95 respirators and develop a formula that reimburses hospitals that purchase domestic surgical N95s directly from manufacturers at a locked price. A few commenters encouraged CMS to increase education and communication of the payment adjustment to hospital purchasing decision-makers within the healthcare system.

Some comments addressed the issue of why use of the payment adjustments has been limited. A few commenters supportive of the payment adjustment stated that they believe providers may not be taking advantage of the adjustment because they still have stockpiles of surgical N95 respirators available to them that were purchased during the COVID–19 pandemic. A commenter stated its belief that use of the payment adjustments has been limited because the current supply and production capacity of wholly domestically made surgical N95 respirators is insufficient. One commenter stated that the payment adjustment does not result in a significant decrease in cost for providers. One commenter expressed that hospitals primarily buy surgical N95 respirators through distributors and that these distributors are not incentivized to purchase and make available to hospitals more expensive domestically produced surgical N95 respirators.

One commenter indicated that hospitals would be more inclined to purchase domestically made surgical N95 respirators if more information was made available regarding the production capabilities of domestic suppliers. The commenter stated it is crucial for any health care facility considering incorporating new types of surgical N95 respirators into their operations to understand certain factors such as whether the manufacturer has the capability to scale up production to meet spikes in demand and what the manufacturer's lead time is for supplying new customers with surgical N95 respirators. The commenter stated that due to the fit-testing requirements, it is crucial for health care facilities to understand lead times of N95 manufacturers to ensure that respiratory protection is available when it is needed.

As reflected in the following discussion of the comments on payment adjustment eligibility, some commenters also believe that challenges in identifying surgical N95 respirators that are wholly domestically manufactured and documenting that fact for any purchased surgical N95 respirators have disincentivized hospitals from utilizing the payment adjustment. As reflected in the following discussion of the types of N95 respirators, a few commenters indicated that because non-surgical N95 respirators represent most of the N95 respirators purchased by hospitals, the fact that non-surgical N95 respirators are not eligible for the payment adjustment contributes to the lack of uptake for surgical N95 respirators.

Payment adjustment eligibility: In the CY 2023 OPPS/ASC final rule with comment period, we stated that we recognize that a hospital cannot fully independently determine if a NIOSH-approved surgical N95 respirator it purchases is domestic under our definition. Therefore, we finalized that a hospital may rely on a written statement from the manufacturer stating that the NIOSH-approved surgical N95 respirator the hospital purchased is domestic under our definition. In the CY 2025 OPPS/ASC proposed rule, we solicited comment on the following questions:

- Do hospitals have sufficient access to information on which surgical N95 models on the market are wholly domestically made?
- Have hospitals been able to obtain written statements from manufacturers stating that the NIOSH-approved surgical N95 respirator the hospital purchased is domestic under our definition?
- Would a publicly available list of products eligible for the payment adjustment (for example, if provided by CMS, NIOSH, or another government entity) make it easier for hospitals to locate products eligible for the payment adjustment?
- If we modified the payment adjustment such that hospitals that attested to purchasing wholly domestically made surgical N95 models from such a list did not need to obtain a written statement from the manufacturer, would hospitals more easily be able to utilize the payment adjustment?

Comment: In general, commenters were supportive of making publicly available a list of products eligible for the payment adjustment. Some commenters indicated that hospitals have had difficulty ascertaining which products meet the definition of domestic under this policy. Some commenters stated that hospitals have had difficulty obtaining written statements from manufacturers attesting to their products meeting the policy's definition of domestic.

Commenters stated that a publicly available list would simplify the procurement process and make it easier for hospitals to identify, locate, and purchase products eligible for the payment adjustment. Commenters also indicated that if such a list was made available, CMS should modify the payment adjustment such that hospitals that attest to purchasing wholly domestically made surgical N95 models from such a list do not need to obtain a written statement from the manufacturer. A commenter stated that removing the attestation requirement would streamline the process of purchasing eligible products and could encourage uptake of the payment adjustment. A commenter encouraged CMS to establish an ongoing process that would enable manufacturers or hospitals to submit products for certification and addition to the list. Some commenters stated that, if a list of eligible products were established, products not on the list should still be eligible for the payment adjustment if the product could be verified as domestic by some other means, such as through a written statement from the manufacturer.

One commenter stated that requiring hospitals to acquire this written attestation from manufacturers is not burdensome and believes that CMS should retain this requirement to ensure hospital accountability. One commenter stated that CMS should explore labeling requirements for manufacturers to facilitate the identification of domestic and non-domestic products. Another commenter stated that to alleviate hospital burden, CMS should work with hospital and supply chain communities to automate the reporting to CMS of domestic products purchased by hospitals.

Types of N95 respirators: In the CY 2023 OPPS/ASC proposed rule, for purposes of the payment adjustment policy, we proposed to categorize all NIOSH-approved surgical N95 respirators purchased by hospitals into two categories: (1) Domestic NIOSH-approved surgical N95 respirators; and (2) Non-domestic NIOSH-approved surgical N95 respirators. Feedback from external stakeholders has suggested that it is a challenge that the payment adjustments are limited to surgical N95 respirators, given some hospitals also procure non-surgical N95 respirators. Both surgical N95 respirators and non-surgical N95 respirators are primarily used to protect the wearer from inhaling airborne particles, including infectious agents like bacteria and viruses. They are highly efficient at filtering out at least 95% of airborne particles and are commonly used by healthcare workers during procedures that may generate aerosols, such as intubation or suctioning, or when caring for patients with infectious respiratory diseases like tuberculosis or coronavirus. Both types of N95 respirators serve as frontline defense for medical professionals. They are crucial for preventing the transmission of diseases within healthcare settings and safeguarding the health and well-being of both healthcare workers and patients. Surgical N95 respirators have the added protection against fluid penetration, and may be most useful in specialized healthcare settings (*e.g.,* ICU, Emergency Department, Operating Room) where the risk of fluid exposure may be greater. Additionally, during the COVID–19 pandemic, both types of N95 respirators saw issues around lack of availability and risk of counterfeit outlined in the CY 2023 OPPS/ASC final rule with comment period—issues which could compromise the safety of healthcare personnel and patients. In the CY 2025 OPPS/ASC proposed rule, we solicited comment on the following questions:

- Do hospitals procure both surgical N95 respirators and non-surgical N95 respirators?
- Has the payment adjustment's current focus on surgical N95 respirators inhibited uptake of the payment adjustments?
- Are the quality differentials between domestic and non-domestic surgical respirators also applicable to non-surgical respirators, and is a

sustained and reliable source of domestically made non-surgical N95 respirators important for strengthening hospitals' ability to protect the health and safety of personnel and patients in a public health emergency?

- Should CMS consider expanding the payment adjustments to include all domestic NIOSH-approved N95 respirators—*i.e.,* non-surgical and surgical N95 respirators?
- If we expanded the payment adjustments to include all domestic NIOSH-approved N95 respirators, and if we modified the payment adjustment methodology calculation to provide a national standard unit cost differential between domestic and non-domestic NIOSH-approved surgical N95 respirators (rather than on a hospital-by-hospital basis), would the unit cost differential for non-surgical N95 respirators be different than the one for surgical N95 respirators?

Comment: Commenters were supportive of expanding the payment adjustment to include non-surgical N95 respirators. Commenters stated that expanding the payment adjustment to include non-surgical N95 respirators would ensure a more comprehensive and resilient domestic supply chain. A few commenters indicated that non-surgical N95 respirators represent most of the N95 respirators purchased by healthcare providers and that including them in the payment adjustment would lead to greater utilization of the payment adjustment by hospitals. A commenter stated that it would be less burdensome and more cost-effective for hospitals to procure and receive the payment adjustment for all domestic NIOSH-approved N95 respirators. A commenter stated the payment adjustment methodology could utilize the same national standard unit cost differential for surgical and non-surgical N95 respirators.

3. Potential Modifications To Include Nitrile Gloves

In addition to N95 respirators, nitrile gloves are another type of PPE for which it is particularly crucial to maintain a resilient, quality supply. Nitrile gloves protect healthcare workers and patients from the spread of micro-organisms that may potentially cause infection or illness during medical procedures and examination. They create a barrier between germs and the wearer's hands, and are generally worn anytime a healthcare worker touches blood, bodily fluids, bodily tissues, mucous membranes, or broken skin. They are disposable, enabling the use of new gloves for each patient. A resilient healthcare system needs readily available, high-quality nitrile gloves to respond efficiently and effectively to public health emergencies. During the COVID–19 pandemic, supply chain breakdowns limited the supply of quality nitrile gloves, putting U.S. healthcare workers and patients at risk. As with N95 respirators, non-domestic-sourced gloves during the COVID–19 pandemic saw counterfeit and quality challenges. The receipt of non-U.S.-made counterfeit or already-used gloves put the safety of healthcare workers and patients at risk.[171] [172] Prior to 2020, over 95 percent of nitrile gloves sold in the U.S. came from other countries. As the pandemic escalated in 2020, U.S. demand for gloves outstripped available supply, leading to shortages. Around the same time, supply was also limited by coronavirus-related lockdowns in other countries that decreased production capacity, and by export restrictions of PPE. Further adding to supply pressures, forced labor violations by subsidiaries of a major glove producer led U.S. Customs and Border Protection (CBP) to issue a Withhold and Release Order, resulting in seizure of all listed products, including nitrile gloves, at CBP inspections. During the initial months of the pandemic, the cost of gloves increased, rising 18 percent from July to August 2020 (to $0.03 per glove) and then an additional 20 percent from November to December 2020 (to $0.05 per glove).[173]

During the pandemic, the U.S. government has invested in domestic glove manufacturing capabilities. U.S. glove-manufacturing projects received approximately $290 million in public funding as part of a broader $1.5-billion investment to support domestic glove manufacturing. These investments have resulted in an increase of 3.91 billion in annual production capacity for domestically manufactured nitrile gloves. The U.S. government also invested in manufacturing capacity for nitrile glove inputs such as nitrile butadiene rubber, and this manufacturing capacity is expected to become available in 2026.

However, since the pandemic began, some U.S. factories have been forced to consolidate operations or exit the industry. Further, non-U.S. nitrile glove producers have deployed cost-cutting tactics such as using lower-grade raw materials, prompting some purchasers to seek other sources out of concern for quality.[174] Producers of these lower quality products began selling gloves for the price of $0.02 each, rapidly increasing U.S. market share, going from 13% of U.S. market share in July 2020 to 19 percent in February 2021. As of 2024, only three producers of nitrile gloves are left in the United States, and they supply an estimated .05% percent of U.S. demand for nitrile gloves.

As with N95 respirators, a resilient public health industrial base requires baseline manufacturing capacity for nitrile gloves as critical PPE items, to ensure that hospitals and other institutions will be able to procure high quality gloves reliably. To help achieve this goal, certain U.S. Government departments have committed to purchase wholly domestically made nitrile gloves in line with the requirements in section 70953 of the Infrastructure Investment and Jobs Act. However, Federal demand alone cannot sustain a baseline level of nitrile glove production in the U.S. Private medical and health care users are the primary purchasers and users of medical-grade PPE, including nitrile gloves.

To ensure access to high quality products, as with N95 respirators, it is critically important to ensure that a sufficient share of nitrile gloves is wholly made in the U.S.—that is, including raw materials and components. In the CY 2023 OPPS/ASC rule, we stated our belief that the most appropriate framework for determining if a NIOSH-approved surgical N95 respirator is wholly made in the U.S. and therefore, considered domestic for purposes of the proposed adjustments, is the Berry Amendment. The Berry Amendment is a statutory requirement familiar to manufacturers that restricts the Department of Defense (DoD) from using funds appropriated or otherwise available to DoD for procurement of food, clothing, fabrics, fibers, yarns, other made-up textiles, and hand or measuring tools that are not grown, reprocessed, reused, or produced in the United States. For nitrile gloves, which are not covered by the Berry Amendment, we believe the Make PPE in America domestic content requirements outlined in section 70953 of the Infrastructure Investment and Jobs Act is the most appropriate framework for determining if a nitrile glove is wholly made in the U.S. These statutory requirements, which apply to procurement of nitrile gloves and other PPE by the U.S. Departments of Health and Human Services, and Veterans Affairs, and Homeland Security, require

[171] *https://www.cnn.com/2021/10/24/health/medical-gloves-us-thailand-investigation-cmd-intl/index.html.*

[172] *https://www.propublica.org/article/ppe-covid-scams-fraud-nitrile-gloves.*

[173] Glove Story Global Glove Production Amidst the COVID–19 Pandemic (*usitc.gov*).

[174] Glove Story Global Glove Production Amidst the COVID–19 Pandemic (*usitc.gov*).

the procurement PPE, including the materials and components thereof, that is grown, reprocessed, reused, or produced in the U.S. These statutory requirements have become familiar to manufacturers of nitrile gloves and other PPE. With respect to domestic manufacturing capabilities for raw materials and components, we understand that nitrile butadiene rubber (NBR), a key nitrile glove input, is currently not yet available domestically in sufficient quantity or quality to meet market needs. We understand that U.S. manufacturers do anticipate having the capability to source and manufacture all glove components domestically within the next two years.

Wholly domestically made, high quality nitrile gloves are generally more expensive than foreign-made ones, especially those of lower quality. This fact is also true for domestically made nitrile gloves that include non-domestically sourced NBR. These higher prices primarily stem from higher costs of manufacturing labor in the U.S. compared to costs in other countries, where most nitrile gloves and their inputs are made, and higher quality standards. These higher prices mean higher marginal costs for hospitals for procuring wholly domestically made nitrile gloves. Based on available data, our best estimate of the difference in the average unit cost of domestic and non-domestic nitrile gloves, is $0.13 per glove.

As outlined in this section, quality nitrile gloves are a crucial component of PPE needed to ensure the safety of health care workers and patients. The COVID–19 pandemic highlighted how overreliance on foreign imports of gloves jeopardized public health and the health and safety of healthcare workers and patients. In the CY 2025 OPPS/ASC proposed rule, we solicited comment on the following questions:

- Would modifying the payment adjustment to include nitrile gloves help offset the marginal costs that hospitals face in procuring high quality domestically made nitrile gloves?
- Would modifying the payment adjustment to include nitrile gloves help to sustain a baseline level of domestic manufacturing of nitrile gloves to ensure that hospitals and other stakeholders have ongoing, reliable access to an adequate supply of quality product?
- Would having access to a sustained and reliable source of domestically made nitrile gloves strengthen hospitals' ability to protect the health and safety of personnel and patients in a public health emergency?
- Are there other reasons why hospitals would benefit from an extension of the payment adjustment to include nitrile gloves not covered in the preceding questions?
- Do stakeholders believe a significant portion of hospitals would use domestic nitrile gloves if the payment adjustment were offered?
- If the payment adjustment was modified to include nitrile gloves, how should CMS define wholly domestically made nitrile gloves? Would it be appropriate to categorize all nitrile gloves purchased by hospitals into two categories: (1) domestic nitrile gloves that—with the exception of nitrile butadiene rubber (NBR)—comply with the Infrastructure Investment and Jobs Act's Make PPE in America Act domestic content requirements; and (2) non-domestic nitrile gloves?
- If the payment adjustment was modified to include nitrile gloves, and the categories were defined as described previously, would it be appropriate to eliminate the domestic content exception for NBR if domestic NBR production reaches a sufficient level to meet market needs?
- If the payment adjustment was modified to include nitrile gloves, should a national standard unit cost differential between domestic and non-domestic nitrile gloves be used to calculate the payment adjustment, and if so, what should the current unit cost differential be (or, what should the data source be)?

Comment: In general, commenters were supportive of modifying the payment adjustment to include nitrile gloves. Commenters explained why they believe it is important for the United States to maintain a baseline level of domestic manufacturing of nitrile gloves. For example, commenters cited quality concerns that have arisen with non-domestic nitrile gloves purchased by hospitals, especially during times of emergencies. A commenter stated that a domestic supply chain of nitrile gloves would significantly improve lead times compared to a foreign supply chain. One commenter stated that hospitals and purchasing entities desire to purchase domestically manufactured nitrile gloves to maintain stable supplies during global supply chain disruptions and to better ensure the health and safety of patients and workers.

Commenters indicated that certain domestic nitrile glove manufacturers have ceased operations. A commenter stated that the driving factor in these closures was a lack of market for domestic nitrile gloves due to their higher prices. This commenter, and other commenters, indicated that reducing or eliminating the price difference between domestic and non-domestic nitrile gloves would increase utilization of domestic nitrile gloves.

A few commenters that supported including nitrile gloves in the payment adjustment stated that it would be appropriate to apply the Make PPE in America Act requirements when defining domestic nitrile gloves for purposes of this policy. These commenters also agreed that there should be a temporary exception for NBR that could be eliminated when domestic supply of NBR is sufficient to support domestic demand. One commenter expressed concerns that neither the Berry Amendment nor the Make PPE in America Act requirements are commonly used by hospitals and health systems and therefore urged CMS to consider utilizing another standard.

A few commenters that supported including nitrile gloves in the payment adjustment also supported using a national standard unit cost differential between domestic and non-domestic nitrile gloves to calculate the payment adjustment. One commenter stated that the $0.13 per glove difference in the average unit cost of domestic and non-domestic nitrile gloves estimated by CMS is accurate and appropriate to use as the national standard unit cost differential. This commenter urged CMS to monitor the nitrile glove market and regularly update this differential to ensure hospitals are adequately reimbursed for their purchases of domestic nitrile gloves. Another commenter stated that the $0.13 per glove estimate was significantly higher than what they believe is the actual price differential between domestic and non-domestic nitrile gloves. This commenter stated that 100 percent domestically produced nitrile medical gloves sell for less than $0.13 per glove and that the actual price differential would likely be between $0.01 to $0.03 per glove. This commenter also requested that CMS work with industry experts to establish the national standard unit cost differential.

One commenter that supported including nitrile gloves in the payment adjustment stated that CMS should maintain a publicly available list of nitrile glove products that would qualify as domestic under such a policy. One commenter stated that access to a payment adjustment should be limited to hospitals that purchase at least 25% to 35% of their nitrile gloves from domestic manufacturers. A couple of commenters stated that the current production capability of domestic manufacturers is too small for the inclusion of nitrile gloves in the payment adjustment to have a meaningful impact. For this reason, a

commenter urged CMS to not include nitrile gloves in the payment adjustment.

4. Potential Modifications To Include Other PPE and Medical Devices

As noted in the CY 2023 OPPS/ASC final rule with comment period, we received many comments urging CMS to expand this policy to cover other forms of PPE and critical medical supplies. A few commenters stated that other forms of PPE suffered shortages during the pandemic similar to surgical N95 respirators and therefore investing in domestic production for these products was also important for future emergency preparedness. We stated that we will consider these comments for future rulemaking if appropriate as we gain more experience with our policy. We sought comment on other PPE types and medical devices that could be appropriate for a similar payment adjustment.

Comment: Several commenters urged CMS to expand the payment adjustment to include other PPE types and medical devices. Examples included gowns, hair nets, beard covers, bouffant caps, shoe covers, face shields, ASTM level II and III surgical masks, powered air purifying respirators, elastomeric respirators, syringes, needles, catheters, and wound care dressings. Commenters indicated that many of these products are currently being purchased from non-domestic manufacturers and have been prone to shortages and quality issues. For example, a commenter cited safety concerns regarding the quality of imported syringes and needles which they stated have had issues ranging from leaks to breakages that compromise patient safety. Some commenters indicated that domestic versions of the products they recommend including in the payment adjustment are more costly to produce than non-domestic versions. For example, one commenter stated that the higher cost of labor in the U.S. in addition to imbalances in costs of manufacturing certain inputs contributes to the cost differential between domestic and non-domestic syringes and needles. Commenters expressed that expanding the payment adjustment to more products would increase uptake of the payment adjustment by hospitals, strengthen the existing U.S. manufacturing base, incentivize other manufacturers to prioritize domestic production, and protect access to high-quality products.

Response: We greatly appreciate the many thoughtful and informative comments we received in response to our request for comment on payment adjustments under the IPPS and OPPS for domestic personal protective equipment, including potential modifications to include non-surgical N95 respirators, potential modifications to include nitrile gloves, potential modifications to include other PPE and medical devices, and potential modifications to the methodology used to calculate the payment adjustments. We thank the commenters for their feedback and agree with comments calling for improvements to and expansion of these payment adjustments. In 2026 rulemaking, we intend to propose a new payment methodology, such as one that no longer relies exclusively on hospital-specific data. In this rulemaking, we also intend to propose to expand the payment adjustments to domestic non-surgical N95 respirators and domestic nitrile gloves. We also intend to continue exploring expansion of the payment adjustments to include other types of domestically made PPE and other medical products. Hospitals are the primary purchasers and users of medical PPE, and PPE are essential for the protection of patients and hospital personnel. We believe payment modifications that account for the potentially higher cost of domestically produced critical PPE help to safeguard hospital personnel and beneficiary safety over the long term by sustaining domestic production and availability of these PPE. Finally, we will explore the feasibility of creating a list of qualifying surgical N95 respirators that are domestically made PPE given feedback from commenters. We again thank commenters for their feedback regarding these payment adjustments.

F. Payment for HIV Pre-Exposure Prophylaxis (PrEP) in Hospital Outpatient Departments

On July 12, 2023, we proposed a National Coverage Determination (NCD) to cover Pre-Exposure Prophylaxis (PrEP) to prevent Human Immunodeficiency Virus (HIV) under Medicare Part B. The proposed coverage would include coverage for the PrEP for HIV drugs, drug administration, HIV and hepatitis B screening, and individual counseling performed by either physicians or certain other health care practitioners. We explained that, if finalized as proposed, all of the components would be covered as an additional preventive service without Part B cost-sharing (*i.e.,* deductibles or co-pays). The final NCD was not issued before the proposed rule was issued.[175] (89 FR 59399 through 59402) The final decision memorandum for the NCD was issued and was effective on September 30, 2024. [*https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=310&fromTracking=Y&*]

As explained in the proposed rule, the HCPCS codes that describe these services are outlined in Table 142.

[175] *https://www.cms.gov/files/document/faq-prep-hiv-06242024.pdf.*

TABLE 142: HCPCS Coding and Long Descriptors for PrEP for HIV Drugs and Services

HCPCS Code	Long Descriptor
J0739	Injection, cabotegravir, 1mg, fda approved prescription, only for use as hiv pre-exposure prophylaxis (not for use as treatment for hiv)
J0750	Emtricitabine 200mg and tenofovir disoproxil fumarate 300mg, oral, fda approved prescription, only for use as hiv pre-exposure prophylaxis (not for use as treatment of hiv)
J0751	Emtricitabine 200mg and tenofovir alafenamide 25mg, oral, fda approved prescription, only for use as hiv pre-exposure prophylaxis (not for use as treatment of hiv)
G0011	Individual counseling for pre-exposure prophylaxis (prep) by physician or qualified health care professional (qhp) to prevent human immunodeficiency virus (hiv), includes hiv risk assessment (initial or continued assessment of risk), hiv risk reduction and medication adherence, 15-30 minutes
G0012	Injection of pre-exposure prophylaxis (prep) drug for hiv prevention, under skin or into muscle
G0013	Individual counseling for pre-exposure prophylaxis (prep) by clinical staff to prevent human immunodeficiency virus (hiv), includes: hiv risk assessment (initial or continued assessment of risk), hiv risk reduction and medication adherence
J0799	Fda approved prescription drug, only for use as hiv pre-exposure prophylaxis (not for use as treatment of hiv), not otherwise classified

For CY 2025, we proposed to pay for PrEP for HIV drugs and related services as additional preventive services under the OPPS, if covered in the final NCD. We stated that we believe the resource costs for HCPCS codes listed in Table 142 would be similar across different settings of care, including the HOPD and physician office, and therefore the proposed policies for determining the payment limits for drugs covered as additional preventive services (DCAPS drugs) in the CY 2025 PFS proposed rule (89 FR 61596), which would include PrEP for HIV drugs, would be appropriate for use under the OPPS as well. Therefore, we proposed to pay for the HCPCS codes listed in Table 142 that are furnished in HOPDs in a similar manner as when these codes are furnished in the physician office.

HCPCS code G0012 (Injection of pre-exposure prophylaxis (prep) drug for hiv prevention, under skin or into muscle) may be used to describe the injection of a PrEP drug for HIV prevention. For CY 2025, if covered as an additional preventive service, we proposed to assign this HCPCS code to APC 5692 (Level 2 Drug Administration) based on the crosswalk to HCPCS code 96372 (Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular) based on the anticipated similarity in resource use. For the PrEP for HIV counseling services performed by hospital staff, specifically HCPCS code G0013, if covered as an additional preventive service, we proposed to assign this service to a clinical APC with a payment rate that approximates the payment rate in the physician office setting. The proposed CY 2025 payment rates can be found in Addendum B to the CY 2025 OPPS/ASC proposed rule on the CMS website. We did not propose to pay for PrEP for HIV counseling, described by HCPCS code G0011, performed by physicians under the OPPS as this is a physician-only service.

To determine the OPPS payment amount for PrEP for HIV drugs, we proposed to utilize the ASP methodology under section 1847A of the Act when ASP data is available. As discussed in the CY 2025 PFS proposed rule (89 FR 61596), we believed and continue to believe, that the use of ASP data would be preferable for determining the payment amounts for DCAPS drugs, including PrEP for HIV, for two reasons. First, this approach would determine the payment amount for these drugs in the same way as the payment amount is usually determined for most other drugs that are separately payable under Part B, when possible. This would include the application of payment limit calculations for multiple source drugs, single source drugs and biologicals, and biosimilar biological products, as is done for products under section 1847A of the Act, for each applicable billing and payment code. Second, because section 1847A(c)(3) of the Act requires that calculation of the

manufacturer's ASP for an NDC must include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under the Medicaid drug rebate program, discounts under the 340B Program, and rebates under the Part B and Part D Medicare inflation rebate program), this would set a payment amount that would likely better reflect acquisition cost of the drug than list prices in available compendia (such as Wholesale Acquisition Cost (WAC)).

Specifically, if ASP data is not available for a particular DCAPS drug, the PFS proposal described the use of alternative pricing sources. As previously stated, we believe the resource costs should be similar regardless of whether DCAPS drugs like PrEP for HIV drugs are furnished in the HOPD or the physician office, and we propose to use the same method of utilizing alternative pricing sources for drugs paid under the OPPS as additional preventive services as was proposed under the PFS.

If ASP data for DCAPS drugs like PrEP for HIV is not available, we proposed to determine the payment amount for the applicable billing and payment code using the most recently published amount for the drug in Medicaid's National Average Drug Acquisition Cost (NADAC) survey (OMB control number 0938–1041).[176] When using NADAC data, we proposed to determine the payment amount per billing unit, which would be an average of NADAC prices for all NDCs for the drug. If a drug is available in generic and brand formulations, we proposed all NDCs will be averaged together to determine the payment amount.

As described in the CY 2025 OPPS/ASC proposed rule (89 FR 59401), regarding which NADAC survey will be used, we specified that we will use the survey ''most recently published for purposes of this policy,'' which means the most recently updated NADAC survey available 30 days after the close of the quarter for which ASP data would have been reported if it were available.[177] For example, if NADAC is used to determine the payment amount effective for dates of service in the third calendar quarter, CMS would use the most recent NADAC survey update available on the 30th day after the close of the first calendar quarter. This survey provides a national drug pricing benchmark for certain drugs that is adequately comprehensive to serve as the first alternative pricing source in the case that ASP data is not available. CMS conducts surveys of retail community pharmacy prices to develop the NADAC pricing benchmark in the annual NADAC pricing file. The pricing benchmark is reflective of the prices paid by retail community pharmacies to acquire prescription and over-the-counter covered outpatient drugs. NADAC data is publicly available and it can be accessed at *https://data.medicaid.gov/nadac*.

We stated in the CY 2025 OPPS/ASC proposed rule (89 FR 59401), that since NADAC pricing is only available for drugs typically dispensed through retail community pharmacies, there could be circumstances in which ASP and NADAC are not available for DCAPS drugs like PreP for HIV. Therefore, if both ASP and NADAC pricing data are not available for a DCAPS drug, we proposed to use the most recently published and listed prices for pharmaceutical products in the Federal Supply Schedule (FSS) to calculate the payment amount for the applicable billing and payment code. Most recently published for purposes of this policy means the most recently updated FSS survey available 30 days after the close of the quarter for which ASP data would have been reported if it were available.[178] For example, if FSS is used to determine the payment amount effective for dates of service in the third calendar quarter, CMS would use the most recent FSS update available on the 30th day after the close of the first calendar quarter. When using the FSS, we proposed that we would calculate the average price per billing unit (as described in the billing and payment code for the drug) for all NDCs listed for a drug. Drug pricing information, including FSS pricing, from the Veteran Affairs' (VA's) pharmaceutical pricing database is publicly available at the NDC level and published at *https://www.va.gov/opal/nac/fss/pharmPrices.asp*.

We proposed to use FSS data when ASP and NADAC data are not available because FSS data is one of the few existing options for drug pricing that includes a wide variety of drug formulations, including both self-administered drugs typically dispensed through retail community pharmacies and drugs administered incident to a physician's service. For more details on the proposed pricing methodology for the physician office setting, please see the CY 2025 PFS proposed rule (89 FR 61596).

We note that the PFS proposal included a final step of invoice pricing; however, invoice pricing is not currently available under the OPPS, so we proposed not to adopt that portion of the PFS proposal. However, please see our Invoice Drug Pricing Policy for CY 2026 in section V.B.2.d. of this final rule with comment period. Because invoice pricing is not available in the OPPS currently, we proposed that if ASP, NADAC, and FSS pricing are not available for a particular drug covered as an additional preventive service, we will use WAC plus 6 percent, or 3 percent if in an initial sales period, consistent with payment for separately payable drugs paid under the OPPS. This would result in different pricing between the OPPS and PFS if ASP, NADAC, and FSS pricing are not available, but we believe it is appropriate because invoice pricing is not currently an option under the OPPS and this pricing metric should only apply to a small subset of drugs covered as additional preventive services until one of the other pricing metrics becomes available. We proposed to treat other drugs covered as additional preventive services under this same methodology.

As we stated in the CY 2025 OPPS/ASC proposed rule (89 FR 59401), if the PreP for HIV drugs would be covered as additional preventive services, we proposed to update the payment rates determined using the methodologies previously summarized on January 1, 2025, or the date of coverage, whichever is later, which would be further updated on the same schedule as the ASP pricing file, which is updated each calendar quarter. We proposed to assign the drug products covered as additional preventive services to status indicator K (Nonpass-Through Drugs and Nonimplantable Biologicals, Including Therapeutic Radiopharmaceuticals; Paid under OPPS; separate APC payment), as this status indicator identifies drugs and biologicals that are separately paid under the OPPS and therefore would allow us to operationalize separate payment for PrEP drugs. We explained that if the PrEP for HIV drugs are covered as additional preventive services, on January 1, 2025, or the date of coverage, whichever is later, we proposed that we would assign each PrEP for HIV drug covered as an additional preventive service to its own APC, which will have a payment rate assigned according to the previously defined methodology.

As described in the CY 2025 OPPS/ASC proposed rule (89 FR 59401 through 59402), HCPCS code J0799 (HIV prep, FDA approved, noc) was created effective January 2, 2024, and may be

[176] *https://www.medicaid.gov/medicaid/prescription-drugs/retail-price-survey/index.html.*

[177] 42 CFR 414.804(a)(5).

[178] 42 CFR 414.804(a)(5).

used to describe a PrEP for HIV drug that is FDA approved but is not otherwise classified. We proposed to pay 95 percent of AWP for HCPCS code J0799, which is consistent with how unlisted drugs and biologicals are paid under the OPPS when they are reported with HCPCS code C9399 (Unclassified drugs or biologicals). As HCPCS code J0799 and HCPCS code C9399 both describe drugs that are unclassified or not otherwise classified, we believe the payment methodologies should be similarly aligned. Section 1833(t)(15) of the Act, as added by section 621(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173), provides for payment under the OPPS for new drugs and biologicals until HCPCS codes are assigned. Under this provision, we are required to make payment for a covered outpatient drug or biological that is furnished as part of covered outpatient department services but for which a HCPCS code has not yet been assigned in an amount equal to 95 percent of AWP for the drug or biological.

In the CY 2005 OPPS/ASC final rule with comment period (69 FR 65805), we implemented section 1833(t)(15) of the Act by instructing hospitals to bill for a drug or biological that is newly approved by the FDA and that does not yet have a HCPCS code by reporting the NDC for the product along with the newly created HCPCS code C9399 (Unclassified drugs or biologicals). We explained that when HCPCS code C9399 appears on a claim, the Shared Systems suspends the claim for manual pricing by the Medicare Administrative Contractor (MAC). The MAC prices the claim at 95 percent of the drug or biological's AWP, using Red Book or an equivalent recognized compendium, and processes the claim for payment. We emphasized that this approach enables hospitals to bill and receive payment for a new drug or biological concurrent with its approval by the FDA. The hospital does not have to wait for the next quarterly release or for approval of a product-specific HCPCS code to receive payment for a newly approved drug or biological or to resubmit claims for adjustment. We instructed that hospitals would discontinue billing HCPCS code C9399 and the NDC upon implementation of a product specific HCPCS code, status indicator, and appropriate payment amount with the next quarterly update. While the statute does not require DCAPS drugs to be paid at 95 percent of AWP when not assigned to a product specific HCPCS code, we believe it would be appropriate to create a parallel policy given that HCPCS code J0799 and HCPCS code C9399 both describe drugs that are unclassified or not otherwise classified. As the payment amount for HCPCS code C9399 is statutorily mandated at 95 percent of AWP, we believe that the payment amount for HCPCS code J0799 should also be 95 percent of AWP.

Therefore, we proposed to establish an identical payment policy for HCPCS code J0799, which may be used to describe drugs that are FDA-approved for PrEP for HIV and are covered as additional preventive services. In order to effectuate payment at 95 percent of AWP, we proposed to require hospitals to bill for a drug that is newly FDA approved for PrEP for HIV, and covered as an additional preventive service, and that does not yet have a HCPCS code, by reporting the NDC for the product along with the newly created HCPCS code J0799. Similar to HCPCS code C9399, when HCPCS code J0799 appears on a claim, the Shared Systems will suspend the claim for manual pricing by the MAC. The MAC would price the claim at 95 percent of the drug or biological's AWP, using Red Book or an equivalent recognized compendium, and process the claim for payment. This approach would enable hospitals to bill and receive payment for a drug that is newly FDA approved for PrEP for HIV and covered as an additional preventive service concurrent with its approval by the FDA. The hospital would not have to wait for the next quarterly release or for approval of a product-specific HCPCS code to receive payment for a newly approved drug or to resubmit claims for adjustment. We would instruct hospitals to discontinue billing HCPCS code J0799 and the NDC upon implementation of a product specific HCPCS code, status indicator, and appropriate payment amount with the next quarterly update.

Finally, if covered as an additional preventive service, we proposed to assign all HCPCS codes describing pharmacy supplying fees for PrEP for HIV to an OPPS status indicator of ''B''. This follows the longstanding OPPS practice of assigning HCPCS codes that describe a pharmacy supply or dispensing fee to status indicator ''B'' (Codes that are not recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and 13x); Not paid under OPPS), such as HCPCS code Q0512 (Pharmacy supply fee for oral anti-cancer, oral anti-emetic or immunosuppressive drug(s); for a subsequent prescription in a 30-day period) and HCPCS code Q0513 (Pharmacy dispensing fee for inhalation drug(s); per 30 days).

Comment: Several commenters were supportive of CMS's proposed payment policies and encouraged CMS to use its authority to pay for PrEP for HIV drugs and services as additional preventive services.

Response: We thank commenters for their support. The final decision memorandum for the NCD was issued and was effective on September 30, 2024 [*https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=310&fromTracking=Y&*]. For the interim period of September 30, 2024, until December 31, 2024, before the DCAPS payment policy being finalized in this rule is effective, CMS will pay for PrEP for HIV drugs under the OPPS in a manner that closely aligns with how payment is currently made for drugs under the OPPS, which is generally based off of the ASP methodology. However, beginning January 1, 2025, as discussed in more detail below, we are finalizing a payment approach for determining a payment limit for DCAPS drugs. As PrEP for HIV is a DCAPS drug, payment will be made in accordance with the finalized payment approach.

Comment: Several commenters supported CMS's proposal to use ASP plus 6 percent as the basis of payment; however, they recommended CMS revise the proposed payment approach specifically for PrEP for HIV, or in some cases DCAPS payment in general, in situations in which ASP data is unavailable. For example, commenters recommended in situations in which ASP is unavailable, CMS should base payment on WAC plus 3 or 6 percent, rather than NADAC or FSS pricing. There were concerns from commenters that NADAC or FSS pricing were inadequate payment methodologies and could lead to underpayments that would discourage utilization.

Response: We continue to believe that NADAC and FSS pricing are appropriate payment methodologies to determine a payment limit under the OPPS for DCAPS drugs in instances in which ASP data is not available. In the CY 2020 PFS final rule (84 FR 62655), we stated that we believe NADAC survey data on invoice prices provides the closest pricing metric to ASP-based payment limits that is available. FSS data is one of the few existing options for drug pricing that includes a wide variety of drug formulations, which is why CMS chose it as an additional alternative for drugs covered as additional preventive services. Thus, our proposal explained that ASP, NADAC, and FSS are all drug pricing options that aim to estimate the accurate acquisition cost of a drug, rather than WAC, which is a list price.

Therefore, we believe WAC should be the payment methodology used under the OPPS only if ASP, NADAC, or FSS pricing are not available, as invoice pricing is not currently an option for determining a payment limit for a drug under the OPPS, unlike under the PFS.

Comment: A few commenters stated Medicare should ensure adequate payment for these services in a way that takes into account the site of service, since, in their view, hospital outpatient departments are more likely to care for patients who are more medically and socially complex than those cared for in physicians' offices. These commenters recommended that CMS calculate the payment for PrEP for HIV services furnished in an HOPD in the same manner as it does for other OPPS services, and not at the PFS rate.

Response: We thank commenters for their feedback. We continue to believe that the additional preventive services discussed in this section generally should have resource costs that align between care settings, such as the HOPD and the physician's office. Accordingly, we are adopting a similar payment approach for the drugs covered as additional preventive services as under the fee schedule for DCAPS drugs in the physician office setting.

For the PrEP for HIV counseling services performed by hospital staff, specifically HCPCS code G0013, we are finalizing our proposal to assign this service to a clinical APC with a payment rate that approximates the payment rate in the physician office setting, consistent with our belief that the resource costs would be similar across different settings of care. Based on updated data available for this final rule, as well as the expected physician office setting payment rate, this corresponds to an APC assignment of APC 5821 (Level 1 Health and Behavior Services) for HCPCS G0013. We will continue to monitor the appropriateness of these APC assignments.

We note that for the administration of the drug; however, we are finalizing our proposed assignment of HCPCS code G0012 (Injection of pre-exposure prophylaxis (prep) drug for hiv prevention, under skin or into muscle), which may be used to describe the injection of a PrEP drug for HIV prevention, to APC 5692 (Level 2 Drug Administration) based on the OPPS specific crosswalk to HCPCS code 96372 (Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular) based on the anticipated similarity in resource use to other codes assigned to this APC. Since we have an existing crosswalk code under the OPPS on which to base payment for HCPCS code G0012, we believe it is appropriate to finalize the assignment of that code to APC 5692, rather than the PFS payment rate.

Comment: Several commenters shared concerns or support for the Proposed NCD for Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Infection Prevention, published on July 12, 2023, as the NCD was not yet finalized as of the end of the comment period for the CY 2025 PFS proposed rule on September 9, 2024. This included concerns regarding unintended consequences of NCD finalization, such as having the same drugs covered under Medicare Part B or Part D depending on the indication in which they are used, which a commenter believed would be administratively burdensome. There were also concerns regarding pharmacists being unable to enroll as prescribers under Medicare Part B. The commenters also included support for certain payment methodologies for Medicare to adopt in the interim period after the NCD was finalized, but before this rule takes effect on January 1, 2025. Commenters also expressed concerns regarding Medicare Advantage Utilization Management controls being used for products potentially covered under the NCD.

Response: We thank commenters for their feedback; however, we note comments related to the proposed and final coverage decision are out of scope for purposes of our proposed payment policies. Additionally, as the proposed and finalized policies in this rule are for payment for DCAPS drugs, including PrEP for HIV drugs, beginning January 1, 2025, comments regarding the interim payment rate for PrEP for HIV are outside the scope of this rulemaking. The public comment period on the proposed NCD for PrEP for HIV coverage under Medicare Part B was from January 12, 2023, to February 11, 2023. The final NCD was released on September 30, 2024, and is available at *https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=310&fromTracking=Y&*. We direct interested parties to *https://www.cms.gov/medicare/coverage/prep* for more information on the final NCD and the transition of PrEP for HIV coverage and payment from Part D to Part B. This CMS PrEP web page contains and/or will contain additional guidance on implementation of PreP for HIV coverage under Part B, including coding and billing information, payments for PrEP for HIV for the period of September 30–December 31, 2024, and the implementation of the payment approach for DCAPS drugs, including PreP for HIV drugs, effective January 1, 2025.

Comment: A commenter strongly opposed use of FSS pricing to pay for PrEP for HIV drugs, but asked that we confirm that we will utilize the Other Government Agency (OGA) FSS price if we proceed with finalizing the use of the FSS price in cases where ASP and NADAC pricing data are not available. The commenter believed basing payment on the OGA FSS price would better support patient access to PrEP for HIV drugs compared to the Big 4 FSS price (the Department of Veterans Affairs (VA), DoD, the Public Health Service, and the Coast Guard), which the commenter stated reflects substantial statutory discounts that do not apply to Medicare Part B providers and they stated this could lead to significant under-payment for PrEP for HIV drugs.

Response: We confirm that the FSS pricing data used will be the OGA prices.

As previously described, the NCD was finalized on September 30th, 2024. On that date Medicare began coverage and payment for PrEP for HIV and associated services. The payment assignments for the interim period (that is, September 30, 2024, to December 31, 2024) are in Table 143.

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TABLE 143: OPPS PAYMENT FOR PREP FOR HIV DRUGS AND SERVICES SEPTEMBER 30 THROUGH DECEMBER 31, 2024

HCPCS Code	Long Descriptor	Status Indicator	APC
J0739	Injection, cabotegravir, 1mg, fda approved prescription, only for use as hiv pre-exposure prophylaxis (not for use as treatment for hiv)	K	0805
J0750	Emtricitabine 200mg and tenofovir disoproxil fumarate 300mg, oral, fda approved prescription, only for use as hiv pre-exposure prophylaxis (not for use as treatment of hiv)	K	0806
J0751	Emtricitabine 200mg and tenofovir alafenamide 25mg, oral, fda approved prescription, only for use as hiv pre-exposure prophylaxis (not for use as treatment of hiv)	K	0808
G0011	Individual counseling for pre-exposure prophylaxis (prep) by physician or qualified health care professional (qhp) to prevent human immunodeficiency virus (hiv), includes hiv risk assessment (initial or continued assessment of risk), hiv risk reduction and medication adherence, 15-30 minutes	B	Not Applicable for SI = "B"
G0012	Injection of pre-exposure prophylaxis (prep) drug for hiv prevention, under skin or into muscle	S	5692
G0013	Individual counseling for pre-exposure prophylaxis (prep) by clinical staff to prevent human immunodeficiency virus (hiv), includes: hiv risk assessment (initial or continued assessment of risk), hiv risk reduction and medication adherence	S	5822
J0799	Fda approved prescription drug, only for use as hiv pre-exposure prophylaxis (not for use as treatment of hiv), not otherwise classified	A	Not Applicable for SI = "A"
Q0516	Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription oral drug, per 30-days	B	Not Applicable for SI = "B"
Q0517	Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription oral drug, per 60-days	B	Not Applicable

HCPCS Code	Long Descriptor	Status Indicator	APC
			for SI = "B"
Q0518	Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription oral drug, per 90-days	B	Not Applicable for SI = "B"
Q0519	Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription injectable drug, per 30-days	B	Not Applicable for SI = "B"
Q0520	Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription injectable drug, per 60-days	B	Not Applicable for SI = "B"

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After consideration of the public comments we received, we are finalizing our proposal with slight modifications. For CY 2025, we are finalizing our proposal to pay for PrEP for HIV drugs and related services as additional preventive services under the OPPS. That is, we are finalizing our proposal that PrEP for HIV will be paid in accordance with the payment approach we are finalizing for all DCAPS drugs. We are finalizing the APC assignments in Table 144 generally consistent with our proposal.

We are finalizing some modifications to our proposed policies. When using NADAC pricing to determine a payment rate, and the drug is available in generic and brand formulations, we proposed all NDCs will be averaged together to determine the payment amount. Similarly, when using the FSS to determine a payment rate, we proposed that we would calculate the average price per billing unit (as described in the billing and payment code for the drug) for all NDCs listed for a drug.

In this final rule, to maintain consistency with the PFS finalized policy and comments received, we are amending our proposal, to finalize a policy to treat brand and generic drugs in a similar manner to the description in the Medicare Claims Processing Manual, Chapter 17, sections 20.1.3 and 20.4. That is, when calculating the price for multiple-source DCAPS drugs using NADAC or FSS pricing, we will use the lesser price of: (1) The median of all generic forms of the drug; or (2) The lowest brand name product.

Additionally, after consideration of public comments, we are finalizing the following payment approach for drugs covered as additional preventive services and paid under the OPPS, and note the actual rates used for payment will be published on the CMS website and updated quarterly:

- If ASP data is available for the DCAPS drug, the payment limit will be determined based on the methodology under section 1847A(b) of the Act (usually 106 percent of ASP);
- If ASP data is not available, the payment limit will be calculated using NADAC prices for the drug;
- If ASP data and NADAC prices are not available, the payment limit will be calculated using the FSS prices for the drug; and
- If ASP data, NADAC prices, and FSS prices are not available, payment will be WAC plus 6 percent, or 3 percent if in an initial sales period, consistent with payment for separately payable drugs paid under the OPPS. Because invoice pricing is not currently available in the OPPS, if ASP, NADAC, and FSS pricing are not available for a particular drug covered as an additional preventive service, we will use WAC plus 6 percent, or 3 percent if in an initial sales period.

However, as discussed in section V.B.2.d. (Invoice Drug Pricing for CY 2026) of this final rule with comment period, we are finalizing a policy to begin to price certain drugs based on their invoices starting in CY 2026. As such, we are making a conforming change such that, starting in CY 2026, if ASP data, NADAC prices, and FSS prices are not available, the payment rate would be based on the invoice price. For CY 2025 only, if ASP data, NADAC prices, and FSS prices are not available, payment will be based on WAC plus 6 percent, or 3 percent of in an initial sales period. We note this may result in different approaches to setting a payment rate between the OPPS and PFS if ASP, NADAC, and FSS pricing are not available, but we believe it is appropriate because invoice pricing is not currently an option under the OPPS and this pricing metric should only apply to a small subset of DCAPS drugs, until one of the other pricing metrics becomes available. As mentioned in CMS's responses to comments above, we are clarifying that the FSS price is the ''other government agencies'' price.

Finally, in the CY 2025 OPPS/ASC proposed rule, we proposed that if covered as an additional preventive service, we would assign all HCPCS

codes describing pharmacy supplying fees for PrEP for HIV to an OPPS status indicator of ''B''. We stated this follows the longstanding OPPS practice of assigning HCPCS codes that describe a pharmacy supply or dispensing fee to status indicator ''B'' (Codes that are not recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and 13x); Not paid under OPPS), such as HCPCS code Q0512 (Pharmacy supply fee for oral anti-cancer, oral anti-emetic or immunosuppressive drug(s); for a subsequent prescription in a 30-day period) and HCPCS code Q0513 (Pharmacy dispensing fee for inhalation drug(s); per 30 days). While our longstanding OPPS practice has been to assign all HCPCS codes describing pharmacy supplying or dispensing fees to an OPPS status indicator of ''B'' indicating that the code is not payable under the OPPS, we believe assignment of these HCPCS codes describing pharmacy supplying or dispensing fees would be most accurately assigned to a status indicator of ''M'' (Items and Services Not Billable to the MAC; Not paid under OPPS), which also indicates that the codes are not paid under the OPPS. Status indicator ''M'' codes are not billable to the MAC. We believe status indicator ''M'' more clearly articulates that these codes are not billable to the MAC by hospitals and pharmacies should bill these HCPCS codes to their appropriate MAC. Whereas, status indicator ''B'' states the code is not recognized by OPPS, while that is true, we believe the definition for status indicator ''M'' is more comprehensive and better instructs proper billing as it is communicating to all hospitals that these codes are not billable to their MAC, rather than just not recognized by the OPPS. Therefore, we are finalizing this technical refinement to assign HCPCS code Q0521 (Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription) to status indicator ''M.'' We note, HCPCS code Q0521 replaces HCPCS codes Q0516, Q0517, Q0518, Q0519, and Q0520 starting January 1, 2025.

To maintain consistency with regard to the use of status indicators under the OPPS, we are also applying this technical refinement and assigning a status indicator of ''M'' to other pharmacy supplying and dispensing HCPCS codes. This is consistent with our discussion and intent in the CY 2025 OPPS/ASC proposed rule, where it was discussed that pharmacy supplying and dispensing codes, such as HCPCS codes Q0512 (Pharmacy supply fee for oral anti-cancer, oral anti-emetic or immunosuppressive drug(s); for a subsequent prescription in a 30-day period) and HCPCS code Q0513 (Pharmacy dispensing fee for inhalation drug(s); per 30 days) were historically assigned to a non-payable status indicator. The pharmacy supplying and dispensing codes that we are assigning to a status indicator of ''M'' for CY 2025 include: Q0510 (Pharmacy supply fee for initial immunosuppressive drug(s), first month following transplant); Q0511 (Pharmacy supply fee for oral anti-cancer, oral anti-emetic or immunosuppressive drug(s); for the first prescription in a 30-day period); Q0512 (Pharmacy supply fee for oral anti-cancer, oral anti-emetic or immunosuppressive drug(s); for a subsequent prescription in a 30-day period); Q0513 (Pharmacy dispensing fee for inhalation drug(s); per 30 days); Q0514 (Pharmacy dispensing fee for inhalation drug(s); per 90 days). As described in the preceding paragraph, we believe status indicator ''M'' more clearly articulates that these codes are not billable to the MAC by hospitals and pharmacies should bill these HCPCS codes to their appropriate MAC. Whereas, status indicator ''B'' states the code is not recognized by OPPS, while that is true, we believe the definition for status indicator ''M'' is more comprehensive and better instructs proper billing as it is communicating to all hospitals that these codes are not billable to their MAC, rather than just not recognized by the OPPS. Similarly, as we previously summarized, we are not paying for PrEP for HIV counseling, described by HCPCS code G0011, performed by physicians under the OPPS as this is a physician-only service. Therefore, following the same logic as just discussed for the pharmacy supplying and dispensing codes, we are also finalizing assignment of this code to a status indicator of ''M'' to better instruct proper billing.

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TABLE 144: CY 2025 FINAL OPPS STATUS INDICATOR AND APC ASSIGNMENTS FOR PrEP FOR HIV DRUGS AND SERVICES

HCPCS Code	Long Descriptor	Status Indicator	APC
J0739	Injection, cabotegravir, 1mg, fda approved prescription, only for use as hiv pre-exposure prophylaxis (not for use as treatment for hiv)	K	0805
J0750	Emtricitabine 200mg and tenofovir disoproxil fumarate 300mg, oral, fda approved prescription, only for use as hiv pre-exposure prophylaxis (not for use as treatment of hiv)	K	0806
J0751	Emtricitabine 200mg and tenofovir alafenamide 25mg, oral, fda approved prescription, only for use as hiv pre-exposure prophylaxis (not for use as treatment of hiv)	K	0808
G0011	Individual counseling for pre-exposure prophylaxis (prep) by physician or qualified health care professional (qhp) to prevent human immunodeficiency virus (hiv), includes hiv risk assessment (initial or continued assessment of risk), hiv risk reduction and medication adherence, 15-30 minutes	M	Not Applicable for SI = "M"
G0012	Injection of pre-exposure prophylaxis (prep) drug for hiv prevention, under skin or into muscle	S	5692
G0013	Individual counseling for pre-exposure prophylaxis (prep) by clinical staff to prevent human immunodeficiency virus (hiv), includes: hiv risk assessment (initial or continued assessment of risk), hiv risk reduction and medication adherence	S	5821
J0799	Fda approved prescription drug, only for use as hiv pre-exposure prophylaxis (not for use as treatment of hiv), not otherwise classified	A	Not Applicable for SI = "A"
Q0516	Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription oral drug, per 30-days	D	Not Applicable
Q0517	Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription oral drug, per 60-days	D	Not Applicable

HCPCS Code	Long Descriptor	Status Indicator	APC
Q0518	Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription oral drug, per 90-days	D	Not Applicable
Q0519	Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription injectable drug, per 30-days	D	Not Applicable
Q0520	Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription injectable drug, per 60-days	D	Not Applicable
Q0521	Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription	M	Not Applicable for SI = "M"

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Final definitions of status indicators for CY 2025 can be found in Addendum D1 to this final rule with comment period. Additionally, final CY 2025 APC payment rates can be found in Addenda A and B. Addenda to this final rule with comment period can be found on the CMS OPPS web page.

Corresponding with the finalization of this policy, we are adding conforming regulation text changes by adding new paragraph (j) to § 419.41. This new paragraph details the payment amounts for drugs covered as additional preventive services under the OPPS and includes the finalized payment methodology hierarchy as described in this section.

G. Payment Policy for Devices in Category B Investigational Device Exemption (IDE) Clinical Trials Policy and Drugs/Devices With a Medicare Coverage With Evidence Development (CED) Designation

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72027), and as authorized by section 1833(w) of the Act, we finalized a policy to make a single blended payment for devices and services in Category B IDE studies, in order to preserve the scientific validity of these studies by avoiding differences in Medicare payment methods that would otherwise reveal the group (treatment or control) to which a patient has been assigned. Specifically, we codified our process of utilizing a single packaged payment for Category B IDE studies, including the cost of the device and routine care items and services, in the regulation text for payment to hospitals in a new § 419.47. We provided in new § 419.47(a) and (b) that CMS will create a new HCPCS code, or revise an existing HCPCS code, to describe a Category B IDE study, which will include both the treatment and control arms, related device(s) of the study, as well as routine care items and services, as specified under 42 CFR 405.201, when CMS determines that the Medicare coverage IDE study criteria at § 405.212 are met, and a new or revised code is necessary to preserve the scientific validity of the IDE study, such as by preventing the unblinding of the study.

We finalized that the single blended payment rate would be dependent on the specific trial protocol and would account for the frequency with which the investigational device is used compared to the control where the investigational device is not used. For example, in a study for which CMS determines the Medicare coverage IDE study criteria in § 405.212 are met and where there is a 1:1 assignment of the device to control (no device), Medicare's payment rate would prospectively average the payment for the device with the zero payment for the control in a 1:1 ratio. Furthermore, costs for routine care items and services in the study, as specified under § 405.201, would be included in the single blended payment (87 FR 72026 through 72027).

Since implementing this policy, we have heard from interested parties that our regulation at § 419.47(a) and (b) excluded clinical trials for which there is no control arm. We appreciate the input. Category B IDE studies with no control arm would be paid normally because an alternative payment methodology would not be necessary to preserve their scientific validity. Our policy at § 419.47 applies only to IDE studies with a control arm and where a payment adjustment is necessary to preserve the scientific validity of such a study. The rule was not intended to suggest that CMS will not pay for Category B IDEs with no control arm, provided the studies meet the coverage criteria. In those circumstances, Medicare payments would be made using the usual Medicare payment methodologies.

In many instances, requests for coding and payment for devices in Category B IDE studies are submitted through our New Technology APC application process and include the submission of cost information. However, we have encountered difficulties determining accurate payment rates for Category B IDE studies in the absence of New Technology APC applications, such as

when coding for Category B IDE studies is developed through the CPT Editorial Panel process. We encourage interested parties to use the New Technology APC application process, where applicable, to submit cost information to CMS. Absent information on the resource costs associated with the services and devices in a Category B IDE study, we may assign a SI of ''E2'' to indicate an item, code or service for which pricing information and claims data are not available, and, therefore, the item, code or service is not paid by Medicare when submitted by an outpatient claim.

For CY 2025, we proposed to utilize a payment methodology similar to the one developed for Category B IDE clinical trials for drugs and devices covered under a national coverage determination (NCD) that uses the Coverage with Evidence Development (CED) paradigm when a payment adjustment is necessary to preserve the scientific validity of such a study. Specifically, we proposed to use our authority at section 1833(w) of the Act to develop alternative methods of payment under Medicare Part B for drugs and devices being studied in clinical trials under a CED NCD. These CED NCDs will be listed on the CMS CED website.[179]

Similar to our policy on devices in Category B IDE trials, for devices under a CED NCD, we proposed to make a single blended payment rate that would be dependent on the specific trial protocol and would account for the frequency with which the investigational device is used compared to the control where the investigational device is not used. For example, in a study for which there is a 1:1 assignment of the device to control (no device), Medicare's payment rate would prospectively average the payment for the device with the zero payment for the control in a 1:1 ratio.

As previously described, when necessary to preserve the scientific validity of the study, we proposed to make payment using an adjusted payment level representing the frequency with which the study drug and placebo, or comparator drug, is furnished. A placebo, or comparator drug, could represent what a beneficiary would typically receive in order to serve as a comparator to assess the effectiveness, or therapeutic benefit, of the study drug. These adjusted payments would protect the scientific validity of the trial by avoiding differences in Medicare payment methods that could otherwise invalidate the scientific validity of the trial, such as by revealing the group (treatment or control) to which a patient has been assigned. We proposed to base the payment amount for the study drug, or active comparator drug, on the ASP methodology, that is ASP plus 6 percent if ASP data is available. If ASP data is not available, then we proposed to pay the wholesale acquisition cost (WAC). During an initial sales period, we proposed to base the payment on WAC plus 3 percent, otherwise, we proposed to base payment on WAC plus 6 percent. If WAC is not available, then we proposed to pay 95 percent of average wholesale price (AWP). This payment hierarchy is consistent with CMS payment for non-passthrough separately payable drugs in the OPPS as discussed in section V.B. of the CY 2025 OPPS/ASC proposed rule.

These payment amounts would be used to calculate the adjusted payment level representing the frequency with which the study drug and placebo, or comparator drug, is furnished. For purposes of setting this adjusted payment level, we proposed to use a zero dollar amount for a placebo or comparator. A new, or revised, HCPCS code would be created for the drug and placebo or comparator in the CED study. We proposed that we would assign this HCPCS code to its own APC reflecting the payment amount determined appropriate based on available pricing information and the frequency with which the study drug and placebo, or comparator drug, is used.

For example, as most drugs are currently paid per dosage unit, such as per 1 mg, a payment rate, potentially priced per 1 mg of drug, placebo, or active comparator, might be based on the average sales price methodology for the drug averaged with a zero-dollar payment for the placebo, or the applicable payment rate of the comparator drug. A single averaged payment would be made regardless of whether 1 mg of study drug, 1 mg of placebo, or 1 mg of comparator drug is used. If the trial is a 1:1 (treatment: placebo) then the payment rate would be the same for every trial participant and would represent half of the total payment for the drug. In a simplified example, if the ASP plus 6 percent payment rate for Drug X was $1 per 1 mg then in this example, the payment rate for the blended code of Drug X and placebo would be $0.50 per 1 mg. If a beneficiary received 100 mg of the study drug, then a $50 payment would be made. If a beneficiary received 100 mg of the placebo, then a $50 payment would be made. The same HCPCS code would be billed in both the study drug and placebo examples. The same payment methodology would apply if the study design was 1:2 (treatment: placebos, which equals payment at ⅓ the cost of the study drug) or 1:3 (treatment: placebos, which equals payment at ¼ the cost of the study drug).

In situations where there are multi-arm, or single-arm, cross over trials where participants receive placebo, or sham, for the first half of the trial and then the study drug for the second half of the trial, the payment would be reflective of this, and set in the same manner as a 1:1 trial, since half of the time the beneficiary would receive the placebo and the other half they would receive the study drug. No matter the trial design, CMS payment would be reflective of the expected frequency with which the study treatment, control, active comparator, or placebo is provided. We noted that we proposed to assign payment rates based on an adjusted payment level representing the frequency with which the study drug and placebo, or comparator drug, is projected to be furnished for the trial as a whole, and not necessarily the exact frequency with which the study drug and placebo, or comparator drug, is furnished to a particular hospital enrolled as a clinical trial site. Clinical trial sponsors should work with CMS to ensure timely establishment of payment and coding for drugs being studied under a CED designation requiring an adjusted level of payment.

While the items and services furnished as placebo controls may not be considered reasonable and necessary under section 1862(a)(1)(A) of the Act because they have no health benefit, these items and services can be necessary in order to conduct a scientifically valid clinical study. As such, these items can be covered under section 1862(a)(1)(E) of the Act when furnished in the context of a qualifying clinical study.[180]

CMS may cover and pay for routine costs of an approved clinical trial in both the treatment arm and the control (standard of care or placebo). Routine costs include all items and services that are otherwise generally available to Medicare beneficiaries (*i.e.,* there exists a benefit category for the item or service, coverage is not statutorily excluded for the item or service, and there is not a national non-coverage decision for the item or service) that are provided in either the experimental or the control

[179] *https://www.cms.gov/medicare/coverage/evidence.*

[180] Coverage with Evidence Development: Guidance Document. August 7, 2024. *https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?mcdid=38.*

arms of a clinical trial. Although CMS may cover and pay for routine costs of an CED approved clinical trial in both the treatment arm and the control (standard of care or placebo), there may be circumstances, such as single arm studies, where no unique coding or unique payment would be required to preserve the scientific validity of such a study created for routine costs associated with clinical trials. Similarly, if the routine costs are the exact same between different arms of a trial, and routine billing and payment of those routine costs would not unblind a study, then no unique coding or payment would be required for those costs. There would be no need to include these routine costs in the HCPCS code assigned to a blended payment rate. If covered, these routine costs would be paid according to existing coding and Medicare payment mechanisms. Under the proposal, an alternate method of payment would be established only when necessary to maintain the scientific validity of the trial, such as to prevent the billing and payment of routine costs from unblinding the trial. These determinations would be made based on the clinical trial protocol communicated to CMS by the clinical trial sponsor, before CMS would establish an appropriate code with an adjusted payment level for routine costs for CED trials. CMS's determination in CED trials would differ from our policy regarding devices and procedures in Category B IDE trials, where the provision of an investigational device usually requires a combination of procedures or services to implant, or administer, the device to a patient. In contrast, the infusion of a drug is typically a more straightforward process, and associated routine costs may not be provided at the same time that the drug is administered, making it impractical to create a single code to describe the study drug and all associated routine costs.

Finally, we wanted to be sure there are no other instances where Medicare payment methodologies might interfere with the scientific validity of a trial. We sought comment on these possible alternative scenarios, such as Medicare payment interfering with clinical trial recruitment in such a way that could compromise the scientific integrity of a clinical trial and would consider adjustments to our payment policy for devices in Category B IDE clinical trials and devices/drugs in clinical trials with a CED designation in future rulemaking.

We proposed to codify our coding and payment policy to Category B IDE clinical trials with control arms through revisions to § 419.47(a) to specify that these are placebo control arms. We also proposed to codify our proposed process for developing coding and payment for devices/drugs in CED-designated clinical trials by adding new paragraphs (c) and (d) to § 419.47. Specifically, we proposed to provide in new § 419.47(c) that CMS would create a new HCPCS code, or revise an existing HCPCS code, to describe a device/drug studied in a clinical trial with the Medicare CED designation, which would include the study device/drug and control arm, when CMS determines it is necessary to establish a CED designation for a device/drug subsequent to a CED NCD. Additionally, in new § 419.47(d) we proposed that when we create a new HCPCS code or revise an existing HCPCS code under proposed paragraph (c), we would make a single payment for the HCPCS code that includes payment for the investigational device/drug and any control.

Comment: Several commenters were not supportive of our proposal because they believed the single blended payment rate would lower payments and disincentivize provider participation in clinical trials for drugs and devices with a CED designation. One commenter stated that the practical application of this policy would reduce the pool of eligible providers to those participating in settings such as academic medical centers and facilities that are already performing a high volume of procedures. The commenter further explained that if clinical trial sites were limited to academic medical centers and other facilities performing a high volume of procedures, the commenter believed that communities of color and rural communities would disproportionally face access issues, due to the use of the CED paradigm.

Response: We appreciate the commenters' input and will continue to consider the implications of a single blended payment rate to hospital outpatient departments for drugs and devices in clinical trials covered under an NCD with a CED designation, including the access and health equity impacts.

Comment: A comment signed by 18 organizations explained that it was unethical to require patients to participate in a study so that they might get access to a drug that is already FDA approved. Another commenter believed it was unethical for patients to pay for a placebo when there is an FDA approved treatment available.

Response: We appreciate the input and are sympathetic to the commenters' concerns. Although we appreciate the viewpoint of commenters expressing concern for assigning a CED designation to FDA approved drugs, we note that the comments are out of scope because they do not relate to the proposed payment methodology for CED drugs and devices. With regard to the comment stating that it was unethical for patients enrolled in clinical trials to pay for a placebo, we need additional time to consider the ethical implications of requiring a 20 percent coinsurance for all study participants, as proposed, including those that do not receive the CED drug or device. We welcome public engagement and comments on this final rule with comment period regarding the implications of requiring a coinsurance payment for beneficiaries participating in trials for CED drugs and devices, as well as the relevant statutory authorities that may allow for an adjustment of the coinsurance amount for beneficiaries participating in clinical trials for CED drugs and devices. We will continue to consider the ethical implications as part of future policymaking on payments for clinical trials.

Comment: Several commenters did not support CMS applying CED designation to drugs and biologics that are already approved by the FDA because they believe it would impede beneficiary access to medicines that FDA has already determined to be safe and effective. Two commenters stated that our proposed policy seemed to indicate that more FDA-approved drugs and biologics will be covered by Medicare under the CED pathway in the future. Commenters urged CMS to exercise caution, maintain very limited use of CED for Part B drugs, and not use CED to conduct control arm studies or to prevent access to FDA approved treatments.

Response: We appreciate hearing the public comments and concerns about the potential coverage of drugs and biologicals in future CED trials. However, these comments are outside the scope of our proposed rule because they relate to the coverage pathway for certain drugs and devices rather than the proposed payment methodology for CED drugs and devices. Because the comments relate to coverage decisions that are entirely separate from the proposed payment methodology for CED drugs and devices, we did not consider the comments submitted for this final rule with comment period. We refer readers to the ''Coverage with Evidence Development: Guidance Document'' issued on August 7, 2024, for more

information on CMS's policy for making NCDs using the CED paradigm.[181]

Comment: We received several comments, including from a drug manufacturer, supporting our proposal for both CED drugs and devices. Commenters stated that they believed it was necessary for CMS to finalize this policy to preserve the scientific integrity of future trials. One commenter explained that the policy's emphasis on scientific validity outweighed the small chance of lower payment for trial sites that perform more placebo or sham services versus intervention services. A couple of commenters supported our proposal and requested additional billing and coding guidance for trial sites, as well as timely, transparent, and efficient implementation of the policy.

Response: We thank the commenters for their support. While we agree that the proposed payment methodology for CED drugs and devices may have the effect of preserving the scientific integrity of CED trials, other commenters raised concerns regarding the impact of the proposed policy on provider payments, study enrollment, and beneficiary coinsurance amounts for study enrollees, that need to be further considered prior to finalizing a payment policy. Because we are not finalizing the proposed rule at this time, we will consider the comments if we undertake future rulemaking.

After consideration of the public comments we received, we are not finalizing our proposal to use our authority at section 1833(w) of the Act to develop alternative methods of payment under Medicare Part B for drugs and devices being studied in clinical trials under a CED NCD at this time. We believe that there are broader policy implications to our proposal that require further consideration prior to finalizing a payment policy for CED drugs and devices. For example, we need additional time to consider the ethical implications of requiring a coinsurance payment for all beneficiaries participating in a clinical trial for a CED drug or device, including those that do not receive the investigational treatment. We also need additional time to consider the potential impacts of a single blended payment rate on clinical trial enrollment for drugs and devices in CED trials. We will carefully consider the issues raised in the public comments received in developing a payment policy for CED drugs and devices for future rulemaking.

Accordingly, we are not revising the regulation text at § 419.47 as proposed to include a payment methodology for CED drugs and devices. We are finalizing our proposal to codify our coding and payment policy for Category B IDE clinical trials with control arms through revisions to § 419.47(a) to specify that our policy applies only to IDE studies with a control arm and where a payment adjustment is necessary to preserve the scientific validity of such a study.

XI. CY 2025 OPPS Payment Status and Comment Indicators

A. CY 2025 OPPS Payment Status Indicator Definitions

Payment status indicators (SIs) that we assign to HCPCS codes and APCs serve an important role in determining payment for services under the OPPS. They indicate whether a service represented by a HCPCS code is payable under the OPPS or another payment system and whether particular OPPS policies apply to the code.

For CY 2025 and subsequent years, we proposed to create two new status indicators, ''K1'' and ''H1.'' We proposed these two new status indicators to identify the products that qualify for separate payment under our new payment policy for non-opioid post-surgical pain management drugs, biologicals, and devices, as authorized by section 4135 of the Consolidated Appropriations Act, 2023. This policy is discussed further in section XIII.E of this final rule. The final definitions and payment status of status indicators ''K1'' and ''H1'' can be found in Table 145.

TABLE 145: FINALIZED DEFINITIONS AND PAYMENT STATUS OF STATUS INDICATORS K1 AND H1

Final Status Indicator	Final Descriptor	Final OPPS Payment Status
K1	Non-Opioid Drugs and Biologicals For Post-Surgical Pain Relief	Paid under OPPS; separate APC payment. Subject to criteria and payment limitation under Section 4135 of the CAA, 2023.
H1	Non-Opioid Medical Devices For Post-Surgical Pain Relief	Paid under OPPS; separate payment based on hospital's charges adjusted to cost. Subject to criteria and payment limitation under Section 4135 of the CAA, 2023.

For CY 2025 and subsequent years, we proposed to modify the definition of status indicator ''K'' to remove the word ''therapeutic'' from the phrase ''therapeutic radiopharmaceuticals'' to indicate that both diagnostic and therapeutic radiopharmaceuticals may be assigned to status indicator ''K'' in accordance with our policy proposal in section II.A.3.a. of this final rule. The final definition and payment status of status indicator ''K'' can be found in Table 146.

[181] *https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?mcdid=38.*

TABLE 146: FINALIZED DEFINITION AND PAYMENT STATUS OF STATUS INDICATOR K

Final Status Indicator	Final Descriptor	Final OPPS Payment Status
K	Nonpass-Through Drugs and Nonimplantable Biologicals, Including Radiopharmaceuticals	Paid under OPPS; separate APC payment.

We solicited public comments on the proposed definitions of the OPPS payment status indicators for 2025. We did not propose to make any other changes to the existing definitions of status indicators that were listed in Addendum D1 to this final rule with comment period, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices*.

Comment: Commenters were supportive of our proposed creation of status indicators ''K1'' and ''H1'' to identify the products that qualify for separate payment under our new payment policy for non-opioid post-surgical pain management drugs, biologicals, and devices, as authorized by section 4135 of the Consolidated Appropriations Act, 2023.

Response: We thank the commenters for their support.

Comment: We did not receive any specific comments regarding our proposal to revise status indicator ''K'' to remove the word ''therapeutic'' from the phrase ''therapeutic radiopharmaceuticals'' to indicate that both diagnostic and therapeutic radiopharmaceuticals may be assigned to status indicator ''K'' in accordance with our policy proposal in section II.A.3.a. of the CY 2025 OPPS/ASC proposed rule (89 FR 59427 through 59433). However, commenters were generally supportive of our proposals to pay separately for qualifying diagnostic radiopharmaceuticals as discussed in section II.A.3.a. of this final rule with comment period.

Response: We thank the commenters for their support.

After consideration of the public comments received on our proposal related to the definitions of the status indicators ''K1,'' ''H1,'' and ''K,'' we are finalizing our proposal without modification.

Additionally, in order to conform with the policy being finalized in section X.F. of this final rule with comment period, we are revising status indicator ''A'' to list HCPCS code J0799 (FDA approved prescription drug, only for use as HIV pre-exposure prophylaxis (not for use as treatment of HIV), not otherwise classified) in addition to HCPCS code C9399 (Unclassified drugs or biologicals) as the finalized policy treats the two unlisted drug related codes in a similar manner. Therefore, the definition for status indicator ''A'' will now read: ''Unclassified drugs and biologicals reportable under HCPCS code C9399 and not otherwise classified FDA-approved prescription drugs for HIV PrEP reported under HCPCS code J0799.''

We are also finalizing additional policies that exclude certain items or services from C–APC packaging, impacting the definitions of status indicators for comprehensive-APCs, as described in section II.A.2.b. We are revising the ''J1'' and ''J2'' descriptors to refer to the most recent OPPS Addendum J for a list of the C–APC exclusions rather than listing them all in the status indicator definition. Therefore, status indicator ''J1'' will be revised to: ''Paid under OPPS; all covered Part B services on the claim are packaged with the primary 'J1' service for the claim, except the Comprehensive APC payment policy exclusions found in the most recent Addendum J.'' Similarly, status indicator ''J2'' will be revised to: ''(1) Comprehensive APC payment based on OPPS comprehensive-specific payment criteria. Payment for all covered Part B services on the claim is packaged into a single payment for specific combinations of services, except the Comprehensive APC payment policy exclusions found in the most recent Addendum J.''

The complete list of CY 2025 payment status indicators and their definitions is displayed in Addendum D1 to this final rule with comment period, which is available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*.

The CY 2025 payment status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively, to this final rule with comment period, which are available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*.

B. CY 2025 Comment Indicator Definitions

We proposed to use four comment indicators for the CY 2025 OPPS. These comment indicators, ''CH,'' ''NC,'' ''NI,'' and ''NP,'' are in effect for CY 2024; and we proposed to continue their use in CY 2025. The proposed CY 2025 OPPS comment indicators are as follows:

- ''CH''—Active HCPCS code in current and next calendar year, status indicator and/or APC assignment has changed; or active HCPCS code that will be discontinued at the end of the current calendar year.
- ''NC''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year for which we requested comments in the proposed rule; final APC assignment; comments will not be accepted on the final APC assignment for the new code.
- ''NI''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year, interim APC assignment; comments will be accepted on the interim APC assignment for the new code.
- ''NP''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year, proposed APC assignment; comments will be accepted on the proposed APC assignment for the new code.

The definitions of the OPPS comment indicators for CY 2025 are listed in Addendum D2 to this final rule with comment period, which is available on

the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*.

We solicited public comments on our proposed definitions of the OPPS comment indicators for 2025.

We did not receive any public comments on our proposal and therefore, we are finalizing those definitions without modification for CY 2025.

XII. MedPAC Recommendations

The Medicare Payment Advisory Commission (MedPAC) was established under section 1805 of the Act in large part to advise the U.S. Congress on issues affecting the Medicare program. As required under the statute, MedPAC submits reports to the Congress no later than March and June of each year that present its Medicare payment policy recommendations. The March report typically provides discussion of Medicare payment policy across different payment systems and the June report typically discusses selected Medicare issues. We are including this section to make stakeholders aware of certain MedPAC recommendations for the OPPS and ASC payment systems as discussed in its March 2024 report.

A. OPPS Payment Rates Update

The March 2024 MedPAC ''Report to the Congress: Medicare Payment Policy,'' recommended that Congress update Medicare OPPS payment rates by the amount specified in current law plus 1.5 percent. We refer readers to the March 2024 report for a complete discussion of this recommendation.[182] We appreciate MedPAC's recommendation and, as discussed further in section II.B of this final rule with comment period, we proposed to increase the OPPS payment rates by the amount specified in current law. Comments received from MedPAC on other OPPS policies are discussed in the applicable sections of this final rule with comment period.

B. Medicare Safety Net Index

In the March 2024 MedPAC ''Report to the Congress: Medicare Payment Policy,'' MedPAC stated that their recommended update to IPPS and OPPS payment rates of current law plus 1.5 percent may not be sufficient to ensure the financial viability of some Medicare safety-net hospitals with a poor payer mix. MedPAC recommends redistributing the current Medicare safety-net payments (disproportionate share hospital and uncompensated care payments) using the MedPAC-developed Medicare Safety-Net Index (MSNI) for hospitals. In addition, MedPAC recommends adding $4 billion to this MSNI pool of funds to help maintain the financial viability of Medicare safety-net hospitals and recommended to the Congress transitional approaches for a MSNI policy.

As discussed in the FY 2025 IPPS/LTCH PPS final rule with comment period (89 FR 70045), we look forward to working with Congress on these matters. In the FY 2024 IPPS/LTCH PPS proposed rule, we sought comments on the challenges faced by safety-net hospitals and potential approaches to help safety net hospitals meet those challenges. These comments will inform and guide our future rulemaking and other actions in this area.

C. ASC Cost Data

In the March 2024 MedPAC ''Report to the Congress: Medicare Payment Policy,'' MedPAC reiterated its longstanding recommendation that Congress require ASCs to report cost data to enable the Commission to examine the growth of ASCs' costs over time and analyze Medicare payments relative to the costs of efficient providers. MedPAC suggested that such cost data would enable policymakers to establish payment rates that accurately reflect ASC costs and are also necessary to determine whether an existing Medicare market basket is an appropriate proxy for ASC costs or whether an ASC-specific market basket should be developed, stating both the CPI–U and hospital market basket update likely do not reflect an ASC's cost structure. MedPAC contended that it is feasible for small facilities, such as ASCs, to provide cost information since other small facilities, such as home health agencies, hospices, and rural health clinics, currently furnish cost data to CMS. Further, ASCs in Pennsylvania submit cost and revenue data annually to a state agency to estimate margins for those ASCs, and that, as businesses, ASCs keep records of their costs for filing taxes and other purposes.[183]

While we recognize that the submission of cost data could place additional administrative burden on most ASCs, and we did not propose any cost reporting requirements for ASCs in the CY 2025 OPPS/ASC proposed rule, as in previous years, we sought public comment on methods that would mitigate the burden of reporting costs on ASCs while also collecting enough data to reliably use such data in the determination of ASC costs. Such cost data would be beneficial in establishing an ASC-specific market basket for updating payment rates under the ASC payment system.

Comment: A trade group representing ASCs suggested that a starting point on reporting ASC costs could be an effort to identify and calculate expense categories as a percentage of total expenses to help determine the appropriate weights and price proxies for the ASC setting. Further, the commenter stated that cost variability can differ greatly based on specialty, facility size, geographic location, and capital equipment of the facility. One commenter recommended that any such cost data collection should be used to inform a market basket index that is applied to both HOPDs and ASCs to ensure payments are aligned over time.

Response: We appreciate the commenters' thoughtful responses. We will take these comments into consideration in future rulemaking.

Comments received from MedPAC for other ASC payment system policies are discussed in the applicable sections of this final rule with comment period.

XIII. Updates to the Ambulatory Surgical Center (ASC) Payment System

A. Background, Legislative History, Statutory Authority, and Prior Rulemaking for the ASC Payment System

For a detailed discussion of the legislative history and statutory authority related to payments to ASCs under Medicare, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74377 through 74378) and the June 12, 1998 proposed rule (63 FR 32291 through 32292). For a discussion of prior rulemaking on the ASC payment system, we refer readers to the CYs 2012 to 2024 OPPS/ASC final rules with comment period (76 FR 74378 through 74379; 77 FR 68434 through 68467; 78 FR 75064 through 75090; 79 FR 66915 through 66940; 80 FR 70474 through 70502; 81 FR 79732 through 79753; 82 FR 59401 through 59424; 83 FR 59028 through 59080; 84 FR 61370 through 61410; 85 FR 86121 through 86179; 86 FR 63761 through 63815; 87 FR 72054 through 72096; and 88 FR 81900 through 81961).

[182] Medicare Payment Advisory Committee. March 2024 Report to the Congress. Chapter 3: Hospital inpatient and outpatient services, p.49. Available at: *https://www.medpac.gov*.

[183] Medicare Payment Advisory Committee. March 2024 Report to the Congress. Chapter 10: Ambulatory surgical center services: Status report, p.297. Available at: *https://www.medpac.gov/wp-content/uploads/2024/03/Mar24_MedPAC_Report_To_Congress_SEC.pdf*.

B. ASC Treatment of New and Revised Codes

1. Background on Process for New and Revised HCPCS Codes

We update the lists and payment rates for covered surgical procedures and covered ancillary services in ASCs in conjunction with the annual proposed and final rulemaking process to update the OPPS and the ASC payment systems (§ 416.173; 72 FR 42535). We base ASC payment and policies for most covered surgical procedures, drugs, biologicals, and certain other covered ancillary services on the OPPS payment policies and we use quarterly change requests (CRs) to update services paid for under the OPPS. We also provide quarterly update CRs for ASC covered surgical procedures and covered ancillary services throughout the year (January, April, July, and October). We release new and revised Level II HCPCS codes and recognize the release of new and revised CPT codes by the American Medical Association (AMA) and make these codes effective (that is, the codes are recognized on Medicare claims) via these ASC quarterly update CRs. We recognize the release of new and revised Category III CPT codes in the July and January CRs. These updates implement newly created and revised Level II HCPCS and Category III CPT codes for ASC payments and update the payment rates for separately paid drugs and biologicals based on the most recently submitted ASP data. New and revised Category I CPT codes, except vaccine codes, are released only once a year, and are implemented only through the January quarterly CR update. New and revised Category I CPT vaccine codes are released twice a year and are implemented through the January and July quarterly CR updates. We refer readers to Table 41 in the CY 2012 OPPS/ASC proposed rule for an example of how this process is used to update HCPCS and CPT codes, which we finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 42291; 76 FR 74380 through 74384).

In our annual updates to the ASC list of, and payment rates for, covered surgical procedures and covered ancillary services, we undertake a review of excluded surgical procedures, new codes, and codes with revised descriptors, to identify any that we believe meet the criteria for designation as ASC covered surgical procedures or covered ancillary services. Updating the lists of ASC covered surgical procedures and covered ancillary services, as well as their payment rates, in association with the annual OPPS rulemaking cycle, is particularly important because the OPPS relative payment weights and, in some cases, payment rates, are used as the basis for the payment of many covered surgical procedures and covered ancillary services under the revised ASC payment system. This joint update process ensures that the ASC updates occur in a regular, predictable, and timely manner.

Payment for ASC procedures, services, and items are generally based on medical billing codes, specifically, HCPCS codes, that are reported on ASC claims. The HCPCS is divided into two principal subsystems, referred to as Level I and Level II. Level I is comprised of CPT (Current Procedural Terminology) codes, a numeric and alphanumeric coding system maintained by the AMA, and includes Category I, II, and III CPT codes. Level II of the HCPCS, which is maintained by CMS, is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes. Together, Level I and II HCPCS codes are used to report procedures, services, items, and supplies under the ASC payment system. Specifically, we recognize the following codes on ASC claims:

- Category I CPT codes, which describe surgical procedures, diagnostic and therapeutic services, and vaccine codes;
- Category III CPT codes, which describe new and emerging technologies, services, and procedures; and
- Level II HCPCS codes (also known as alpha-numeric codes), which are used primarily to identify drugs, devices, supplies, temporary procedures, and services not described by CPT codes.

We finalized a policy in the August 2, 2007 final rule (72 FR 42533 through 42535) to evaluate each year all new and revised Category I and Category III CPT codes and Level II HCPCS codes that describe surgical procedures, and to make preliminary determinations during the annual OPPS/ASC rulemaking process regarding whether or not they meet the criteria for payment in the ASC setting as covered surgical procedures and, if so, whether or not they are office-based procedures. In addition, we identify new and revised codes as ASC covered ancillary services based upon the final payment policies of the revised ASC payment system. In prior rulemakings, we refer to this process as recognizing new codes. However, this process has always involved the recognition of new and revised codes. We consider revised codes to be new when they have substantial revision to their code descriptors that necessitate a change in the current ASC payment indicator. To clarify, we refer to these codes as new and revised in this CY 2025 OPPS/ASC final rule.

We have separated our discussion below based on when the codes are released and whether we propose to solicit public comments in the proposed rule (and respond to those comments in this final rule with comment period) or whether we will be soliciting public comments in this CY 2025 OPPS/ASC final rule with comment period (and responding to those comments in the CY 2026 OPPS/ASC final rule with comment period).

2. April 2024 HCPCS Codes Proposed Rule Comment Solicitation

For the April 2024 update, there were no new CPT codes; however, there were several new Level II HCPCS codes. In the April 2024 ASC quarterly update (Transmittal 12559, dated March 28, 2024, CR 13577), we added several new Level II HCPCS codes to the list of covered ancillary services. Table 147 (New Level II HCPCS Codes for Ancillary Services Effective April 1, 2024) of the CY 2025 OPPS/ASC proposed rule (89 FR 59408), displayed the new Level II HCPCS codes that were implemented April 1, 2024. These new codes that were effective April 1, 2024, were assigned to comment indicator ''NP'' in Addendum BB to the proposed rule to indicate that the codes were assigned to an interim APC assignment and that comments would be accepted on their interim APC assignments. In addition, we note that the entire ASC addenda, which consist of the addenda listed below, are available via the internet on the CMS website, specifically, at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*:

- ASC Addendum AA: ASC Covered Surgical Procedures (Including Surgical Procedures for Which Payment is Packaged).
- ASC Addendum BB: ASC Covered Ancillary Services Integral to Covered Surgical Procedures (Including Ancillary Services for Which Payment is Packaged).
- ASC Addendum DD1: ASC Payment Indicators (PI).
- ASC Addendum DD2: ASC Comment Indicators (CI).
- ASC Addendum EE: Surgical Procedures to be Excluded from Payment in ASCs
- ASC Addendum FF: ASC Device Offset Percentages.
- Addendum O: Long Descriptors for New Category I CPT Codes, Category III

CPT Codes, C-codes, and G-Codes Effective January 1, 2025.

We invited public comments on the proposed payment indicators for the new HCPCS codes that were recognized as ASC covered ancillary services in April 2024 through the quarterly update CRs, as listed in Table 147 (New Level II HCPCS Codes for Ancillary Services Effective April 1, 2024). The new codes that were effective April 1, 2024, were assigned to comment indicator ''NP'' in ASC Addendum BB to the CY 2025 OPPS/ASC proposed rule to indicate that the codes are assigned to interim payment indicators and comments would be accepted on their interim assignments. We proposed to finalize the payment indicators in this CY 2025 OPPS/ASC final rule with comment period. We did not receive any comments on the proposed ASC payment indicator assignments for the new Level II HCPCS codes implemented in April 2024 and are finalizing the proposed ASC payment indicator assignments for these codes.

We note that several of the temporary drug HCPCS C-codes have been replaced with permanent drug HCPCS J-codes. Their replacement codes are also listed in Table 147. In addition, although in prior years we included the final ASC payment indicators in the coding tables in the preamble, because we include the same information in the ASC addenda, we have not included them in Table 147. Therefore, readers are advised to refer to the ASC addenda for the final ASC payment indicators and payment rates for all codes reported under the ASC payment system. The list of ASC payment indicators and definitions used under the ASC payment system can be found in the ASC addenda. We note that the ASC addenda (AA, BB, DD1, DD2, EE, and FF) are available via the internet on the CMS website.

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TABLE 147: NEW LEVEL II HCPCS CODES FOR ASC COVERED ANCILLARY SERVICES EFFECTIVE APRIL 1, 2024

April 2024 HCPCS Code	CY 2025 HCPCS Code	CY 2025 Long Descriptor
C9166	C9166	Injection, secukinumab, intravenous, 1 mg
C9167	C9167	Injection, adamts13, recombinant-krhn, 10 iu
C9168	C9168	Injection, mirikizumab-mrkz, 1 mg
C9161	J0177	Injection, aflibercept hd, 1 mg
J0577	J0577	Injection, buprenorphine extended-release (brixadi), less than or equal to 7 days of therapy
J0578	J0578	Injection, buprenorphine extended release (brixadi), greater than 7 days and up to 28 days of therapy
C9160	J0589	Injection, daxibotulinumtoxina-lanm, 1 unit
J0651	J0651	Injection, levothyroxine sodium (fresenius kabi) not therapeutically equivalent to J0650, 10 mcg
J0652	J0652	Injection, levothyroxine sodium (hikma) not therapeutically equivalent to J0650, 10 mcg
J1203	J1203	Injection, cipaglucosidase alfa-atga, 5 mg
C9165	J1323	Injection, elranatamab-bcmm, 1 mg
J2277	J2277	Injection, motixafortide, 0.25 mg
C9162	J2782	Injection, avacincaptad pegol, 0.1 mg
J2801	J2801	Injection, risperidone (rykindo), 0.5 mg
C9163	J3055	Injection, talquetamab-tgvs, 0.25 mg
J3424	J3424	Injection, hydroxocobalamin, intravenous, 10 grams
C9159	J7165	Injection, prothrombin complexconcentrate, human-lans, per i.u. of factor ix activity
C9164	J7354	Cantharidin for topical administration, 0.7%, single unit dose applicator (3.2 mg)
J9073	J9073	Injection, cyclophosphamide (ingenus), 5 mg
J9075	J9075	Injection, cyclophosphamide, not otherwise specified, 5 mg
J9248	J9248	Injection, melphalan (hepzato), 1 mg
Q4305	Q4305	American amnion ac tri-layer, per square centimeter
Q4306	Q4306	American amnion ac, per square centimeter
Q4307	Q4307	American amnion, per square centimeter
Q4308	Q4308	Sanopellis, per square centimeter
Q4309	Q4309	Via matrix, per square centimeter
Q4310	Q4310	Procenta, per 100 mg

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3. July 2024 HCPCS Codes Proposed Rule Comment Solicitation

In the July 2024 ASC quarterly update (Transmittal 12673, Change Request 13656, dated June 13, 2024), we added several separately payable CPT and Level II HCPCS codes to the list of covered surgical procedures and covered ancillary services. Table 76 (New HCPCS Codes for Covered Surgical Procedures and Covered Ancillary Services Effective July 1, 2024) of the CY 2025 OPPS/ASC proposed rule (89 FR 59409), displayed the new HCPCS codes that are effective July 1, 2024. We invited public comments on the proposed payment indicators for these Level II HCPCS codes, and indicated that the proposed comment indicators, payment indicators, and payment rates for these codes were listed in Addendum AA and Addendum BB of the proposed rule. These new codes that were effective July 1, 2024, were assigned to comment indicator ''NP'' in ASC Addendum AA and Addendum BB to the CY 2025 OPPS/ASC proposed rule to indicate that the codes were assigned to interim payment indicators and comments would be accepted on their interim

assignments. We further stated that we proposed to finalize the payment indicators in this CY 2025 OPPS/ASC final rule with comment period. We note that several of the temporary drug HCPCS C-codes have been replaced with HCPCS J-codes. Their replacement codes are also listed in Table 148. In addition, in prior years we included the final ASC payment indicators in the coding preamble tables, however, because the same information can be found in Addendum AA and Addendum BB, we are no longer including them in Table 148. Therefore, readers are advised to refer to the ASC addenda for the final ASC payment indicators and payment rates for all codes reported under the ASC payment system.

We did not receive any comments on the proposed ASC payment indicator assignments for the new Level II HCPCS codes that were added to the list of covered surgical procedures and ancillary services implemented in July 2024. Therefore, we are finalizing the proposed ASC payment indicator assignments for the codes.

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TABLE 148: NEW LEVEL II HCPCS CODES FOR ASC COVERED SURGICAL PROCEDURES AND ANCILLARY SERVICES EFFECTIVE JULY 1, 2024

July 2024 HCPCS Code	CY 2025 HCPCS Code	CY 2025 Long Descriptor
A9506	A9506	Graphite crucible for preparation of technetium Tc 99m-labeled carbon aerosol, each
C1605	C1605	Pacemaker, leadless, dual chamber (right atrial and right ventricular implantable components), rate-responsive, including all necessary components for implantation
C1606	C1606	Adapter, single-use (i.e. disposable), for attaching ultrasound system to upper gastrointestinal endoscope
J0211	J0211	Injection, sodium nitrite 3 mg and sodium thiosulfate 125 mg (nithiodote)
J0687	J0687	Injection, cefazolin sodium (wg critical care), not therapeutically equivalent to j0690, 500 mg
J0872	J0872	Injection, daptomycin (xellia), unrefrigerated, not therapeutically equivalent to j0878 or j0873, 1 mg
J0911	J0911	Instillation, taurolidine 1.35 mg and heparin sodium 100 units (central venous catheter lock for esrd on dialysis adult patients receiving chronic hemodialysis)
C9166	J3247	Injection, secukinumab, intravenous, 1 mg
J3263	J3263	Injection, toripalimab-tpzi, 1 mg
J3393	J3393	Injection, betibeglogene autotemcel, per treatment
J3394	J3394	Injection, lovotibeglogene autotemcel, per treatment
C9167	J7171	Injection, adamts13, recombinant-krhn, 10 iu
J7355	J7355	Injection, travoprost, intracameral implant, 1 microgram
J8611	J8611	Methotrexate (jylamvo), oral, 2.5 mg
J8612	J8612	Methotrexate (xatmep), oral, 2.5 mg
0621T	0621T	Trabeculostomy ab interno by laser;
0867T	0867T	Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance; prostate volume greater than or equal to 50 mL
0869T	0869T	Injection(s), bone-substitute material for bone and/or soft tissue hardware fixation augmentation, including intraoperative imaging guidance, when performed
0884T	0884T	Esophagoscopy, flexible, transoral, with initial transendoscopic mechanical dilation (eg, nondrug-coated balloon) followed by therapeutic drug delivery by drug-coated balloon catheter for esophageal stricture, including fluoroscopic guidance, when performed
0885T	0885T	Colonoscopy, flexible, with initial transendoscopic mechanical dilation (eg, nondrug-coated balloon) followed by therapeutic drug delivery by drug-coated balloon catheter for colonic stricture, including fluoroscopic guidance, when performed
0886T	0886T	Sigmoidoscopy, flexible, with initial transendoscopic mechanical dilation (eg, nondrug-coated balloon) followed by therapeutic drug delivery by drug-coated balloon catheter for colonic stricture, including fluoroscopic guidance, when performed
0888T	0888T	Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant renal tissue, including imaging guidance

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4. October 2024 HCPCS Codes Final Rule Comment Solicitation

For CY 2025, consistent with our established policy, we proposed in the CY 2025 OPPS/ASC proposed rule (89 FR 59410) that the Level II HCPCS codes that will be effective October 1, 2024, would be flagged with comment indicator ''NI'' in Addendum BB to the CY 2025 OPPS/ASC final rule with comment period to indicate that we have assigned the codes an interim ASC payment status for CY 2025. In the October 2024 ASC quarterly update (Transmittal 12824, Change Request 13800, dated September 5, 2024), we added several separately payable Level II HCPCS codes to the list of covered surgical procedures and covered ancillary services. Table 149 below lists the codes that were effective October 1, 2024. We are inviting public comments on this final rule with comment period on the interim payment indicators, which would be finalized in the CY 2026 OPPS/ASC final rule with comment period. We note these codes will be subject to comment in the CY 2026 OPPS/ASC proposed rule with comment period, which would be finalized in the CY 2026 OPPS/ASC final rule with comment period.

TABLE 149: NEW LEVEL II HCPCS CODES FOR ASC COVERED ANCILLARY SERVICES EFFECTIVE OCTOBER 1, 2024

October 2024 HCPCS Code	CY 2025 HCPCS Code	CY 2025 Long Descriptor
C9169	C9169	Injection, nogapendekin alfa inbakiceptpmln, for intravesical use, 1 microgram
C9170	C9170	Injection, tarlatamab-dlle, 1 mg
C9171	C9171	Injection, pegulicianine, 1 mg
C9172	C9172	Injection, fidanacogene elaparvovecdzkt, per therapeutic dose
J1434	J1434	Injection, fosaprepitant (focinvez), 1 mg
J2601	J2601	Injection, vasopressin (baxter), 1 unit
J9172	J9172	Injection, docetaxel (avyxa) not therapeutically equivalent to J9171, 1 mg
J9324	J9324	Injection, pemetrexed (pemrydi rtu), 10 mg
Q5133	Q5133	Injection, tocilizumab-bavi (tofidence), biosimilar, 1 mg
Q5135	Q5135	Injection, tocilizumab-aazg (tyenne), biosimilar, 1 mg

5. January 2025 HCPCS Codes

a. New Level II HCPCS Codes Final Rule Comment Solicitation

As has been our practice in the past, we incorporate those new Level II HCPCS codes that are effective January 1 in the final rule with comment period, thereby updating the ASC payment system for the calendar year. We note that unlike the CPT codes that are effective January 1 and are included in the OPPS/ASC proposed rules, and except for the G-codes listed in Addendum O to the CY 2025 OPPS/ASC proposed rule, most Level II HCPCS codes are not released until sometime around November to be effective January 1. Because these codes are not available until November, we are unable to include them in the OPPS/ASC proposed rule; however, the codes are flagged with comment indicator ''NI'' in ASC Addendum AA and Addendum BB to this final rule with comment period to indicate that we are assigning them an interim payment status, which is subject to public comment. Therefore, as we stated in the CY 2025 OPPS/ASC proposed rule, these Level II HCPCS codes that will be effective January 1, 2025, are included in this final rule with comment period and will also be released to the public through in the January 2025 ASC Update CR and the CMS HCPCS website. We are inviting public comments in this final rule with comment period on the payment indicator assignments, which would be finalized in the CY 2026 OPPS/ASC final rule with comment period. Similar to the codes effective October 1, 2024, these new Level II HCPCS codes that will be effective January 1, 2025, will be subject to comment in the CY 2026 OPPS/ASC proposed rule, which would

be finalized in the CY 2026 OPPS/ASC final rule with comment period.

b. New CY 2025 CPT Codes Proposed Rule Comment Solicitation

For the CY 2025 ASC update, we received the CPT codes that will be effective January 1, 2025, from the AMA in time to be included in the CY 2025 OPPS/ASC proposed rule. The new, revised, and deleted CPT codes can be found in ASC Addendum AA and Addendum BB to the CY 2024 OPPS/ASC proposed rule, which are available via the internet on the CMS website. We note that the new and revised CPT codes are assigned to comment indicator ''NP'' in ASC Addendum AA and Addendum BB of the CY 2025 OPPS/ASC proposed rule to indicate that the code is new for the next calendar year, or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to the current calendar year with a proposed payment indicator assignment. We stated that we would accept comments and finalize the payment indicators in this CY 2025 OPPS/ASC final rule with comment period. Further, we remind readers that the CPT code descriptors that appeared in Addendum AA and Addendum BB are short descriptors and do not describe the complete procedure, service, or item described by the CPT code. Therefore, we included the 5-digit placeholder codes and their long descriptors for the new CY 2025 CPT codes in Addendum O to the CY 2025 OPPS/ASC proposed rule so that the public could comment on our proposed payment indicator assignments. The 5-digit placeholder codes were listed in Addendum O to the CY 2025 OPPS/ASC proposed rule, specifically under the column labeled ''CY 2025 OPPS/ASC Proposed Rule 5-Digit Placeholder Code.'' We also stated that we would include the final CPT code numbers in this CY 2025 OPPS/ASC final rule with comment period.

We did not receive any comments on the proposed ASC payment indicators for the new CPT codes effective January 1, 2025, so we are finalizing these codes as proposed.

Finally, in Table 150, we summarize our process for updating codes through our ASC quarterly update CRs, seeking public comments, and finalizing the treatment of these new codes under the ASC payment system.

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TABLE 150: COMMENT AND FINALIZATION TIMEFRAMES FOR NEW AND REVISED ASC-RELATED HCPCS CODES

ASC Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 2024	HCPCS (CPT and Level II codes)	April 1, 2024	CY 2025 OPPS/ASC proposed rule	CY 2025 OPPS/ASC final rule with comment period
July 2024	HCPCS (CPT and Level II codes)	July 1, 2024	CY 2025 OPPS/ASC proposed rule	CY 2025 OPPS/ASC final rule with comment period
October 2024	HCPCS (CPT and Level II codes)	October 1, 2024	CY 2025 OPPS/ASC final rule with comment period	CY 2026 OPPS/ASC final rule with comment period
January 2025	CPT Codes	January 1, 2025	CY 2025 OPPS/ASC proposed rule	CY 2025 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2025	CY 2025 OPPS/ASC final rule with comment period	CY 2026 OPPS/ASC final rule with comment period

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6. ASC Payment and Comment Indicators

a. Background

In addition to the payment indicators that we introduced in the August 2, 2007 ASC final rule, we created final comment indicators for the ASC payment system in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66855). We created Addendum DD1 to define ASC payment indicators that we use in Addenda AA and BB to provide payment information regarding covered surgical procedures and covered ancillary services, respectively, under the revised ASC payment system. The ASC payment indicators in Addendum DD1 are intended to capture policy-relevant characteristics of HCPCS

codes that may receive packaged or separate payment in ASCs, such as whether they were on the ASC CPL prior to CY 2008; payment designation, such as device-intensive or office-based, and the corresponding ASC payment methodology; and their classification as separately payable ancillary services, including radiology services, brachytherapy sources, OPPS pass-through devices, corneal tissue acquisition services, drugs or biologicals, or NTIOLs.

We also created Addendum DD2 that lists the ASC comment indicators. The ASC comment indicators included in Addenda AA and BB to the proposed rules and final rules with comment period serve to identify, for the revised ASC payment system, the status of a specific HCPCS code and its payment indicator with respect to the timeframe when comments will be accepted. The comment indicator ''NI'' is used in the OPPS/ASC final rule with comment period to indicate new codes for the next calendar year for which the interim payment indicator assigned is subject to comment. The comment indicator ''NI'' also is assigned to existing codes with substantial revisions to their descriptors such that we consider them to be describing new services, and the interim payment indicator assigned is subject to comment, as discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60622).

The comment indicator ''NP'' is used in the OPPS/ASC proposed rule to indicate new codes for the next calendar year for which the proposed payment indicator assigned is subject to comment. The comment indicator ''NP'' also is assigned to existing codes with substantial revisions to their descriptors, such that we consider them to be describing new services, and the proposed payment indicator assigned is subject to comment, as discussed in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70497).

The ''CH'' comment indicator is used in Addenda AA and BB to the proposed rule (these addenda are available via the internet on the CMS website) to indicate that the payment indicator assignment has changed for an active HCPCS code in the current year and the next calendar year, for example, if an active HCPCS code is newly recognized as payable in ASCs or an active HCPCS code is discontinued at the end of the current calendar year. The ''CH'' comment indicators that are published in the final rule are provided to alert readers that a change has been made from one calendar year to the next, but do not indicate that the change is subject to comment.

In the CY 2021 OPPS/ASC final rule with comment period, we finalized the addition of ASC payment indicator ''K5''—Items, Codes, and Services for which pricing information and claims data are not available. No payment made.—to ASC Addendum DD1 (which is available via the internet on the CMS website) to indicate those services and procedures that CMS anticipates will become payable when claims data or payment information becomes available.

In CY 2024 OPPS/ASC final rule with comment period, we finalized the addition of two ASC payment indicators, ''D1''—''Ancillary dental service/item; no separate payment made'' and ''D2''—''Non office-based dental procedure added in CY 2024 or later'', for new dental codes for CY 2024 and subsequent calendar years to indicate potentially payable dental services and procedures in the ASC setting (88 FR 81907). We added these two codes to Addendum DD1 (which is available via the internet on the CMS website).

b. Final ASC Payment and Comment Indicators for CY 2025

For CY 2025, we proposed new and revised Category I and III CPT codes as well as new and revised Level II HCPCS codes. Proposed Category I and III CPT codes that are new and revised for CY 2025 and any new and existing Level II HCPCS codes with substantial revisions to the code descriptors for CY 2025, compared to the CY 2024 descriptors, are included in ASC Addenda AA and BB to the CY 2025 OPPS/ASC proposed rule and labeled with comment indicator ''NP'' to indicate that these CPT and Level II HCPCS codes are open for comment as part of the CY 2025 OPPS/ASC proposed rule.

We proposed to modify the descriptor of ASC payment indicator ''L6''—''New Technology Intraocular Lens (NTIOL); special payment'' to ''Special payment; New Technology Intraocular Lens (NTIOL) or qualifying non-opioid devices'', to account for non-opioid devices paid for under the ASC payment system pursuant to section 4135 of the CAA, 2023. More information about this non-opioid policy can be found in section XIII.E of this final rule with comment period.

We refer readers to Addenda DD1 and DD2 of this final rule with comment period (these addenda are available via the internet on the CMS website) for the complete list of ASC payment and comment indicators proposed for the CY 2025 update.

We did not receive any public comments on our proposal and therefore, we are finalizing our proposal to modify the descriptor of ASC payment indicator ''L6''—''New Technology Intraocular Lens (NTIOL); special payment'' to ''Special payment; New Technology Intraocular Lens (NTIOL) or qualifying non-opioid devices'', to account for non-opioid devices paid for under the ASC payment system pursuant to section 4135 of the CAA, 2023.

C. Payment Policies Under the ASC Payment System

1. Final ASC Payment for Covered Surgical Procedures

a. Background

Our ASC payment policies for covered surgical procedures under the revised ASC payment system are described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66828 through 66831). Under our established policy, we use the ASC standard ratesetting methodology of multiplying the ASC relative payment weight for the procedure by the ASC conversion factor for that same year to calculate the national unadjusted payment rates for procedures with payment indicators ''G2'' and ''A2.'' Payment indicator ''A2'' was developed to identify procedures that were included on the list of ASC covered surgical procedures in CY 2007 and, therefore, were subject to transitional payment prior to CY 2011. Although the 4-year transitional period has ended and payment indicator ''A2'' is no longer required to identify surgical procedures subject to transitional payment, we have retained payment indicator ''A2'' because it is used to identify procedures that are exempted from the application of the office-based designation.

Payment rates for office-based procedures (payment indicators ''P2,'' ''P3,'' and ''R2'') are the lower of the PFS nonfacility PE RVU-based amount or the amount calculated using the ASC standard rate setting methodology for the procedure. As detailed in section XIII.C.3.b of this final rule with comment period, we update the payment amounts for office-based procedures (payment indicators ''P2,'' ''P3,'' and ''R2'') using the most recent available MPFS and OPPS data. We compare the estimated current year rate for each of the office-based procedures, calculated according to the ASC standard rate setting methodology, to the PFS nonfacility PE RVU-based amount to determine which is lower and, therefore, would be the current year payment rate for the procedure under our final policy for the revised ASC payment system (§ 416.171(d)).

The rate calculation established for device-intensive procedures (payment indicator ''J8'') is structured so only the service (non-device) portion of the rate is subject to the ASC conversion factor. We update the payment rates for device-intensive procedures to incorporate the most recent device offset percentages calculated under the ASC standard ratesetting methodology, as discussed in section XIII.C.4 of this final rule with comment period.

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75081), we finalized our proposal to calculate the CY 2014 payment rates for ASC covered surgical procedures according to our established methodologies, with the exception of device removal procedures. For CY 2014, we finalized a policy to conditionally package payment for device removal procedures under the OPPS. Under the OPPS, a conditionally packaged procedure (status indicators ''Q1'' and ''Q2'') describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a covered surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are always packaged (payment indicator ''N1'') under the ASC payment system. Under the OPPS, device removal procedures are conditionally packaged and, therefore, would be packaged under the ASC payment system. There is no Medicare payment made when a device removal procedure is performed in an ASC without another surgical procedure included on the claim; therefore, no Medicare payment would be made if a device was removed but not replaced. To ensure that the ASC payment system provides separate payment for surgical procedures that only involve device removal—conditionally packaged in the OPPS (status indicator ''Q2'')—we have continued to provide separate payment since CY 2014 and assign the current ASC payment indicators associated with these procedures.

b. Update to ASC Covered Surgical Procedure Payment Rates for CY 2025

We proposed to update ASC payment rates for CY 2025 and subsequent years using the established rate calculation methodologies under § 416.171 and using our definition of device-intensive procedures, as discussed in section XIII.C.4 of this final rule with comment period. As the proposed OPPS relative payment weights are generally based on geometric mean costs, we proposed that the ASC payment system will generally use the geometric mean cost to determine proposed relative payment weights under the ASC standard methodology. We proposed to continue to use the amount calculated under the ASC standard ratesetting methodology for procedures assigned payment indicators ''A2'' and ''G2.''

We proposed to calculate payment rates for office-based procedures (payment indicators ''P2,'' ''P3,'' and ''R2'') and device-intensive procedures (payment indicator ''J8'') according to our established policies and to identify device-intensive procedures using the methodology discussed in section XIII.C.4 of this final rule with comment period. Therefore, we proposed to update the payment amount for the service portion (the non-device portion) of the device-intensive procedures using the standard ASC ratesetting methodology and the payment amount for the device portion based on the proposed CY 2025 device offset percentages that have been calculated using the standard OPPS APC ratesetting methodology. We proposed that payment for office-based procedures would be at the lesser of the proposed CY 2025 MPFS nonfacility PE RVU-based amount or the proposed CY 2025 ASC payment amount calculated according to the ASC standard ratesetting methodology.

As we did for CYs 2014 through 2024, for CY 2025, we proposed to continue our policy for device removal procedures, such that device removal procedures that are conditionally packaged in the OPPS (status indicators ''Q1'' and ''Q2'') will be assigned the current ASC payment indicators associated with those procedures and will continue to be paid separately under the ASC payment system.

Comment: One commenter expressed concern about the lack of a cap on beneficiary coinsurance in the ASC setting while there is a statutory cap on beneficiary coinsurance when a procedure is performed in the HOPD setting. The commenter believes the lack of such a cap poses a financial challenge for beneficiaries, particularly with respect to transitional pass-through devices and higher-cost procedures that are device intensive, because in such cases, the coinsurance could be higher in the ASC setting than in the HOPD setting.

Response: We thank the commenter for its input but note that comments related to statutory changes are out of scope for this final rule.

After consideration of the public comments we received, we are finalizing our proposed policies without modification to calculate the CY 2025 payment rates for ASC covered surgical procedures according to our established rate calculation methodologies under § 416.171 and our device-intensive methodology as discussed in section XIII.C.1.b. of this CY 2025 OPPS/ASC final rule with comment period. For covered office-based surgical procedures, the payment rate is the lesser of the final CY 2025 MPFS nonfacility PE RVU-based amount or the CY 2025 ASC payment amount calculated according to the ASC standard ratesetting methodology. The final payment indicators and rates set forth in this final rule with comment period are based on a comparison using the PFS PE RVUs and the conversion factor effective January 1, 2025.

c. Final Payment for ASC Add-On Procedures Eligible for Complexity Adjustments Under the OPPS

In this section, we discuss the policy to provide increased payment under the ASC payment system for combinations of certain ''J1'' service codes and add-on procedure codes that are eligible for a complexity adjustment under the OPPS.

(1) OPPS C–APC Complexity Adjustment Policy

Under the OPPS, complexity adjustments are utilized to provide increased payment for certain comprehensive services. As discussed in section II.A.2.b of this final rule with comment period, we apply a complexity adjustment by promoting qualifying paired ''J1'' service code combinations or paired code combinations of ''J1'' services and add-on codes from the originating Comprehensive APC (C–APC) (the C–APC to which the designated primary service is first assigned) to the next higher paying C–APC in the same clinical family of C–APCs. A ''J1'' status indicator refers to a hospital outpatient service paid through a C–APC. We package payment for all add-on codes, which are codes that describe a procedure or service always performed in addition to a primary service or procedure, into the payment for the C–APC. However, certain combinations of primary service codes and add-on codes may qualify for a complexity adjustment.

We apply complexity adjustments when the paired code combination represents a complex, costly form or version of the primary service when the frequency and cost thresholds are met. The frequency threshold is met when there are 25 or more claims reporting the code combination, and the cost threshold is met when there is a violation of the 2 times rule, as specified in section 1833(t)(2) of the Act and

described in section III.A.2.b of this final rule with comment period, in the originating C–APC. These paired code combinations that meet the frequency and cost threshold criteria represent those that exhibit materially greater resource requirements than the primary service. After designating a single primary service for a claim, we evaluate that service in combination with each of the other procedure codes reported on the claim that are either assigned to status indicator ''J1'' or add-on codes to determine if there are paired code combinations that meet the complexity adjustment criteria. Once we have determined that a particular combination of ''J1'' services, or combinations of a ''J1'' service and add-on code, represents a complex version of the primary service because it is sufficiently costly, frequent, and a subset of the primary comprehensive service overall according to the criteria described previously, we promote the claim to the next higher cost C–APC within the clinical family unless the primary service is already assigned to the highest cost APC within the C–APC clinical family or assigned to the only C–APC in a clinical family. We do not create new C–APCs with a comprehensive geometric mean cost that is higher than the highest geometric mean cost (or only) C–APC in a clinical family just to accommodate potential complexity adjustments. Therefore, the highest payment for any claim including a code combination for services assigned to a C–APC would be the highest paying C–APC in the clinical family (79 FR 66802).

As previously stated, we package payment for add-on codes into the C–APC payment rate. If any add-on code reported in conjunction with the ''J1'' primary service code does not qualify for a complexity adjustment, payment for the add-on service continues to be packaged into the payment for the primary service and the primary service code reported with the add-on code is not reassigned to the next higher cost C–APC. We list the final complexity adjustments for ''J1'' and add-on code combinations for CY 2025, along with all of the other final complexity adjustments, in Addendum J to this final rule with comment period (which is available via the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*).

(2) CY 2025 ASC Special Payment Policy for OPPS Complexity-Adjusted C–APCs

For CY 2025, we proposed to continue the special payment policy and methodology for OPPS complexity-adjusted C–APCs that was finalized in the CY 2023 OPPS/ASC final rule with comment period (87 FR 72078 through 72080).

For those ASC complexity adjustment codes for which we have claims data, we proposed to use the claims data to calculate the code combination utilization and estimated payments for the ASC payment system budget neutrality calculations for CY 2025. The ASC complexity adjustment budget neutrality calculations are discussed further in section XIII.H.2.a of this final rule with comment period. The full list of the proposed ASC complexity adjustment codes for CY 2025 can be found in the CY 2025 proposed ASC addenda and the supplemental policy file, which also includes both the existing ASC complexity adjustment codes and proposed additions and was published on the CMS website at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/ascpayment/asc-regulations-and-notices*. Since the complexity adjustment assignments change each year under the OPPS, the proposed list of ASC complexity adjustment codes eligible for the proposed payment policy changed slightly from the previous year.

Comment: A few commenters noted that there was a decline in the number of ASC complexity adjustment codes for the CY 2025 OPPS/ASC proposed rule compared to years prior. The commenters noted that there were 55 ASC complexity adjustment codes in 2023, 47 ASC complexity adjustment codes in 2024, and only 45 ASC proposed complexity adjustment codes for CY 2025. Other commenters recommended specific ASC complexity adjustment codes we did not propose.

Several commenters were concerned with how the device portion for ASC complexity adjustment codes are determined. Commenters believed we were potentially missing large device costs associated with the packaged add-on procedure that could only be realized if the device offset percentage of the ASC complexity adjustment code was calculated from the subset of ''J1'' primary service and add-on code claim combinations.

Response: Since the number of OPPS complexity adjustments fluctuate on a year-to-year basis, the number of ASC complexity adjustment codes will also fluctuate each calendar year. For this CY 2025 OPPS/ASC final rule with comment period, we are finalizing 49 ASC complexity adjustment codes, which is an increase from the 47 ASC complexity adjustment codes for CY 2024. Additionally, we rely on the complexity adjustment criteria under the OPPS, as described in section II.A.2.b. of this final rule with comment period, for determining eligible ASC complexity adjustment codes under the ASC payment system and do not accept specific code combination recommendations, such as those recommended by commenters, if they do not meet these criteria.

With respect to the commenters' concerns regarding the device portion of ASC complexity adjustment codes, we believe the current methodology of assigning the device portion from the primary ''J1'' procedure to the ASC complexity adjustment code is the most appropriate. As shown in Addendum J (which can be found on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*), the evaluation subset for a ''J1'' and add-on code combination is often less than 100 claims and can be significantly less than the total number of claims for that primary ''J1'' procedure used for ratesetting. We are concerned that using such a small subset of a procedure's available claims for determining the device portion of a device-intensive ASC complexity adjustment code would introduce unnecessary volatility. We believe that assigning a device portion for a device-intensive ASC complexity adjustment code based on the device portion of the primary ''J1'' procedure accurately reflects the device costs of the primary ''J1'' procedure—since the device costs associated with the add-on code are already packaged into the cost of the primary procedure—and provides a more stable payment rate by using the greater number of claims that are available from the primary ''J1'' procedure, as opposed to the subset of claims with a ''J1'' and add-on code combination. However, we appreciate the commenters' recommendation and may take this comment into consideration in future rulemaking.

After consideration of the public comments we received, we are finalizing the ASC special payment policy for OPPS complexity-adjusted C–APCs, as proposed. The final ASC complexity adjustment codes, based on the most recent data available for this CY 2025 OPPS/ASC final rule with comment period, can be found on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-*

payment-systems/ambulatory-surgical-center-asc/annual-policy-files. Existing ASC complexity adjustment codes that do not meet our criteria for separate payment for CY 2025 because the code combination is not eligible for a complexity adjustment under the OPPS for CY 2025 will be non-payable and assigned a status indicator of ''B5''—''Alternative code may be available; no payment made''—for CY 2025. Additionally, proposed ASC complexity adjustment codes that met our criteria based on data available for the CY 2025 OPPS/ASC proposed rule but do not meet our criteria based on claims data available for this final rule with comment period will be deleted and assigned a payment indicator of ''D5''—''Deleted/discontinued code; no payment made''.

d. Final Low Volume APCs and Limit on ASC Payment Rates for Procedures Assigned to Low Volume APCs

As stated in section XIII.D.1.b of the CY 2025 OPPS/ASC proposed rule, the ASC payment system generally uses OPPS geometric mean costs under the standard methodology to determine proposed relative payment weights under the standard ASC ratesetting methodology.

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63743 through 63747), we adopted a universal Low Volume APC policy for CY 2022 and subsequent calendar years. Under our policy, we expanded the low volume adjustment policy that is applied to procedures assigned to New Technology APCs to also apply to clinical and brachytherapy APCs. Specifically, a clinical APC or brachytherapy APC with fewer than 100 claims per year would be designated as a Low Volume APC. For items or services assigned to a Low Volume APC, we use up to 4 years of claims data to establish a payment rate for the APC as we currently do for low volume services assigned to New Technology APCs. The payment rate for a Low Volume APC or a low volume New Technology procedure would be based on the highest of the median cost, arithmetic mean cost, or geometric mean cost calculated using multiple years of claims data.

Based on claims data available for the CY 2025 OPPS/ASC proposed rule, we proposed to designate six brachytherapy APCs and four clinical APCs as Low Volume APCs under the ASC payment system (89 FR 59414). The four clinical APCs and six brachytherapy APCs met our criteria of having fewer than 100 single claims in the relevant claims year (CY 2023 for the CY 2025 OPPS/ASC proposed rule) and therefore, we proposed that they would be subject to our universal Low Volume APC policy and the APC cost metric would be based on the greater of the median cost, arithmetic mean cost, or geometric mean cost using up to 4 years of claims data. Nine of the ten APCs were designated as low volume APCs in CY 2024. Based on data for the CY 2025 OPPS/ASC proposed rule, APC 2645 (Brachytx, non-stranded, hold-198) met our criteria to be designated a low volume APC; and we proposed to designate it as such for CY 2025.

Comment: Commenters supported our proposal to assign the ten APCs as Low Volume APCs.

Response: We thank the commenters for their support. Based on claims data available for this final rule with comment period, we are finalizing our proposal to designate the 4 clinical APCs and 6 brachytherapy APCs shown in Table 151 as Low Volume APCs under the ASC payment system, because they continue to meet our criteria of having fewer than 100 single claims in the relevant claims year (2023). Table 151 includes the CY 2023 claims available for ratesetting for each of the APCs we are finalizing to be designated as Low Volume APCs for CY 2025. The cost statistics for our Low Volume APCs, such as the median, arithmetic mean, and geometric mean cost are available for download with this final rule with comment period on the CMS website. We refer readers to our website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-regulations-and-notices*; click on the relevant regulation to download the Low Volume APC cost statistics under the standard (ASC) ratesetting methodology in the ''Downloads'' section of the web page.

TABLE 151: FINAL LOW VOLUME APCS USING STANDARD (ASC) RATESETTING METHODOLOGY FOR CY 2025

APC	APC Description	CY 2023 Claims Available for Ratesetting
2632	Iodine I-125 sodium iodide	1
2635	Brachytx, non-str, HA, P-103	20
2636	Brachy linear, non-str, P-103	1
2642	Brachytx, stranded, C-131	95
2645	Brachytx, non-str, gold-198	96
2647	Brachytx, NS, Non-HDRIr-192	2
5244	Level 4 Blood Product Exchanges and Related Services	2
5494	Level 4 Intraocular Procedures	17
5495	Level 5 Intraocular Procedures	39
5496	Level 6 Intraocular Procedures	15

2. Payment for Covered Ancillary Services

a. Background

Our payment policies under the ASC payment system for covered ancillary services generally vary according to the particular type of service and its payment policy under the OPPS. Our overall policy provides separate ASC payment for certain ancillary items and services integrally related to the provision of ASC covered surgical procedures that are paid separately under the OPPS and provides packaged ASC payment for other ancillary items and services that are packaged or conditionally packaged (status indicators ''N,'' ''Q1,'' and ''Q2'') under the OPPS.

In the CY 2013 OPPS/ASC rulemaking (77 FR 45169 and 77 FR 68457 through 68458), we further clarified our policy regarding the payment indicator assignment for procedures that are conditionally packaged in the OPPS (status indicators ''Q1'' and ''Q2''). Under the OPPS, a conditionally packaged procedure describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are generally packaged (payment indictor ''N1'') under the ASC payment system (except for device removal procedures, as discussed in the CY 2022 OPPS/ASC proposed rule (86 FR 42083)). Thus, our policy generally aligns ASC payment bundles with those under the OPPS (72 FR 42495). In all cases, in order for ancillary items and services also to be paid, the ancillary items and services must be provided integral to the performance of ASC covered surgical procedures for which the ASC bills Medicare.

Our ASC payment policies generally provide separate payment for drugs and biologicals that are separately paid under the OPPS at the OPPS rates and package payment for drugs and biologicals for which payment is packaged under the OPPS. However, as discussed in the CY 2022 OPPS/ASC final rule with comment period, for CY 2022, we finalized a policy to unpackage and pay separately at ASP plus 6 percent for the cost of non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure as determined by CMS under § 416.174 (86 FR 63483).

We generally pay for separately payable radiology services at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (72 FR 42497). However, as finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72050), payment indicators for all nuclear medicine procedures (defined as CPT codes in the range of 78000 through 78999) that are designated as radiology services that are paid separately when provided integral to a surgical procedure on the ASC list are set to ''Z2'' so that payment is made based on the ASC standard ratesetting methodology rather than the MPFS nonfacility PE RVU amount (''Z3''), regardless of which is lower (§ 416.171(d)(1)).

Similarly, we also finalized our policy to set the payment indicator to ''Z2'' for radiology services that use contrast agents so that payment for these procedures will be based on the OPPS relative payment weight using the ASC standard ratesetting methodology and, therefore, will include the cost for the contrast agent (§ 416.171(d)(2)).

ASC payment policy for brachytherapy sources mirrors the payment policy under the OPPS. ASCs are paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS or, if OPPS rates are unavailable, at contractor-priced rates (72 FR 42499). Since December 31, 2009, ASCs have been paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS.

Our ASC policies also provide separate payment for: (1) certain items and services that CMS designates as contractor-priced, including, but not limited to, the procurement of corneal tissue; and (2) certain implantable items that have pass-through payment status under the OPPS. These categories do not have prospectively established ASC payment rates according to ASC payment system policies (72 FR 42502 and 42508 through 42509; § 416.164(b)). Under the ASC payment system, we have designated corneal tissue acquisition and hepatitis B vaccines as contractor-priced. Corneal tissue acquisition is contractor-priced based on the invoiced costs for acquiring the corneal tissue for transplantation. Hepatitis B vaccines are contractor-priced based on invoiced costs for the vaccine.

Devices that are eligible for pass-through payment under the OPPS are separately paid under the ASC payment system and are contractor-priced. Under the revised ASC payment system (72 FR 42502), payment for the surgical procedure associated with the pass-through device is made according to our standard methodology for the ASC payment system, based on only the service (non-device) portion of the procedure's OPPS relative payment weight if the APC weight for the procedure includes other packaged device costs. We also refer to this methodology as applying a ''device offset'' to the ASC payment for the associated surgical procedure. This ensures that duplicate payment is not provided for any portion of an implanted device with OPPS pass-through payment status.

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized that, beginning in CY 2015, certain diagnostic tests within the medicine range of CPT codes for which separate payment is allowed under the OPPS are covered ancillary services when they are integral to an ASC covered surgical procedure. We finalized that diagnostic tests within the medicine range of CPT codes include all Category I CPT codes in the medicine range established by CPT, from 90000 to 99999, and Category III CPT codes and Level II HCPCS codes that describe diagnostic tests that crosswalk or are clinically similar to procedures in the medicine range established by CPT. In the CY 2015 OPPS/ASC final rule with comment period, we also finalized our policy to pay for these tests at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (79 FR 66933 through 66934). We finalized that the diagnostic tests for which the payment is based on the ASC standard ratesetting methodology be assigned to payment indicator ''Z2'' and revised the definition of payment indicator ''Z2'' to include a reference to diagnostic services and those for which the payment is based on the PFS nonfacility PE RVU-based amount be assigned payment indicator ''Z3,'' and revised the definition of payment indicator ''Z3'' to include a reference to diagnostic services.

b. Final Payment for Covered Ancillary Services for CY 2025

We proposed to update the ASC payment rates and to make changes to ASC payment indicators, as necessary, to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services and the proposed CY 2025 OPPS and ASC

payment rates and subsequent years' payment rates. We also proposed to continue to set the CY 2025 ASC payment rates and subsequent years' payment rates for brachytherapy sources and separately payable drugs and biologicals equal to the OPPS payment rates for CY 2025 and subsequent years' payment rates.

Covered ancillary services and their final payment indicators for CY 2025 are listed in Addendum BB of this final rule with comment period (which is available via the internet on the CMS website). For those covered ancillary services where the payment rate is the lower of the rate under the ASC standard rate setting methodology and the PFS final rates (similar to our office-based payment policy), the final payment indicators and rates set forth in this final rule are based on a comparison using the final PFS rates effective January 1, 2025. For a discussion of the PFS rates, we refer readers to the CY 2025 PFS proposed rule.

Comment: One commenter stated that there is currently no CMS-level guidance on how MACs should establish separate payment under the ASC payment system for devices that are eligible for pass-through payment under the OPPS. The commenter recommends that CMS specify that payment should be at least equal to the device cost as reported by the ASC in box 19 on the ASC claim form.

Response: As previously discussed, devices that are eligible for pass-through payment under the OPPS may be separately paid under the ASC payment system and are contractor-priced. Currently, MACs have been instructed to pay for such devices in the ASC setting based on invoice or cost of the approved transitional pass-through device category. While we understand that many products with different price points may use the same approved transitional pass-through device category, we rely on the MACs to efficiently process these claims such that ASCs can be reimbursed in a timely manner for the services provided and that reimbursement for these pass-through devices is justified with supporting documentation. Therefore, we do not believe it would be appropriate to require MACs to provide payment based on the figure reported in box 19 of the ASC claim form. We believe the current guidance provided in Chapter 14, section 50 of the Medicare Claims Processing Manual (Pub. 100–04) is sufficient.

After consideration of the public comments we received, we are finalizing our proposal to update the ASC payment rates and to make changes to ASC payment indicators, as necessary, to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services and the final CY 2025 OPPS and ASC payment rates and subsequent years' payment rates.

We did not receive any public comments on and are also finalizing without modification our proposal to continue to set the CY 2025 ASC payment rates and subsequent years' payment rates for brachytherapy sources and separately payable drugs and biologicals equal to the OPPS payment rates for CY 2025 and subsequent years' payment rates.

3. Covered Surgical Procedures Designated as Office-Based Procedures

a. Background

In the August 2, 2007 ASC final rule, we finalized our policy to designate as ''office-based'' those procedures that are added to the ASC Covered Procedures List (CPL) in CY 2008 or later years that we determine are furnished predominantly (more than 50 percent of the time) in physicians' offices based on consideration of the most recent available volume and utilization data for each individual procedure code and/or, if appropriate, the clinical characteristics, utilization, and volume of related codes. In that final rule, we also finalized our policy to exempt all procedures on the CY 2007 ASC list from application of the office-based classification (72 FR 42512). The procedures that were added to the ASC CPL beginning in CY 2008 that we determined were office-based were identified in Addendum AA to that final rule with payment indicator ''P2'' (Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight); ''P3'' (Office-based surgical procedures added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on MPFS nonfacility PE RVUs); or ''R2'' (Office-based surgical procedure added to ASC list in CY 2008 or later without MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight), depending on whether we estimated the procedure would be paid according to the ASC standard ratesetting methodology based on its OPPS relative payment weight or at the MPFS nonfacility PE RVU-based amount.

Consistent with our final policy to annually review and update the ASC CPL to include all covered surgical procedures eligible for payment in ASCs, each year we identify covered surgical procedures as either temporarily office-based (these are new procedure codes with little or no utilization data that we have determined are clinically similar to other procedures that are permanently office-based), permanently office-based, or nonoffice-based, after taking into account updated volume and utilization data.

b. CY 2025 Final Office-Based Procedures

In developing the CY 2025 OPPS/ASC proposed rule, we followed our policy to annually review and update the covered surgical procedures for which ASC payment is made and to identify new procedures that may be appropriate for ASC payment, including their potential designation as office-based. Historically, we also review the most recent claims volume and utilization data (CY 2023 claims) and the clinical characteristics for all covered surgical procedures that are currently assigned a payment indicator in CY 2024 of ''G2'' (Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) as well as for those procedures assigned one of the temporary office-based payment indicators, specifically ''P2,'' ''P3,'' or ''R2'' in the CY 2023 OPPS/ASC final rule with comment period (86 FR 63769 through 63773).

Our review of the CY 2023 volume and utilization data of covered surgical procedures currently assigned a payment indicator of ''G2'' (Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) resulted in the identification of two surgical procedures that we believed met the criteria for designation as permanently office-based. The data indicated that these procedures are performed more than 50 percent of the time in physicians' offices, and the services are of a level of complexity consistent with other procedures performed routinely in physicians' offices. The CPT codes that we proposed to permanently designate as office-based for CY 2025 were CPT code 0447T (Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision) and CPT code 21127 (Augmentation, mandibular body or angle; with bone graft, onlay or interpositional (includes obtaining autograft)) and are listed in Table 79 of the CY 2025 OPPS/ASC proposed rule (89 FR 59416) with the associated payment indicators.

As discussed in the August 2, 2007 ASC final rule (72 FR 42533 through 42535), we finalized our policy to

designate certain new surgical procedures as temporarily office-based until adequate claims data are available to assess their predominant sites of service, whereupon if we confirm their office-based nature, the procedures are permanently assigned to the list of office-based procedures. In the absence of claims data, we use other available information, including our clinical advisors' judgment, predecessor CPT and Level II HCPCS codes, information submitted by representatives of specialty societies and professional associations, and information submitted by commenters during the public comment period.

We reviewed CY 2023 volume and utilization data for nine surgical procedures designated as temporarily office-based in the CY 2023 OPPS/ASC final rule with comment period and temporarily assigned one of the office-based payment indicators, specifically ''P2,'' ''P3,'' or ''R2.'' In Table 122 of the CY 2024 OPPS/ASC final rule with comment period, we finalized assigning temporary office-based designations to seven surgical procedures for CY 2024 (88 FR 81919). In Table 80 of the CY 2025 OPPS/ASC proposed rule (89 FR 59417), we showed the surgical procedure we proposed to no longer designate as temporarily office-based. This surgical procedure is CPT code 67516 (Suprachoroidal space injection of pharmacologic agent (separate procedure)) which we proposed to permanently designate as office-based.

We did not receive any public comments on our proposed permanent office-based designations and therefore, we are finalizing our proposal to designate the procedures in Table 152 as permanently office-based beginning in CY 2025.

TABLE 152: ASC COVERED SURGICAL PROCEDURES TO BE NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2025

CY 2025 CPT/HCPCS Code	Long Descriptor	Final CY 2024 ASC Payment Indicator	Final CY 2025 ASC Payment Indicator*
0447T	Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision	G2	P3*
21127	Augmentation, mandibular body or angle; with bone graft, onlay or interpositional (includes obtaining autograft)	G2	P2*
67516	Suprachoroidal space injection of pharmacologic agent (separate procedure	P3	P3*

* Payment indicators were based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the CY 2025 PFS final rates.

In Table 81 of the CY 2025 OPPS/ASC proposed rule (89 FR 59418), we showed the nine surgical procedures, both new and existing, we proposed to designate as temporarily office-based for CY 2025. For CY 2025, we proposed to designate three new CY 2025 CPT codes for ASC covered surgical procedures as temporarily office-based—CPT codes 0910T (placeholder code XX34T) (Removal of integrated neurostimulation system, vagus nerve), 15013 (placeholder code 15XX3) (Preparation of skin cell suspension autograft, requiring enzymatic processing, manual mechanical disaggregation of skin cells, and filtration; first 25 sq cm or less of harvested skin), and 53866 (placeholder code 5XX06) (Catheterization with removal of temporary device for ischemic remodeling (*i.e.,* pressure necrosis) of bladder neck and prostate). After reviewing the clinical characteristics, utilization, and volume of related procedure codes, we determined that CPT code 0910T is most similar to 0588T, which is temporarily designated as an office-based surgical procedure. Additionally, CPT code 15013 is most similar to CPT code 11310 (Shaving of epidermal or dermal lesion, single lesion, face, ears, eyelids, nose, lips, mucous membrane; lesion diameter 0.5 cm or less), which is designated as an office-based surgical procedure. Lastly, CPT code 53866 is most similar to CPT code 51705 (Change of bladder tube) which is also designated as an office-based surgical procedure. We also proposed to continue to designate six existing procedures as temporarily office-based for CY 2025 since we did not have adequate claims data to remove the temporary designation.

Comment: One commenter recommended that we do not finalize our office-based designation for CPT code 15013 and reassign CPT code 15013 from ''R2'' (Office-based surgical procedure added to ASC list in CY 2008 or later without MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight) to ''J8'' (Device-intensive procedure; paid at adjusted rate).

Response: We are not accepting this recommendation. We do not believe this procedure meets our requirements of a device-intensive procedure as described in section XIII.C.4. of this final rule with comment period because it does not use an insertable or implantable single-use device.

After consideration of the public comments we received, we are finalizing our proposal with modification. We are not finalizing our proposed temporary office-based designation to CPT code 0910T (placeholder code XX34T) (Removal of

integrated neurostimulation system, vagus nerve). As discussed in section III.E of this final rule with comment period, since the vagal nerve neurostimulation system has not yet received FDA approval, we are finalizing an OPPS status indicator ''E1'' to indicate that the code is not payable by Medicare when submitted on outpatient claims (any outpatient bill type). Therefore, for the ASC payment system, we are finalizing a payment indicator of ''Y5''—''Nonsurgical procedure/item not valid for Medicare purposes because of coverage, regulation and/or statute; no payment made'' for CY 2025.

Further, we are also not finalizing our temporary office-based designation of CPT code 65785 (Implantation of intrastromal corneal ring segments) as this code meets our criteria to be designated as device-intensive for CY 2025 and we are finalizing that designation for this CPT code. While we are finalizing the payment indicators to the other new and existing procedures which are designated as temporary office-based shown in Table 153, we are also modifying our proposal with the addition of three newly created surgical procedure codes: HCPCS codes C8002 (Preparation of skin cell suspension autograft, automated, including all enzymatic processing and device components (do not report with manual suspension preparation)), G0564 (Creation of subcutaneous pocket with insertion of 365 day implantable interstitial glucose sensor, including system activation and patient training), and G0565 (Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new 365 day implantable sensor, including system activation). We believe HCPCS C8002 is most similar to CPT code 15013 (Preparation of skin cell suspension autograft, requiring enzymatic processing, manual mechanical disaggregation of skin cells, and filtration; first 25 sq cm or less of harvested skin), a CPT code to which we are also finalizing a temporary office-based designation for CY 2025. Additionally, we believe HCPCS codes G0564 and G0565 are most similar to CPT codes 0446T (Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training) and 0448T (Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation), respectively. Both of these CPT codes are designated as office-based procedures; therefore, we are assigning a temporary office-based designation to HCPCS codes G0564 and G0545 as well. The procedures for which the final office-based designation for CY 2025 is temporary are also indicated by an asterisk in Addendum AA to this final rule with comment period (which is available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices*).

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TABLE 153: CY 2025 PAYMENT INDICATORS FOR NEW AND EXISTING ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED

CY 2025 CPT/HCPCS Code	CY 2025 Placeholder CPT Code	Long Descriptor	Final CY 2024 ASC Payment Indicator	Final CY 2025 ASC Payment Indicator*
0581T	NA	Ablation, malignant breast tumor(s), percutaneous, cryotherapy, including imaging guidance when performed, unilateral	R2	J8
0588T	NA	Revision or removal of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve	R2	R2*
0864T	NA	Low-intensity extracorporeal shock wave therapy involving corpus cavernosum, low energy	R2	R2*
15013	15XX3	Preparation of skin cell suspension autograft, requiring enzymatic processing, manual mechanical disaggregation of skin cells, and filtration; first 25 sq cm or less of harvested skin	NA	R2*
53866	5XX06	Catheterization with removal of temporary device for ischemic remodeling (ie, pressure necrosis) of bladder neck and prostate	NA	P3*
64598	NA	Revision or removal of neurostimulator electrode array, peripheral nerve, with integrated neurostimulator	R2	R2*
65785	NA	Implantation of intrastromal corneal ring segments	P3	J8

CY 2025 CPT/HCPCS Code	CY 2025 Placeholder CPT Code	Long Descriptor	Final CY 2024 ASC Payment Indicator	Final CY 2025 ASC Payment Indicator*
67229	NA	Treatment of extensive or progressive retinopathy, 1 or more sessions, preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (e.g., retinopathy of prematurity), photocoagulation or cryotherapy	R2	R2
C8002	NA	Preparation of skin cell suspension autograft, automated, including all enzymatic processing and device components (do not report with manual suspension preparation)	NA	R2*
G0564	NA	Creation of subcutaneous pocket with insertion of 365 day implantable interstitial glucose sensor, including system activation and patient training	NA	R2*
G0565	NA	Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new 365 day implantable sensor, including system activation	NA	R2*

* Payment indicators were based on a comparison of the final rates according to the ASC standard ratesetting methodology and the CY 2025 PFS final rates.

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4. Device-Intensive ASC Covered Surgical Procedures

a. Background

We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59040 through 59041), for a summary of our existing policies regarding ASC covered surgical procedures that are designated as device-intensive.

b. CY 2025 Final Device Intensive Procedures

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59040 through 59043), for CY 2019, we modified our criteria for device-intensive procedures to better capture costs for procedures with significant device costs. We adopted a policy to allow procedures that involve surgically inserted or implanted, high-cost, single-use devices to qualify as device-intensive procedures. In addition, we modified our criteria to lower the device offset percentage threshold from 40 percent to 30 percent. The device offset percentage is the percentage of device costs within a procedure's total costs. Specifically, for CY 2019 and subsequent years, we adopted a policy that device-intensive procedures would be subject to the following criteria:

- All procedures must involve implantable or insertable devices assigned a CPT or HCPCS code;
- The required devices (including single-use devices) must be surgically inserted or implanted; and
- The device offset amount must be significant, which is defined as exceeding 30 percent of the procedure's mean cost. Corresponding to this change in the cost criterion, we adopted a policy that the default device offset for new codes that describe procedures that involve the implantation of medical devices will be 31 percent beginning in CY 2019. For new codes describing procedures that are payable when furnished in an ASC and involve the implantation of a medical device, we adopted a policy that the default device offset would be applied in the same manner as the policy we adopted in section IV.B.2 of the CY 2019 OPPS/ASC final rule with comment period (83 FR 58944 through 58948). We amended § 416.171(b)(2) of the regulations to reflect these new device criteria.

In addition, as also adopted in section IV.B.2 of the CY 2019 OPPS/ASC final rule with comment period, to further align the device-intensive policy with the criteria used for device pass-through status, we specified, for CY 2019 and subsequent years, that for purposes of satisfying the device-intensive criteria, a device-intensive procedure must involve a device that:

- Has received FDA marketing authorization, has received an FDA investigational device exemption (IDE)

and has been classified as a Category B device by FDA in accordance with 42 CFR 405.203 through 405.207 and 405.211 through 405.215, or meets another appropriate FDA exemption from premarket review;

- Is an integral part of the service furnished;
- Is used for one patient only;
- Comes in contact with human tissue;
- Is surgically implanted or inserted (either permanently or temporarily); and
- Is not any of the following:

++ Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or

++ A material or supply furnished incident to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than a radiological site marker).

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63773 through 63775), we modified our approach to assigning device-intensive status to surgical procedures under the ASC payment system. First, we adopted a policy of assigning device-intensive status to procedures that involve surgically inserted or implanted, high-cost, single-use devices if their device offset percentage exceeds 30 percent under the ASC standard ratesetting methodology, even if the procedure is not designated as device-intensive under the OPPS. Second, we adopted a policy that if a procedure is assigned device-intensive status under the OPPS, but has a device offset percentage below the device-intensive threshold under the standard ASC ratesetting methodology, the procedure will be assigned device-intensive status under the ASC payment system with a default device offset percentage of 31 percent. The policies were adopted to provide consistency between the OPPS and ASC payment system and provide a more appropriate payment rate for surgical procedures with significant device costs under the ASC payment system.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72078 through 72080), we finalized our policy to create certain C-codes, or ASC complexity adjustment codes that describe certain combinations of a primary covered surgical procedure as well as a packaged (payment indicator = ''N1'') procedure that are otherwise eligible for a complexity adjustment under the OPPS (as listed in Addendum J). Each ASC complexity adjustment code's APC assignment is based on its corresponding OPPS complexity adjustment code's APC assignment. In the CY 2023 OPPS/ASC final rule with comment period, we stated our belief that it would be appropriate for these ASC complexity adjustment codes to qualify for device-intensive status under the ASC payment system if the primary procedure of the code was also designated as device-intensive. Under our current policy, the ASC complexity adjustment code retains the device portion of the primary procedure (also called the ''device offset amount'') and not the device offset percentage. Therefore, for device-intensive ASC complexity adjustment codes, we set the device portion of the combined procedure equal to the device portion of the primary procedure and calculate the device offset percentage by dividing the device portion by the ASC complexity adjustment code's APC payment rate. Further, we apply our standard ASC payment system ratesetting methodology to the non-device portion of the ASC complexity adjustment code's APC payment rate; that is, we multiply the OPPS relative weight by the ASC budget neutrality adjustment and the ASC conversion factor and sum that amount with the device portion to calculate the ASC payment rate.

As discussed in section IV.B of the CY 2025 OPPS/ASC proposed rule, the purpose of applying the default device offset percentage to new codes that describe procedures that implant or insert devices is to ensure access in the ASC setting for new procedures until claims data become available. Our ratesetting methodology sets the ASC device offset amount constant at the OPPS device offset amount. Device offset amounts under the OPPS and ASC Payment System are the device offset percentages of a procedure multiplied by the OPPS or ASC Payment System payment rate, respectively, for that procedure. While the ASC ratesetting methodology relies on the ASC conversion factor and the scaled OPPS APC relative weights to construct ASC payment rates, for device-intensive procedures, the device offset percentage of the procedure relies on the higher OPPS conversion factor while the non device portion relies on the lower ASC conversion factor. For non device-intensive procedures for which the payment is based on OPPS relative payment weight, one hundred percent of the procedure's payment rate relies on the ASC conversion factor. Therefore, the greater the device offset percentage under the ASC Payment System, the greater the ASC payment rate.

Device offset percentages, which represent the device cost portion of a procedure's total cost, are determined using the most recent claims data for that procedure. For newer procedures that describe procedures which implant or insert single-use devices that meet our definition of a device and for which the device costs are estimated to be greater than 30 percent of the total procedure cost and lack claims data, we have relied on several policies to determine an appropriate device offset percentage until such claims data becomes available. First, if the new procedure has claims data from a predecessor code, as described by CPT coding guidance, we rely on claims data from the predecessor code in assigning the device offset percentage for the new HCPCS code (88 FR 81919 through 81922). Second, in limited instances where a new device-intensive procedure does not have a predecessor code as defined by CPT, but describes a procedure that was previously described by an existing code, we may use clinical discretion to identify HCPCS codes that are clinically related or similar to the new HCPCS code but are not officially recognized as a predecessor code by CPT, and use the claims data of the clinically related or similar code(s) for purposes of determining whether to use the device offset percentage of the clinically related or similar code(s) or to apply the default device offset to the new HCPCS code (83 FR 58946). Clinically related and similar procedures for purposes of this policy are procedures that have few or no clinical differences and use the same device(s). If the new device-intensive procedure does not have claims data from a predecessor code or a clinically similar code that uses the same device, we have assigned a default device offset percentage of 31 percent. While we do allow for additional information in our consideration of a higher offset percentage than the default device offset, our payment policies under both the OPPS and ASC Payment System are meant to encourage efficiencies and promote savings to the Medicare program and we believe relying on claims data rather than external pricing data helps put downward pressure on changes in medical device prices. Therefore, it would be extremely rare that the appropriate determination of a device offset percentage would rely on pricing data or invoices from a device manufacturer rather than the default device offset percentage.

However, we are aware that there may be certain situations where newer

device-intensive procedures lack claims data from a predecessor code and a clinically similar code that uses the same device, but the default device offset percentage would not adequately reflect the existing device portion of the procedure's costs when compared to the cost of similar devices. The difference in the default device portion and the potential device cost could possibly limit access to newer, more complex, device-intensive procedures in the ASC setting if the cost of the new device does indeed reflect a cost equivalent to that of the similar existing devices. As HOPDs and ASCs perform new procedures with significant device costs, we believe it is appropriate to modify our default device offset methodology to pay HOPDs and ASCs more appropriately when we lack claims data for these newer procedures. Therefore, we proposed to modify our default device offset percentage for new device-intensive procedures. Specifically, for all new covered surgical HCPCS codes that describe procedures which implant or insert single-use devices that meet our definition of a device and for which the device costs are estimated to be greater than 30 percent of the total procedure cost and lack claims data, we would apply a default device offset percentage that is the greater of: 31 percent or the device offset percentage of the APC to which the procedure has been assigned. We proposed this methodological change for both the OPPS and ASC Payment System for CY 2025 and subsequent calendar years.

We still believe that a HCPCS code-level device offset is, in most cases, a more accurate representation of a procedure's device cost than an APC-wide average device offset based on the average device offset of all the procedures assigned to an APC. However, because newer device-intensive procedures lack claims data and therefore a HCPCS code-level device offset may not be possible, we believe the APC-wide average device offset percentage is, in most cases, a better reflection of the estimated device costs of the procedure than a default 31 percent offset. Additionally, there can be instances where the typical device costs of procedures in an APC can be significantly greater than the 31 percent default device offset. For these reasons, we propose to modify our methodology for determining the device offset percentage for new procedures that describe the implantation or insertion of a single-use device that meet our definition of a device and for which the device cost is projected to be greater than 30 percent of the total procedure cost that do not yet have associated claims data to apply a device offset percentage that is the greater of 31 percent or the device offset percentage of the APC to which the procedure has been assigned. The proposal would apply to new device-intensive procedures assigned to clinical APCs and would not apply to new procedures assigned to New Technology APCs.

Under our proposal, we would continue to first rely on the associated claims data for the new HCPCS code or any predecessor code, as described by CPT coding guidance, for the new HCPCS code. If there is no claims data from the new HCPCS or any predecessor code, we may continue to use clinical discretion to identify HCPCS codes that are clinically related or similar to the new HCPCS code but are not officially recognized as a predecessor code by CPT, and to use the claims data of the clinically related or similar code(s) for purposes of determining a device offset percentage to the new HCPCS code (83 FR 58946). Clinically related and similar procedures for purposes of this policy are procedures that have few or no clinical differences and use the same devices. For new device-intensive procedures that describe the implantation or insertion of a single-use device that meet our definition of a device and for which the device cost is significant, projected to be greater than 30 percent of the total procedure cost, and lack claims data, we would then rely on our proposed device offset policy and apply the greater of 31 percent or the device offset percentage of the APC to which the procedure has been assigned.

We solicited comments on our proposed changes to our default device offset policy for CY 2025 and subsequent calendar years under the OPPS and ASC payment system. The listing of proposed payment indicators for covered surgical procedures as well as their respective proposed device offset percentages and device offset amounts, which incorporates our proposed changes to the default device offset policy, can be found in Addendum FF to the proposed rule (which is available via the internet on the CMS website).

Comment: Commenters strongly supported our proposed change to our default device offset policy for CY 2025 and subsequent years under the ASC payment system.

Response: We thank the commenters for their support. After consideration of the public comments we received, we are finalizing our proposal without modification to apply the greater of the APC-wide device offset percentage or 31 percent for new HCPCS codes that do not have claims data or any predecessor code as described by CPT coding guidance.

Comment: Many commenters recommended that we assign device-intensive status to HCPCS code C9757 (Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and excision of herniated intervertebral disc, and repair of annular defect with implantation of bone anchored annular closure device, including annular defect measurement, alignment and sizing assessment, and image guidance; 1 interspace, lumbar) and CPT codes 52284 (Cystourethroscopy, with mechanical urethral dilation and urethral therapeutic drug delivery by drug-coated balloon catheter for urethral stricture or stenosis, male, including fluoroscopy, when performed) and 30469 (Repair of nasal valve collapse with low energy, temperature-controlled (*i.e.,* radiofrequency) subcutaneous/submucosal remodeling) under the ASC payment system. The commenters argued that the proposed ASC payment rate would not adequately reimburse for the cost of the devices that are used during the procedures.

Response: As we discussed in section IV.B. of this final rule with comment period, out of concern for hospital nonreporting of device costs for procedures that require devices, we are finalizing a modification to our device edits policy which reinstates device edits for device-intensive procedures created on or after January 1, 2017. Additionally, such device edits will be permanent and will apply regardless of the procedure's device offset percentage. In conjunction with the modification to our device edits policy for CY 2025, for determining device offset percentages for procedures subject to our device edits policy for CY 2025 that cannot bypass such edit by reporting modifier ''CG'', we are relying only on claims from hospitals that reported a device code for determining device offset percentages under the OPPS and ASC payment systems. Based on our revised methodology for this CY 2025 OPPS/ASC final rule with comment period, the device offset percentages for HCPCS code C9757 and CPT codes 30469 and 52284 exceed our device-intensive threshold. Therefore, we are assigning such procedures device-intensive status under the ASC payment system for CY 2025.

Comment: One commenter recommended that we assign device-intensive status to CPT codes 0686T

(Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance) and 0888T (Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant renal tissue, including imaging guidance). While the commenter states the procedure is not invasive, the commenter argues the procedure does require a disposable product.

Response: We are not accepting this recommendation as this procedure does not meet our requirements for a device-intensive assignment. As previously discussed, among other requirements, a device-intensive procedure must involve a device that is surgically implanted or inserted (either permanently or temporarily).

Comment: One commenter recommended that we assign CPT code 58356 (Endometrial cryoablation with ultrasonic guidance, including endometrial curettage, when performed) device-intensive status, or, at the least, to revise the payment indicator to ''A2''—Surgical procedure on ASC list in CY 2007; payment based on OPPS relative payment weight.

Response: We are not accepting this recommendation. CPT code 58356 does not have a device offset percentage that exceeds our device-intensive threshold. Additionally, CPT code 58356 has been designated as permanently office-based surgical procedure since CY 2010.

Comment: One commenter recommended that we use device cost data from CPT code 64590 (Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver) to determine the device offset percentage for CPT code 0786T (Insertion or replacement of percutaneous electrode array, sacral, with integrated neurostimulator, including imaging guidance, when performed). The commenter argues the predecessor code for 0786T is CPT code 64590.

Response: After further review of the CPT coding guidance associated with the neurostimulator codes that were created for CY 2024, we believe applicable predecessor codes for CPT code 0786T could include both CPT code 64590 and CPT code 64561 (Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed). However, as discussed in section III.E of this final rule with comment period, we inadvertently listed the integrated sacral nerve stimulation system associated with CPT code 0786T as receiving FDA-approval. However, it is still pending FDA approval and therefore, we are finalizing an OPPS status indicator of ''E1'' until FDA approval has been received. Therefore, for the ASC payment system, we are not accepting the commenter's recommendation and we are finalizing a payment indicator of ''Y5''—''Nonsurgical procedure/item not valid for Medicare purposes because of coverage, regulation and/or statute; no payment made'' for CY 2025.

Comment: One commenter recommended that we use the device cost data from HCPCS code C9769 (Cystourethroscopy, with insertion of temporary prostatic implant/stent with fixation/anchor and incisional struts) to determine the device offset percentage for CPT code 53865 (Cystourethroscopy with insertion of temporary device for ischemic remodeling (ie, pressure necrosis) of bladder neck and prostate) (placeholder CPT code 5XX05). The commenter argues the predecessor code for CPT code 53865 is HCPCS code C9769.

Response: After further review of the CPT coding guidance associated with newly created CPT code 53865, we agree that the predecessor code for CPT code 53865 includes HCPCS code C9769 as well as unlisted procedures. Therefore, we are accepting the commenter's recommendation and assigning a device offset percentage for CPT code 53865 based on its predecessor code HCPCS code C9769.

Comment: One commenter supported the device offset percentage for HCPCS code C9781 (Arthroscopy, shoulder, surgical; with implantation of subacromial spacer (*e.g.,* balloon), includes debridement (*e.g.,* limited or extensive), subacromial decompression, acromioplasty, and biceps tenodesis when performed) while another commenter recommended that we not reduce the device offset percentage from 64.4% to 61.5% under the ASC payment system.

Response: We appreciate the commenters' feedback and are relying on available claims data for this final rule with comment period in our determination of device-intensive status and device offset percentages under the ASC payment system. For final CY 2025 device offset percentages based on claims data for this final rule with comment period, we refer readers to Addendum FF of this final rule with comment period.

Comment: One commenter recommended we reevaluate the device portion and device-intensive status for the following CPT codes:

- 36563 (Insertion of tunneled centrally inserted central venous access device with subcutaneous pump);
- 36568 (Insertion of peripherally inserted central venous catheter (picc), without subcutaneous port or pump, without imaging guidance; younger than 5 years of age);
- 36570 (Insertion of peripherally inserted central venous access device, with subcutaneous port; younger than 5 years of age);
- 36578 (Replacement, catheter only, of central venous access device, with subcutaneous port or pump, central or peripheral insertion site); and
- 36595 (Mechanical removal of pericatheter obstructive material (e.g, fibrin sheath) from central venous device via separate venous access).

The commenter expressed their concerned with the magnitude of the payment reduction with CPT code 36595, a permanently office-based surgical procedure, experiencing a proposed 78.3 percent reduction from CY 2024 as a result of losing device-intensive status and a proposed payment rate based on the proposed CY 2025 PFS rate.

Response: Based on claims data available for this final rule with comment period, CPT codes 36563, 36568, 36570, and 36595 do not have device offset percentages that exceed the device-intensive threshold of greater than 30 percent. Therefore, we are not assigning device-intensive status to these procedures for CY 2025. However, the device offset percentage for CPT code 36578 exceeds our device-intensive threshold of 30 percent. Therefore, we are maintaining the CY 2024 device-intensive designation of CPT code 36578 for CY 2025.

Regarding the proposed payment rate for CPT code 36595, we believe the stakeholder brings up an important issue regarding the volatility in our payment rates for surgical procedures that are permanently designated as office-based but contain device costs that fluctuate above and below our threshold for device-intensive status. In previous rulemaking, we have stated that office-based surgical procedures that meet our requirements for device-intensive status will be assigned device-intensive status rather than office-based status for the applicable calendar year. However, since this procedure has been assigned office-based status and, based on the most recent claims data available, does not have significant device costs, we believe reassigning the procedure its office-based status for CY 2025 is appropriate. While we believe the number of office-based procedures that may gain or lose device-intensive status

each year is very low, we will monitor payment fluctuations for these procedures going forward and may address these concerns in future rulemaking.

Comment: Many commenters supported the proposed device offset percentages for the following procedures:

- CPT code 0671T (Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more);
- CPT code 0816T (Open insertion or replacement of integrated neurostimulation system for bladder dysfunction including electrode(s) (*e.g.,* array or leadless), and pulse generator or receiver, including analysis, programming, and imaging guidance, when performed, posterior tibial nerve; subcutaneous);
- CPT code 0817T (Open insertion or replacement of integrated neurostimulation system for bladder dysfunction including electrode(s) (*e.g.,* array or leadless), and pulse generator or receiver, including analysis, programming, and imaging guidance, when performed, posterior tibial nerve; subfascial);
- CPT code 31242 (Nasal/sinus endoscopy, surgical; with destruction by radiofrequency ablation, posterior nasal nerve);
- CPT code 31298 (Nasal/sinus endoscopy, surgical, with dilation (*e.g.,* balloon dilation); frontal and sphenoid sinus ostia);
- CPT code 66174 (Transluminal dilation of aqueous outflow canal (*e.g.,* canaloplasty); without retention of device or stent);
- CPT code 66989 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (*e.g.,* irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (*e.g.,* iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with insertion of intraocular (*e.g.,* trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more); and
- CPT code 66991 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (*e.g.,* irrigation and aspiration or phacoemulsification); with insertion of intraocular (*e.g.,* trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more).

Response: We appreciate the commenters' support of the proposed device offset percentages. For these CPT codes, we are finalizing device offset percentages based on claims data available for this final rule with comment period. CPT codes that were designated as device-intensive based on claims data available for the proposed rule may or may not be designated as device-intensive based on claims data available for this final rule with comment period.

For final CY 2025 device offset percentages based on claims data for this final rule with comment period, we refer readers to Addendum FF of this final rule with comment period.

c. Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices

Our ASC payment policy for costly devices implanted or inserted in ASCs at no cost/full credit or partial credit is set forth in § 416.179 of our regulations and is consistent with the OPPS policy that was in effect until CY 2014. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66845 through 66848) for a full discussion of the ASC payment adjustment policy for no cost/full credit and partial credit devices. ASC payment is reduced by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device.

Effective CY 2014, under the OPPS, we finalized our proposal to reduce OPPS payment for applicable APCs by the full or partial credit a provider receives for a device, capped at the device offset amount. Although we finalized our proposal to modify the policy of reducing payments when a hospital furnishes a specified device without cost or with full or partial credit under the OPPS, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75076 through 75080), we finalized our proposal to maintain our ASC policy for reducing payments to ASCs for specified device-intensive procedures when the ASC furnishes a device without cost or with full or partial credit. Unlike the OPPS, there is currently no mechanism within the ASC claims processing system for ASCs to submit to CMS the amount of the actual credit received when furnishing a specified device at full or partial credit. Therefore, under the ASC payment system, we finalized our proposal for CY 2014 to continue to reduce ASC payments by 100 percent or 50 percent of the device offset amount when an ASC furnishes a device without cost or with full or partial credit, respectively.

Under current ASC policy, all ASC device-intensive covered surgical procedures are subject to the no cost/full credit and partial credit device adjustment policy. Specifically, when a device-intensive procedure is performed to implant or insert a device that is furnished at no cost or with full credit from the manufacturer, the ASC appends the HCPCS ''FB'' modifier on the line in the claim with the procedure to implant or insert the device. The contractor reduces payment to the ASC by the device offset amount that we estimate represents the cost of the device when the necessary device is furnished without cost or with full credit to the ASC. We continue to believe that the reduction of ASC payment in these circumstances is necessary to pay appropriately for the covered surgical procedure furnished by the ASC.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59043 through 59044) we adopted a policy to reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the new device. The ASC will append the HCPCS ''FC'' modifier to the HCPCS code for the device-intensive surgical procedure when the facility receives a partial credit of 50 percent or more (but less than 100 percent) of the cost of a device. To report that the ASC received a partial credit of 50 percent or more (but less than 100 percent) of the cost of a new device, ASCs have the option of either: (1) submitting the claim for the device-intensive procedure to their Medicare contractor after the procedure's performance, but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment, once the credit determination is made; or (2) holding the claim for the device implantation or insertion procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the ''FC'' modifier appended to the implantation procedure HCPCS code if the partial

credit is 50 percent or more (but less than 100 percent) of the cost of the device. Beneficiary coinsurance would be based on the reduced payment amount. As finalized in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66926), to ensure our policy covers any situation involving a device-intensive procedure where an ASC may receive a device at no cost or receive full credit or partial credit for the device, we apply our ''FB''/''FC'' modifier policy to all device-intensive procedures.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59043 through 59044) we stated we would reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the device. In the CY 2020 OPPS/ASC final rule with comment period, we finalized continuing our existing policies for CY 2020. We note that we inadvertently omitted language that this policy would apply not just in CY 2019 but also in subsequent calendar years. We intended to apply this policy in CY 2019 and subsequent calendar years. Therefore, we finalized our proposal to apply our policy for partial credits specified in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59043 through 59044) in CY 2022 and subsequent calendar years (86 FR 63775 through 63776). Specifically, for CY 2022 and subsequent calendar years, we would reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the device. To report that the ASC received a partial credit of 50 percent or more (but less than 100 percent) of the cost of a device, ASCs have the option of either: (1) submitting the claim for the device intensive procedure to their Medicare contractor after the procedure's performance, but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment, once the credit determination is made; or (2) holding the claim for the device implantation or insertion procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the ''FC'' modifier appended to the implantation procedure HCPCS code if the partial credit is 50 percent or more (but less than 100 percent) of the cost of the device. Beneficiary coinsurance would be based on the reduced payment amount.

We did not receive any comments on our policies related to no cost/full credit or partial credit devices, and we are finalizing the continuation of our existing policies for CY 2025 without modification.

5. Requirement in the Physician Fee Schedule CY 2025 Proposed Rule for HOPDs and ASCs To Report Discarded Amounts of Certain Single-Dose or Single-Use Package Drugs

Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–9, November 15, 2021) (''the Infrastructure Act'') amended section 1847A of the Act to re-designate subsection (h) as subsection (i) and insert a new subsection (h), which requires manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug.

The CY 2025 PFS proposed rule included proposals related to the discarded drug refund policy, including proposals that may impact hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs). Similar to our CY 2023 and CY 2024 notice in the OPPS/ASC proposed rules (87 FR 71988 and 88 FR 49760), we included a notice in the CY 2025 proposed rule (89 FR 59421) to ensure interested parties were aware of these proposals and knew to refer to the CY 2025 Physician Fee Schedule proposed rule for a full description of the proposed policy. Interested parties were asked to submit comments on any proposals to implement section 90004 of the Infrastructure Act to the CY 2025 PFS proposed rule. We stated that public comments on these proposals would be addressed in the CY 2025 PFS final rule with comment period. We note that this same notice appeared in section V.B.6 of the CY 2025 OPPS/ASC proposed rule (89 FR 59370).

Please see a full description of the finalized policy in section V.B.6 of this CY 2025 OPPS/ASC final rule with comment period.

D. Additions to ASC Covered Surgical Procedures and Covered Ancillary Services Lists

1. Additions to the List of ASC Covered Surgical Procedures

Section 1833(i)(1) of the Act requires us, in part, to specify, in consultation with appropriate medical organizations, surgical procedures that are appropriately performed on an inpatient basis in a hospital but that can also be safely performed in an ASC, a CAH, or an HOPD, and to review and update the list of ASC covered surgical procedures at least every 2 years. We evaluate the ASC covered procedures list (ASC CPL) each year to determine whether procedures should be added to or removed from the list, and changes to the list are often made in response to specific concerns raised by stakeholders.

Under our regulations at §§ 416.2 and 416.166, covered surgical procedures furnished on or after January 1, 2022, are surgical procedures that meet the general standards specified in § 416.166(b) and are not excluded under the general exclusion criteria specified in § 416.166(c). Specifically, under § 416.166(b), the general standards provide that covered surgical procedures are surgical procedures specified by the Secretary and published in the **Federal Register** and/or via the internet on the CMS website that are separately paid under the OPPS, that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure.

Section 416.166(c) sets out the general exclusion criteria used under the ASC payment system to evaluate the safety of procedures for performance in an ASC. The general exclusion criteria provide that covered surgical procedures do not include those surgical procedures that: (1) generally result in extensive blood loss; (2) require major or prolonged invasion of body cavities; (3) directly involve major blood vessels; (4) are generally emergent or life-threatening in nature; (5) commonly require systemic thrombolytic therapy; (6) are designated as requiring inpatient care under § 419.22(n); (7) can only be reported using a CPT unlisted surgical procedure code; or (8) are otherwise excluded under § 411.15.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59029 through 59030), we defined a surgical procedure under the ASC payment system as any procedure described within the range of Category I CPT codes that the CPT Editorial Panel of the AMA defines as ''surgery'' (CPT codes 10000 through 69999) (72 FR 42476), as well as procedures that are described by Level II HCPCS codes or by Category I CPT codes or by Category III CPT codes that directly crosswalk or are clinically

similar to procedures in the CPT surgical range that we determined met the general standards established in previous years for addition to the ASC CPL.

In the CY 2024 OPPS/ASC final rule with comment period, we finalized adding several dental surgical procedures to the ASC CPL that met our regulatory criteria at §§ 416.166. We noted that there are statutory and regulatory limitations regarding Medicare coverage and payment for dental services. Section 1862(a)(12) of the Act generally precludes Medicare Part A or Part B payment for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth (collectively referred to in this section as ''dental services''). The regulation at § 411.15(i) similarly prohibits payment for dental services. In the CY 2023 PFS final rule (87 FR 69663), we explained that there are certain instances where dental services are so integral to other medically necessary services that they are not in connection with dental services within the meaning of section 1862(a)(12) of the Act. Rather, such dental services are inextricably linked to, and substantially related to the clinical success of, other covered services (hereafter in this section, ''inextricably linked''). To provide greater clarity to current policies, the CY 2023 PFS final rule finalized: (1) a clarification of our interpretation of section 1862(a)(12) of the Act to permit payment for dental services that are inextricably linked to other covered services; (2) clarification and codification of certain longstanding Medicare FFS payment policies for dental services that are inextricably linked to other covered services; (3) that, beginning for CY 2023, Medicare Parts A and B payment can be made for certain dental services inextricably linked to Medicare-covered organ transplant, cardiac valve replacement, or valvuloplasty procedures; and, (4) beginning for CY 2024, that Medicare Parts A and B payment can be made for certain dental services inextricably linked to Medicare-covered services for treatment of head and neck cancers (87 FR 69670 through 69671).

For the ASC setting, services must meet all applicable Medicare conditions for coverage and payment to be paid by Medicare, including those as specified under the CY 2023 PFS final rule (87 FR 69687 through 69688) and § 411.15(i)(3). Medicare payment may be made in the ASC setting for dental services for which payment may be made under Medicare Part B, paid under the OPPS, and that meet the ASC CPL criteria. The fact that a drug, device, procedure, or service is assigned a HCPCS code and a payment rate under the ASC payment system indicates only how the product, procedure, or service may be paid if covered by the program. MACs will be involved in the final decision regarding whether a drug, device, procedure, or other service meets all program requirements and conditions for coverage and payment. Therefore, even if a code describing a dental service has an associated payment rate on the ASC CPL, Medicare will only make payment for the service if it meets applicable requirements. We also clarify that adding dental procedures to the ASC CPL does not serve as a coverage determination for dental services under general anesthesia. We direct readers to the CY 2025 PFS proposed rule for additional discussion of Medicare coverage and payment for dental services.

For a detailed discussion of the history of our policies for adding surgical procedures to the ASC CPL, we refer readers to the CY 2021 through CY 2024 OPPS/ASC final rules with comment period (85 FR 86143 through 86145; 86 FR 63777 through 63805; 87 FR 72068 through 72076; and 88 FR 81923 through 81945).

2. Final Changes to the List of ASC Covered Surgical Procedures for CY 2025

Our current policy, which includes consideration of the general standards and exclusion criteria we have historically used to determine whether a surgical procedure should be added to the ASC CPL, is intended to ensure that surgical procedures added to the ASC CPL can be performed safely in the ASC setting on the typical Medicare beneficiary.

As part of our evaluation process to add procedures to the CPL, we assess potential procedures against the specific list of ASC CPL criteria at § 416.166. We also examine clinical data on these procedures from multiple sites of services, review literature and experiential data, and analyze claims data trends to ensure that these procedures meet all our criteria and are not expected to pose a significant risk to beneficiary safety when performed in an ASC. For CY 2025, we also reviewed supporting evidence received in the pre-proposed rule nominations process to inform our procedure evaluations. Based upon this review, we proposed to update the ASC CPL by adding 20 medical and dental surgical procedures to the list for CY 2025.

After reviewing the clinical characteristics of these twenty procedures and consulting with stakeholders and multiple clinical advisors, we determined that these procedures are separately paid under the OPPS, would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and would not be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure. These procedures are surgical or surgery-like, clinically similar to procedures in the CPT surgical range that we determined met the general standards for addition to the ASC CPL. These procedures are not excluded from being included on the ASC CPL because they do not generally result in extensive blood loss, require major or prolonged invasion of body cavities, commonly require systemic thrombolytic therapy, or directly involve major blood vessels; are not generally emergent or life-threatening in nature or designated as requiring inpatient care; or can only be reported using a CPT unlisted surgical procedure code or are otherwise excluded under Medicare. Therefore, we believed these procedures may all be appropriately performed in an ASC and proposed to include them on the ASC CPL for CY 2025.

We continue to focus on maximizing patient access to care by adding procedures to the ASC CPL when appropriate. While expanding the ASC CPL offers benefits, such as preserving the capacity of hospitals to treat more acute patients and promoting site neutrality, we also believe that any additions to the CPL should be added in a carefully calibrated fashion to ensure that the procedure is safe to be performed in the ASC setting. We encourage interested parties to submit procedure recommendations to be added to the ASC CPL, particularly if there is evidence that these procedures meet our criteria and can be safely performed in the ASC setting. We expect to continue to gradually expand the ASC CPL, as medical practice and technology continue to evolve and advance in future years.

Comment: Multiple commenters supported the proposed addition of 20 procedures, including 16 dental procedures, to the ASC CPL for CY 2025.

Response: We thank the commenters for their support.

Comment: A few commenters provided feedback on different approaches for CMS to consider when approaching the ASC CPL. These commenters felt there was a lack of transparency in the pre-proposed rule recommendation process and requested

that CMS provide the full list of recommended procedures and rationales for all procedures recommended by the public, even if CMS did not propose to add those procedures to the ASC CPL. Additionally, one commenter requested greater clarification on the definition of the ''typical Medicare beneficiary.''

Response: We thank the commenters for their input and will consider it for future rulemaking. As part of our evaluation process, we assess recommended procedures against the specific list of ASC CPL criteria at 42 CFR 416.166, examining clinical data on these procedures from multiple sites of services, reviewing the literature and experiential data provided in public comments, and examining claims volume to ensure that procedures are not expected to pose a significant risk to beneficiary safety when performed in an ASC.

While we have not historically published pre-proposed rule recommendations for which we did not propose any changes, we do address and publish a list of all codes that are recommended during the public comment period in the OPPS/ASC final rule. Additionally, in the CY 2022 OPPS/ASC final rule, we provided additional context on the typical Medicare beneficiary, whose health status is representative of the broader Medicare population, and we believe this information is sufficient to understand the typical Medicare beneficiary terminology without additional clarification at this time (86 FR 63777–63779).

Comment: One commenter requested that CMS not finalize its proposal to add two leadless pacemaker procedures, CPT codes 0795T (*Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed; complete system (i.e., right atrial and right ventricular pacemaker components)*) and 0801T (*Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed; dual-chamber system (i.e., right atrial and right ventricular pacemaker components)*), citing previous CMS guidance that excludes contractors from paying claims for leadless pacemakers when the service is provided in the ASC setting.

Response: We thank the commenter for their feedback. As of January 18, 2017, CMS covers leadless pacemakers through Coverage with Evidence Development (CED) when procedures are performed in CMS-approved CED studies and are provided in one of the following places of service: Indian Health Service Provider Based Facility, Inpatient Hospital, On Campus-Outpatient Hospital, and Military Treatment Facility (Medicare Claims Processing Manual (Pub. L. 100–04), Chapter 32, Section 380.1.1). We agree with the commenter that ASCs are excluded from payment for leadless pacemaker procedures under this policy, therefore, we are not finalizing our proposal to add CPT codes 0795T and 0801T to the ASC CPL.

Comment: Most commenters on this policy recommended specific codes to be added to the ASC CPL including arthrodesis, cardiac ablations, echocardiography, electrophysiological studies, vascular injections, and electroconvulsive therapy. We received 74 procedure recommendations for the CPL, listed in Table 155, below.

Response: We thank commenters for their recommendations. We individually assessed each of the recommended procedures, evaluating clinical data on these procedures from multiple sites of service, reviewing the literature and experiential data provided in public comments, and examining claims volume to determine whether these procedures meet each of the regulatory criteria at 42 CFR 416.166.

Based on our review of the clinical characteristics of the procedures and their similarity to other procedures that are currently on the ASC CPL, we believe that 3 procedures (CDT codes D7320, D7321, and D7471) out of the 74 procedure recommendations we received can be safely performed in the ASC setting and meet the general standards and exclusion criteria for the ASC CPL as set forth in 42 CFR 416.166(b) and (c), respectively. We agree with the commenter who provided support and evidence stating that these procedures can be safely performed in an ASC setting. We will continue to monitor clinical data on these services in the ASC setting and address any new trends in future rulemaking. These procedures, listed in Table 155 below, are:

- D7320 (Alveoloplasty not in conjunction with extractions—four or more teeth or tooth spaces, per quadrant).
- D7321 (Alveoloplasty not in conjunction with extractions—one to three teeth or tooth spaces, per quadrant).
- D7471 (Removal of lateral exostosis (maxilla or mandible)).

Below, we explain our rationale for not including the 71 recommended procedures, organized by category.

- 1 anesthesia code for total knee arthroplasty. Payment for anesthesia services is packaged into the ASC payment for covered surgical procedures.
- 2 integumentary system, including placement of breast localization devices. These codes are already on the ASC CPL as packaged procedures. We believe this placement is appropriate, given that these procedures are performed with a primary procedure.
- 18 cardiovascular codes, including cardiac ablations, cardioversion, electrophysiological studies and procedures, and echocardiography. Many of these codes have associated inpatient admissions, where the beneficiary requires active medical monitoring and care at midnight following the procedure. The cardioversion and echocardiography codes are non-surgical procedures, which means they would not qualify for addition to the ASC CPL, and most of the ancillary codes are not integral to a covered surgical procedure on the ASC CPL.
- 2 musculoskeletal code, which are arthrodesis procedures. While these procedures have some claims volume in the outpatient setting, the claims also showed multiple post-operative inpatient days, indicating that the beneficiary would require active monitoring and care past midnight following the procedure. These procedures can also involve prolonged invasion of body cavities. In addition, we acknowledge the findings of studies that commenters provided related to these procedures. However, the studies we received had significant limitations including selection bias and an absence of age groups representative of the Medicare population.
- 1 psychiatry code for electroconvulsive therapy. As this procedure is non-surgical, it would not qualify as a separately payable surgical procedure on the ASC CPL.
- 18 radiology codes, including aortography, angiography, venography, and transvascular biopsy. Most of these codes are currently on the covered ancillary services list. As they are non-surgical, they would not qualify as separately payable surgical procedures on the ASC CPL.
- 29 vascular codes, including catheter placements. Nearly all the catheter placement codes recommended

are already on the ASC CPL as packaged procedures. We believe this placement is appropriate, given that these procedures are performed with a primary service. The remaining vascular codes related to revascularization directly involve major blood vessels and there are concerns for potential extensive blood loss.

Given these considerations, we believe that these 71 codes do not meet the criteria for inclusion on the ASC CPL due to the following factors: likelihood of inpatient admissions, the need for multiple-day stays past midnight, safety risks posed to the typical beneficiary without active postoperative monitoring, involvement of major blood vessels, prolonged invasion of a body cavity, or are non-surgical.

Therefore, in this CY 2025 OPPS/ASC final rule with comment period, we are finalizing our proposal, with modification, to add 21 procedures, including 19 dental procedures, to the ASC CPL. These procedures are listed below in Table 154 of this CY 2025 OPPS/ASC final rule with comment period.

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TABLE 154: CY 2025 FINAL SURGICAL PROCEDURES FOR THE ASC CPL

CY 2025 CPT/HCPCS/CDT Code	CY 2025 Long Descriptor	Final CY 2025 ASC Payment Indicator
0717T	Autologous adipose-derived regenerative cell (adrc) therapy for partial thickness rotator cuff tear; adipose tissue harvesting, isolation and preparation of harvested cells, including incubation with cell dissociation enzymes, filtration, washing, and concentration of adrcs	G2
0718T	Autologous adipose-derived regenerative cell (adrc) therapy for partial thickness rotator cuff tear; injection into supraspinatus tendon including ultrasound guidance, unilateral	G2
D7251	Coronectomy - intentional partial tooth removal, impacted teeth only	D2
D7280	Exposure of an unerupted tooth	D2
D7320	Alveoloplasty not in conjunction with extractions - four or more teeth or tooth spaces, per quadrant	D2
D7321	Alveoloplasty not in conjunction with extractions - one to three teeth or tooth spaces, per quadrant	D2
D7410	Excision of benign lesion up to 1.25 cm	D2
D7411	Excision of benign lesion greater than 1.25 cm	D2
D7412	Excision of benign lesion, complicated	D2
D7413	Excision of malignant lesion up to 1.25 cm	D2
D7414	Excision of malignant lesion greater than 1.25 cm	D2
D7415	Excision of malignant lesion, complicated	D2
D7450	Removal of benign odontogenic cyst or tumor-lesion diameter up to 1.25 cm	D2
D7451	Removal of benign odontogenic cyst or tumor-lesion diameter greater than 1.25 cm	D2
D7460	Removal of benign nonodontogenic cyst or tumor-lesion diameter up to 1.25 cm	D2
D7461	Removal of benign nonodontogenic cyst or tumor-lesion diameter greater than 1.25 cm	D2
D7471	Removal of lateral exostosis (maxilla or mandible)	D2
D7485	Reduction of osseous tuberosity	D2
D7521	Incision and drainage of abscess - extraoral soft tissue - complicated (includes drainage of multiple fascial spaces)	D2
D7530	Removal of foreign body from mucosa, skin, or subcutaneous alveolar tissue	D2
D7540	Removal of reaction-producing foreign bodies-musculoskeletal system	D2

TABLE 155: SURGICAL PROCEDURE RECOMMENDATIONS RECEIVED FROM COMMENTERS

CY 2024 PCT/HCPCS/CDT Code	CY 2025 Long Descriptor	Final CY 2025 ASC Payment Indicator
0505T	Endovenous femoral-popliteal arterial revascularization, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed, with crossing of the occlusive lesion in an extraluminal fashion	X5
01402	Anesthesia for open or surgical arthroscopic procedures on knee joint; total knee arthroplasty	X5
19281	Placement of breast localization device(s) (eg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including mammographic guidance	N1
19285	Placement of breast localization device(s) (eg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including ultrasound guidance	N1
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace, lumbar;	X5
22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace, lumbar;	X5
36005	Injection procedure for extremity venography (including introduction of needle or intracatheter)	N1
36010	Introduction of catheter, superior or inferior vena cava	N1
36011	Selective catheter placement, venous system; first order branch (eg, renal vein, jugular vein)	N1
36012	Selective catheter placement, venous system; second order, or more selective, branch (eg, left adrenal vein, petrosal sinus)	N1
36100	Introduction of needle or intracatheter, carotid or vertebral artery	N1
36140	Introduction of needle or intracatheter, upper or lower extremity artery	N1
36200	Introduction of catheter, aorta	N1
36215	Selective catheter placement, arterial system; each first order thoracic or brachiocephalic branch, within a vascular family	N1
36216	Selective catheter placement, arterial system; initial second order thoracic or brachiocephalic branch, within a vascular family	N1
36217	Selective catheter placement, arterial system; initial third order or more selective thoracic or brachiocephalic branch, within a vascular family	N1
36218	Selective catheter placement, arterial system; additional second order, third order, and beyond, thoracic or brachiocephalic branch, within a vascular family (list in	N1

CY 2024 PCT/HCPCS/CDT Code	CY 2025 Long Descriptor	Final CY 2025 ASC Payment Indicator
	addition to code for initial second or third order vessel as appropriate)	
36221	Non-selective catheter placement, thoracic aorta, with angiography of the extracranial carotid, vertebral, and/or intracranial vessels, unilateral or bilateral, and all associated radiological supervision and interpretation, includes angiography of the cervicocerebral arch, when performed	N1
36222	Selective catheter placement, common carotid or innominate artery, unilateral, any approach, with angiography of the ipsilateral extracranial carotid circulation and all associated radiological supervision and interpretation, includes angiography of the cervicocerebral arch, when performed	N1
36223	Selective catheter placement, common carotid or innominate artery, unilateral, any approach, with angiography of the ipsilateral intracranial carotid circulation and all associated radiological supervision and interpretation, includes angiography of the extracranial carotid and cervicocerebral arch, when performed	N1
36224	Selective catheter placement, internal carotid artery, unilateral, with angiography of the ipsilateral intracranial carotid circulation and all associated radiological supervision and interpretation, includes angiography of the extracranial carotid and cervicocerebral arch, when performed	N1
36225	Selective catheter placement, subclavian or innominate artery, unilateral, with angiography of the ipsilateral vertebral circulation and all associated radiological supervision and interpretation, includes angiography of the cervicocerebral arch, when performed	N1
36226	Selective catheter placement, vertebral artery, unilateral, with angiography of the ipsilateral vertebral circulation and all associated radiological supervision and interpretation, includes angiography of the cervicocerebral arch, when performed	N1
36227	Selective catheter placement, external carotid artery, unilateral, with angiography of the ipsilateral external carotid circulation and all associated radiological supervision and interpretation (list separately in addition to code for primary procedure)	N1
36228	Selective catheter placement, each intracranial branch of the internal carotid or vertebral arteries, unilateral, with angiography of the selected vessel circulation and all associated radiological supervision and interpretation (eg, middle cerebral artery, posterior inferior cerebellar artery) (list separately in addition to code for primary procedure)	N1
36245	Selective catheter placement, arterial system; each first order abdominal, pelvic, or lower extremity artery branch, within a vascular family	N1
36246	Selective catheter placement, arterial system; initial second order abdominal, pelvic, or lower extremity artery branch, within a vascular family	N1

CY 2024 PCT/HCPCS/CDT Code	CY 2025 Long Descriptor	Final CY 2025 ASC Payment Indicator
36247	Selective catheter placement, arterial system; initial third order or more selective abdominal, pelvic, or lower extremity artery branch, within a vascular family	N1
36248	Selective catheter placement, arterial system; additional second order, third order, and beyond, abdominal, pelvic, or lower extremity artery branch, within a vascular family (list in addition to code for initial second or third order vessel as appropriate)	N1
36251	Selective catheter placement (first-order), main renal artery and any accessory renal artery(s) for renal angiography, including arterial puncture and catheter placement(s), fluoroscopy, contrast injection(s), image postprocessing, permanent recording of images, and radiological supervision and interpretation, including pressure gradient measurements when performed, and flush aortogram when performed; unilateral	N1
36252	Selective catheter placement (first-order), main renal artery and any accessory renal artery(s) for renal angiography, including arterial puncture and catheter placement(s), fluoroscopy, contrast injection(s), image postprocessing, permanent recording of images, and radiological supervision and interpretation, including pressure gradient measurements when performed, and flush aortogram when performed; bilateral	N1
36253	Superselective catheter placement (one or more second order or higher renal artery branches) renal artery and any accessory renal artery(s) for renal angiography, including arterial puncture, catheterization, fluoroscopy, contrast injection(s), image postprocessing, permanent recording of images, and radiological supervision and interpretation, including pressure gradient measurements when performed, and flush aortogram when performed; unilateral	N1
36254	Superselective catheter placement (one or more second order or higher renal artery branches) renal artery and any accessory renal artery(s) for renal angiography, including arterial puncture, catheterization, fluoroscopy, contrast injection(s), image postprocessing, permanent recording of images, and radiological supervision and interpretation, including pressure gradient measurements when performed, and flush aortogram when performed; bilateral	N1
37244	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for arterial or venous hemorrhage or lymphatic extravasation	X5
75600	Aortography, thoracic, without serialography, radiological supervision and interpretation	N1
75605	Aortography, thoracic, by serialography, radiological supervision and interpretation	N1
75625	Aortography, abdominal, by serialography, radiological supervision and interpretation	N1

CY 2024 PCT/HCPCS/CDT Code	CY 2025 Long Descriptor	Final CY 2025 ASC Payment Indicator
75630	Aortography, abdominal plus bilateral iliofemoral lower extremity, catheter, by serialography, radiological supervision and interpretation	N1
75710	Angiography, extremity, unilateral, radiological supervision and interpretation	N1
75716	Angiography, extremity, bilateral, radiological supervision and interpretation	N1
75736	Angiography, pelvic, selective or supraselective, radiological supervision and interpretation	N1
75726	Angiography, visceral, selective or supraselective (with or without flush aortogram), radiological supervision and interpretation	N1
75756	Angiography, internal mammary, radiological supervision and interpretation	N1
75774	Angiography, selective, each additional vessel studied after basic examination, radiological supervision and interpretation (list separately in addition to code for primary procedure)	N1
75820	Venography, extremity, unilateral, radiological supervision and interpretation	N1
75822	Venography, extremity, bilateral, radiological supervision and interpretation	Z3
75825	Venography, caval, inferior, with serialography, radiological supervision and interpretation	N1
75827	Venography, caval, superior, with serialography, radiological supervision and interpretation	N1
75831	Venography, renal, unilateral, selective, radiological supervision and interpretation	N1
75833	Venography, renal, bilateral, selective, radiological supervision and interpretation	N1
75860	Venography, venous sinus (eg, petrosal and inferior sagittal) or jugular, catheter, radiological supervision and interpretation	N1
75970	Transcatheter biopsy, radiological supervision and interpretation	N1
90870	Electroconvulsive therapy (includes necessary monitoring)	S1
92960	Cardioversion, elective, electrical conversion of arrhythmia; external	S1
93312	Echocardiography, transesophageal, real-time with image documentation (2d) (with or without m-mode recording); including probe placement, image acquisition, interpretation and report	S1
93313	Echocardiography, transesophageal, real-time with image documentation (2d) (with or without m-mode recording); placement of transesophageal probe only	S1
93314	Echocardiography, transesophageal, real-time with image documentation (2d) (with or without m-mode recording); image acquisition, interpretation and report only	N1
93315	Transesophageal echocardiography for congenital cardiac anomalies; including probe placement, image acquisition, interpretation and report	S1
93316	Transesophageal echocardiography for congenital cardiac anomalies; placement of transesophageal probe only	S1

CY 2024 PCT/HCPCS/CDT Code	CY 2025 Long Descriptor	Final CY 2025 ASC Payment Indicator
93317	Transesophageal echocardiography for congenital cardiac anomalies; image acquisition, interpretation and report only	N1
93318	Echocardiography, transesophageal (tee) for monitoring purposes, including probe placement, real time 2-dimensional image acquisition and interpretation leading to ongoing (continuous) assessment of (dynamically changing) cardiac pumping function and to therapeutic measures on an immediate time basis	S1
93613	Intracardiac electrophysiologic 3-dimensional mapping (list separately in addition to code for primary procedure)	N1
93619	Comprehensive electrophysiologic evaluation with right atrial pacing and recording, right ventricular pacing and recording, his bundle recording, including insertion and repositioning of multiple electrode catheters, without induction or attempted induction of arrhythmia	S1
93620	Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of arrhythmia; with right atrial pacing and recording, right ventricular pacing and recording, his bundle recording	S1
93623	Programmed stimulation and pacing after intravenous drug infusion (list separately in addition to code for primary procedure)	N1
93650	Intracardiac catheter ablation of atrioventricular node function, atrioventricular conduction for creation of complete heart block, with or without temporary pacemaker placement	X5
93653	Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, induction or attempted induction of an arrhythmia with right atrial pacing and recording and catheter ablation of arrhythmogenic focus, including intracardiac electrophysiologic 3-dimensional mapping, right ventricular pacing and recording, left atrial pacing and recording from coronary sinus or left atrium, and his bundle recording, when performed; with treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathway, accessory atrioventricular connection, cavo-tricuspid isthmus or other single atrial focus or source of atrial re-entry	X5
93654	Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, induction or attempted induction of an arrhythmia with right atrial pacing and recording and catheter ablation of arrhythmogenic focus, including intracardiac electrophysiologic 3-dimensional mapping, right ventricular pacing and recording, left atrial pacing and recording from coronary sinus or left atrium, and his bundle recording, when performed; with treatment of ventricular tachycardia	X5

CY 2024 PCT/HCPCS/CDT Code	CY 2025 Long Descriptor	Final CY 2025 ASC Payment Indicator
	or focus of ventricular ectopy including left ventricular pacing and recording, when performed	
93655	Intracardiac catheter ablation of a discrete mechanism of arrhythmia which is distinct from the primary ablated mechanism, including repeat diagnostic maneuvers, to treat a spontaneous or induced arrhythmia (list separately in addition to code for primary procedure)	X5
93656	Comprehensive electrophysiologic evaluation including transseptal catheterizations, insertion and repositioning of multiple electrode catheters with intracardiac catheter ablation of atrial fibrillation by pulmonary vein isolation, including intracardiac electrophysiologic 3-dimensional mapping, intracardiac echocardiography including imaging supervision and interpretation, induction or attempted induction of an arrhythmia including left or right atrial pacing/recording, right ventricular pacing/recording, and his bundle recording, when performed	X5
93657	Additional linear or focal intracardiac catheter ablation of the left or right atrium for treatment of atrial fibrillation remaining after completion of pulmonary vein isolation (list separately in addition to code for primary procedure)	X5

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3. Covered Ancillary Services

Covered ancillary services are specified in § 416.164(b) and, as stated previously, are eligible for separate ASC payment. As provided at § 416.164(b), we make separate ASC payments for ancillary items and services when they are provided integral to ASC covered surgical procedures that include the following: (1) brachytherapy sources; (2) certain implantable items that have pass-through payment status under the OPPS; (3) certain items and services that we designate as contractor-priced, including, but not limited to, procurement of corneal tissue; (4) certain drugs and biologicals for which separate payment is allowed under the OPPS; (5) certain radiology services for which separate payment is allowed under the OPPS; and (6) non-opioid pain management drugs that function as a supply when used in a surgical procedure. Payment for ancillary items and services that are not paid separately under the ASC payment system is packaged into the ASC payment for the covered surgical procedure.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59062 through 59063), consistent with the established ASC payment system policy (72 FR 42497), we finalized the policy to update the ASC list of covered ancillary services to reflect the payment status for the services under the OPPS and to continue this reconciliation of packaged status for subsequent calendar years. As discussed in prior rulemaking, maintaining consistency with the OPPS may result in changes to ASC payment indicators for some covered ancillary services. For example, if a covered ancillary service was separately paid under the ASC payment system in CY 2024, but will be packaged under the CY 2025 OPPS, we would also package the ancillary service under the ASC payment system for CY 2025 to maintain consistency with the OPPS. Comment indicator ''CH'' is used in Addendum BB (which is available via the internet on the CMS website) to indicate covered ancillary services for which we proposed a change in the ASC payment indicator to reflect a proposed change in the OPPS treatment of the service for CY 2025.

In the CY 2022 OPPS/ASC final rule with comment period, we finalized our proposal to revise 42 CFR 416.164(b)(6) to include, as ancillary items that are integral to a covered surgical procedure and for which separate payment is allowed, non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure as determined by CMS (86 FR 63490).

New CPT and HCPCS codes for covered ancillary services for CY 2025 can be found in section XIII.B of this final rule with comment period. All ASC covered ancillary services and their final payment indicators for CY 2025 are also included in Addendum BB to this final rule with comment period (which is available via the internet on the CMS website).

Comment: We received one comment requesting CMS not finalize its proposal to add HCPCS code C1605 to the list of covered ancillary services, due to CMS's policy that excludes contractors from paying claims for leadless pacemakers when the service is provided in the ASC setting.

Response: We thank the commenter for their feedback. As discussed in section XIII.D.2 above, procedures for leadless pacemakers are not covered when provided in the ASC setting (Medicare Claims Processing Manual (Pub. L. 100–04), Chapter 32, section 380.1.1). Therefore, we agree with the commenter and are not finalizing our proposal to add HCPCS code C1605 to the list of covered ancillary services.

Comment: We received several comments from physician societies requesting that CMS not finalize its proposal to add CPT code 93355

(Echocardiography, transesophageal (tee) for guidance of a transcatheter intracardiac or great vessel(s) structural intervention(s) (*e.g.,* tavr, transcatheter pulmonary valve replacement, mitral valve repair, paravalvular regurgitation repair, left atrial appendage occlusion/closure, ventricular septal defect closure) (peri-and intra-procedural), real-time image acquisition and documentation, guidance with quantitative measurements, probe manipulation, interpretation, and report, including diagnostic transesophageal echocardiography and, when performed, administration of ultrasound contrast, doppler, color flow, and 3d) to the covered ancillary procedures list. The commenters expressed safety concerns with adding CPT code 93355 to the covered ancillary services list, as the primary procedures that would be billed with this service are not performed in ASCs, with some of the procedures also being on the inpatient only list.

Response: We thank the commenters for their input. After further review, we agree with the commenters that the majority of primary procedures associated with CPT code 93355 are not on the ASC CPL and/or are performed in the inpatient setting. Therefore, we are not finalizing our proposal to add 93355 to the covered ancillary services list.

Claims Processing Limitations for Covered Ancillary Procedures Performed With G0330

We finalized adding HCPCS code G0330 (*Facility services for dental rehabilitation procedure(s) performed on a patient who requires monitored anesthesia (e.g., general, intravenous sedation (monitored anesthesia care) and use of an operating room)*) to the ASC CPL in the CY 2024 OPPS/ASC final rule (88 FR 81924). In ASC Addendum BB, there is a specific and definitive list of covered ancillary dental services with payment indicator of ''D1,'' indicating an ancillary dental service or item with no separate payment made. In the CY 2024 OPPS/ASC final rule with comment period (88 FR 81945 and 81946), we finalized that code G0330 could only be billed when accompanied by a covered ancillary procedure that has the payment indicator of ''D1.'' Performance of at least one of these covered ancillary services is integral to each of the surgical procedures that correspond to G0330. This limitation ensures that only covered ancillary services we evaluated for safety in the ASC setting could be performed with code G0330.

While HCPCS code G0330 must be billed with a covered ancillary procedure with a payment indicator of ''D1,'' these covered ancillary procedures with a payment indicator of ''D1'' can be billed with surgical procedures other than G0330. When billed with procedures other than code G0330, these ancillary procedures would be packaged in accordance with our policy for covered ancillary procedures. Additionally, other than HCPCS code G0330, procedures assigned to payment indicator ''D2'', indicating non office-based dental procedure added in CY 2024 or later, are not required to be billed with a covered ancillary procedure assigned to payment indicator ''D1'' to receive payment for the procedure.

The fact that a drug, device, procedure, or service is assigned a HCPCS code and a payment rate under the ASC payment system indicates only how the product, procedure, or service may be paid if covered by the program. MACs will be involved in the final decision regarding whether a drug, device, procedure, or other service meets all program requirements and conditions for coverage and payment. Therefore, even if a code describing a dental service has an associated payment rate on the ASC CPL, Medicare will only make payment for the service if it meets applicable requirements.

Comment: One commenter requested that CMS remove the requirement that HCPCS code G0330 must be billed along with a covered but non-payable dental ancillary service. The commenters stated that dental rehabilitation meet the regulatory requirements for inclusion on the ASC CPL.

Response: We thank the commenters for their input. The claims processing limitations around code G0330, for example, the requirement that code G0330 must be billed with a covered dental ancillary procedure with payment indicator ''D1,'' in the ASC setting, allows us to ensure that only covered ancillary services we have evaluated for safety in the ASC setting can be performed with code G0330.

After consideration of the public comments we received, we are finalizing this policy as proposed.

E. ASC Payment Policy for Non-Opioid Post-Surgery Pain Management Drugs, Biologicals, and Devices

1. Background on OPPS/ASC Non-Opioid Pain Management Packaging Policies

On October 24, 2018, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act (Pub. L. 115–271) was enacted. Section 1833(t)(22)(A)(i) of the Act, as added by section 6082(a) of the SUPPORT Act, states that the Secretary must review payments under the OPPS for opioids and evidence based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives. As part of this review, under section 1833(t)(22)(A)(iii) of the Act, the Secretary must consider the extent to which revisions to such payments (such as the creation of additional groups of covered outpatient department (OPD) services to separately classify those procedures that utilize opioids and non-opioid alternatives for pain management) would reduce the payment incentives for using opioids instead of non-opioid alternatives for pain management. In conducting this review and considering any revisions, the Secretary must focus on covered OPD services (or groups of services) assigned to C–APCs, APCs that include surgical services, or services determined by the Secretary that generally involve treatment for pain management. If the Secretary identifies revisions to payments pursuant to section 1833(t)(22)(A)(iii) of the Act, section 1833(t)(22)(C) of the Act requires the Secretary to, as determined appropriate, begin making revisions for services furnished on or after January 1, 2020. Revisions under this paragraph are required to be treated as adjustments for purposes of paragraph (9)(B) of the Act, which requires any adjustments to be made in a budget neutral manner. Section 1833(i)(8) of the Act, as added by section 6082(b) of the SUPPORT Act, requires the Secretary to conduct a similar type of review as required for the OPPS and to make revisions to the ASC payment system in an appropriate manner, as determined by the Secretary.

For a detailed discussion of rulemaking on non-opioid alternatives prior to CY 2020, we refer readers to the CYs 2018 and 2019 OPPS/ASC final rules with comment period (82 FR 59345; 83 FR 58855 through 58860).

For the CY 2020 OPPS/ASC proposed rule (84 FR 39423 through 39427), as required by section 1833(t)(22)(A)(i) of the Act, we reviewed payments under the OPPS for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids

instead of non-opioid alternatives. For the CY 2020 OPPS/ASC proposed rule (84 FR 39423 through 39427), we proposed to continue our policy to pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures when they are furnished in the ASC setting and to continue to package payment for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures in the hospital outpatient department setting.

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61173 through 61180), after reviewing data from stakeholders and Medicare claims data, we did not find compelling evidence to suggest that revisions to our OPPS payment policies for non-opioid pain management alternatives were necessary for CY 2020. We finalized our proposal to continue to unpackage and pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as surgical supplies when furnished in the ASC setting for CY 2020. Under this policy, for CY 2020, the only drug that qualified for separate payment in the ASC setting as a non-opioid pain management drug that functions as a surgical supply was Exparel.

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 85896 through 85899), we continued the policy to pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures when they were furnished in the ASC setting and to continue to package payment for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures in the hospital outpatient department setting for CY 2021. For CY 2021, only Exparel and Omidria met the criteria as non-opioid pain management drugs that function as surgical supplies in the ASC setting and received separate payment under the ASC payment system.

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63483), we finalized a policy to unpackage and pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting, are FDA-approved, have an FDA-approved indication for pain management or as an analgesic, and have a per-day cost above the OPPS/ASC drug packaging threshold; and we finalized our proposed regulation text changes at 42 CFR 416.164(a)(4) and (b)(6), 416.171(b)(1), and 416.174 as proposed.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72089), we determined that five products were eligible for separate payment in the ASC setting under our final policy for CY 2022. We noted that future products, or products not discussed in that rulemaking that may be eligible for separate payment under this policy, would be evaluated in future rulemaking (86 FR 63496). In the CY 2023 final rule with comment period, we finalized that five drugs would receive separate payment in the ASC setting for CY 2023 under the policy for non-opioid pain management drugs and biologicals that function as surgical supplies (86 FR 63496).

In the CY 2023 OPPS/ASC final rule with comment period, we finalized a clarification of our policy by codifying the two additional criteria for separate payment for non-opioid pain management drugs and biologicals that function as surgical supplies in the regulatory text at § 416.174 as a technical change. First, we finalized at new § 416.174(a)(3) that non-opioid pain management drugs or biologicals that function as a supply in a surgical procedure are eligible for separate payment if the drug or biological does not have transitional pass-through payment status under § 419.64. In the case where a drug or biological otherwise meets the requirements under § 416.174 and has transitional pass-through payment status that will expire during the calendar year, the drug or biological would qualify for separate payment under § 416.174 during such calendar year on the first day of the next calendar year quarter after its pass-through status expires. Second, we finalized that new § 416.174(a)(4) would reflect that the drug or biological must not already be separately payable in the OPPS or ASC payment system under a policy other than the one specified in § 416.174.

In the CY 2024 OPPS/ASC final rule with comment period, we finalized four drugs as eligible to receive separate payment as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system and which met the criteria at § 416.174(a) for CY 2024.

F. Final CY 2025 Non-Opioid Policy for Pain Relief Under the OPPS and ASC Payment System

1. Background on Access to Non-Opioid Treatments for Pain Relief

The Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–328), was signed into law on December 29, 2022. Section 4135(a) and (b) of the CAA, 2023, titled Access to Non-Opioid Treatments for Pain Relief, amended section 1833(t)(16) and section 1833(i) of the Social Security Act, respectively, to provide for temporary additional payments for non-opioid treatments for pain relief (as that term is defined in section 1833(t)(16)(G)(i) of the Act). In particular, section 1833(t)(16)(G) provides that with respect to a non-opioid treatment for pain relief furnished on or after January 1, 2025, and before January 1, 2028, the Secretary shall not package payment for the non-opioid treatment for pain relief into payment for a covered OPD service (or group of services) and shall make an additional payment for the non-opioid treatment for pain relief as specified in clause (ii) of that section. Clauses (ii) and (iii) of section 1833(t)(16)(G) of the Act provide for the amount of additional payment and set a limitation on that amount.

Paragraph (10) of section 1833(i) of the Act cross-references the OPPS provisions about the additional payment amount and payment limitation for non-opioid treatments for pain relief and applies them to payment under the ASC payment system. In particular, subparagraph (A) of paragraph (10) of section 1833(i) of the Act, as added by section 4135(b) of the CAA, 2023, provides that in the case of surgical services furnished on or after January 1, 2025, and before January 1, 2028, additional payments shall be made under the ASC payment system for non-opioid treatments for pain relief in the same amount provided in clause (ii) and subject to the limitation in clause (iii) of section 1833(t)(16)(G) of the Act for the OPPS. Subparagraph (B) of section 1833(i)(10) of the Act provides that a drug or biological that meets the requirements of 42 CFR 416.174 and is a non-opioid treatment for pain relief shall also receive additional payment in the amount provided in clause (ii) and subject to the limitation in clause (iii) of section 1833(t)(16)(G) of the Act.

Additional payments are required to begin on January 1, 2025. The statute directs CMS to provide ''additional payment'', and for purposes of the proposal, we interpret this language to be equivalent to ''separate payment,'' since CMS provides an additional payment by unpackaging the product and then making a separate payment. ''Separate payment'' is the more commonly used terminology in the OPPS rule and likely more familiar to readers. To avoid confusion, we will be using ''separate payment'' throughout the rest of this section, which we

believe to be synonymous with ''additional payment.''

Our CY 2025 proposals to implement the amendments to sections 1833(t)(16) and section 1833(i) of the Act required by section 4135 of the CAA, 2023 are discussed below, followed by a summary of comments, our responses to those comments, and our finalized policy for CY 2025.

2. Final CY 2025 Non-Opioid Policy Implementation of Section 4135 of the CAA, 2023

a. Statutory Authority for OPPS/ASC Non-Opioid Policy

Prior to CY 2025, the statutory authority for the ASC non-opioid policy has been section 1833(i)(8) of the Act, as added by section 6082(b) of the SUPPORT Act. Section 1833(i)(8) of the Act refers to paragraph (t)(22), which states that the Secretary shall conduct a similar type of review as the one required for the OPPS for opioids and evidence based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives and make such revisions as the Secretary determines appropriate. As discussed in the previous section, CMS's policy for CY 2024 is to provide separate payment in the ASC setting for certain qualifying non-opioid pain management drugs that function as a supply in a surgical procedure.

As noted previously, section 4135 of the CAA, 2023, provides for temporary separate payments for certain non-opioid treatments for pain relief in both the hospital outpatient department and ambulatory surgical center settings from January 1, 2025, through December 31, 2027. Specifically, these separate payments are for qualifying drugs, biologicals, and devices that, among other requirements, have their payment packaged into payment for a covered OPD service (or group of services). Pursuant to section 1833(t)(2)(E) of the Act, the temporary separate payments must be made in a budget neutral manner.

(1) Drugs and Biologicals Subject to the ASC Non-Opioid Policy (42 CFR 416.174)

Section 1833(i)(10)(B), titled ''Transition,'' provides that a drug or biological that meets the requirements of the regulation at 42 CFR 416.174, the current ASC non-opioid policy, and also meets the definition of a non-opioid treatment for pain relief at section 1833(t)(16)(G)(iv) shall receive separate payments under section 4135 of the CAA, 2023, subject to the payment limitation. In light of this requirement, we proposed that drugs and biologicals that meet the definition of a non-opioid treatment for pain relief for purposes of section 4135 that are currently subject to the ASC policy for non-opioid treatments authorized by section 6082 of the SUPPORT Act, would instead receive separate payments, subject to the limitation, for the duration of the payment period for section 4135. These drugs and biologicals are described in the discussions that follow.

Comment: Commenters were generally supportive of CMS paying for drugs paid under the ASC non-opioid treatment policy authorized by section 6082 of the SUPPORT Act under the policy authorized by section 4135 of the CAA, 2023. Commenters recommended that CMS ensure payment did not decrease, to the extent possible, when the transition between policies occurs. Finally, commenters were looking ahead and recommended that CMS begin to assess its authority for continuing a policy for the payment of non-opioid treatments for pain relief, starting in CY 2028 and beyond. Some commenters recommended CMS assess their waiver authority and look to extend the policy in a non-budget neutral manner.

Response: We thank commenters for their support. As described in the following sections, we must comply with the requirements of the statute in our policy implementation. We will continue to monitor the effects of our payment policies, explore our authorities, and consider what policies may be appropriate in future rulemaking.

Based on the comments received, we are finalizing our proposal that drugs and biologicals that meet the definition of a non-opioid treatment for pain relief for purposes of section 4135 that are currently subject to the ASC policy for non-opioid treatments authorized by section 6082 of the SUPPORT Act, would instead receive separate payments, subject to the payment limitation, for the duration of the payment period for section 4135.

(2) Definition of Non-Opioid Treatment for Pain Relief

Section 1833(t)(16)(G)(iv) of the Act defines a non-opioid treatment for pain relief. In order for a drug or biological product to qualify as a non-opioid treatment for pain relief, pursuant to section 1833(t)(16)(G)(iv)(I), the product must have ''a label indication approved by the Food and Drug Administration to reduce postoperative pain, or produce postsurgical or regional analgesia, without acting upon the body's opioid receptors.'' In order for a medical device to qualify as a non-opioid treatment for pain relief, pursuant to section 1833(t)(16)(G)(iv)(II)(bb), the medical devices must be ''used to deliver a therapy to reduce postoperative pain, or produce post-surgical or regional analgesia.'' This subparagraph also defines such a device as having ''an application under section 515 of the Federal Food, Drug, and Cosmetic Act that has been approved with respect to the device, been cleared for market under section 510(k) of such Act, or is exempt from the requirements of section 510(k) of such Act pursuant to subsection (l) or (m) or section 510 of such Act or section 520(g) of such Act'' and ''demonstrated the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed in a clinical trial or through data published in a peer-reviewed journal.''

Comment: Commenters were very supportive of CMS using the exact language in the statue in the definition of a non-opioid treatment for pain relief. Commenters recommended CMS codify this definition.

Response: We thank commenters for their support.

Comment: One commenter recommended CMS adopt a definition that allows for the combined use of devices and drugs together, rather than just the individual components, for the purposes of separate payment for a non-opioid treatment for pain relief.

Response: We thank the commenter for their suggestion. Section 4135 does not contemplate a situation where a combination of products may qualify. However, if the individual components, either a drug, biological, or device, meet the statutory criteria, it would qualify for separate payment under this provision.

Comment: A couple commenters recommended that CMS include orally self-administered drugs as potentially qualifying drugs for separate payment under this policy. One comment requested CMS affirm that self-administered non-opioid pain relievers will qualify for separate payment and requested CMS affirm that such drugs that function as a supply when used in conjunction with a surgical procedure qualify for separate payment under the proposed policy. Similarly, one drug manufacturer of an investigational oral drug product recommended that self -administered non-opioid treatments for pain relief should qualify for separate payment in certain circumstances. For their specific product, they stated that

they anticipated if the drug is FDA-approved, providers may administer the oral product to beneficiaries before or after a surgical procedure. This commenter stated that the statute makes no distinction between the method of administration of the qualifying drug and that current OPPS regulations indicate that, in certain circumstances, drugs that may be considered usually self-administered by the patient may be paid when they function as supplies.

Response: We thank the commenters for raising these concerns through their comments. We believe it is premature to evaluate a product that is not FDA-approved for inclusion in this policy, as FDA approval is a requirement for drugs and biological products. We will evaluate all products, including newly FDA-approved products, to determine whether they meet the criteria in the statute and the regulations at 42 CFR 419.43(k).

(3) Evidence Requirement for Medical Devices

For CY 2025, to determine whether a medical device fulfills the statutory requirement that it has demonstrated the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed in a clinical trial or through data published in a peer-reviewed journal, we proposed to review all data submitted during the public comment period to determine if the device demonstrates the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids. We encouraged interested parties submitting non-opioid device recommendations for CY 2025 to also submit any relevant literature that demonstrates that the named medical device replaces, reduces, or avoids opioid use per this statutory provision with their public comments. We proposed that CMS would review any literature submitted and determine whether it meets this evidence criterion. We did not require that commenters submit any data or literature with their device recommendations. If there was no data or literature submitted for a medical device, or if the materials submitted do not demonstrate any ability of the medical device to replace, reduce, or avoid opioids, the medical device will not meet this evidence criterion and will therefore not qualify for separate payment under section 4135.

Comment: Most commenters recommended that CMS evaluate any literature submitted and not implement additional or burdensome requirements for peer reviewed literature. For example, one commenter stated that given the unique challenges of testing new non-opioid pain treatments, they believed the need for evidence must be balanced against the costs and time involved in collecting the data and how this process could delay the availability of novel technologies to treat unmet clinical needs. This commenter asked CMS to confirm that well-designed prospective, retrospective, and real-world evidence clinical trials that are published in peer-reviewed journals provide a means of satisfying the requirement for medical devices.

Response: We are adhering to the statutory language of the Act and are requiring that a medical device has demonstrated the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed in a clinical trial or through data published in a peer-reviewed journal. To the extent that literature submitted by interested parties satisfies that requirement, the medical device would qualify for separate payment. We cannot say with certainty that a specific study design would always or would never satisfy this criterion.

After consideration of the public comments we received, we are finalizing our proposal that we will review all data submitted during the public comment period to determine if the device demonstrates the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids.

b. Non-Opioid Product Indications

(1) FDA-Approved Indications for Drugs and Biologicals

Section 1833(t)(16)(G)(iv)(I) of the Act specifies that to meet the definition of a non-opioid treatment for pain relief and to be eligible for separate payment, a drug or biological product must have a label indication approved by the Food and Drug Administration to reduce postoperative pain, or produce postsurgical or regional analgesia, without acting upon the body's opioid receptors.

Given these statutory requirements, we proposed only to approve separate payment for drug or biological products with an FDA-approved indication that closely aligns with the statutorily required indication language to reduce post-operative pain or produce post-surgical or regional analgesia for CY 2025. We noted that products with an indication that does not meet the statutory requirement would not qualify. Table 84 from the CY 2025 OPPS/ASC proposed rule (89 FR 59431), and Table 156 in this final rule with comment period, includes citations to the indications of the drugs and biologicals proposed to have met the statutory requirements and qualify for separate payment in the CY 2025 OPPS/ASC proposed rule.

Comment: The majority of commenters supported CMS using the language in the Act as the basis for determining whether a drug or biologic had the appropriate FDA-approved indication, in order to qualify for separate payment under this policy. A few commenters indicated that the specific indication requirements for drugs and biologicals was an intentional choice, as Congress did not require a specific labeled indication for medical devices.

Response: We thank commenters for their feedback and support.

Comment: Some commenters recommended CMS interpret more broadly the statutory language requiring drugs and biologicals to have an FDA-approved indication to reduce postoperative pain, or produce postsurgical or regional analgesia, without acting upon the body's opioid receptors. For example, one commenter recommended CMS consider drugs that are used off-label for post-surgical pain, meaning a drug that does not have an FDA-approved indication for reducing post-operative pain, but is used for that purpose, based on existing evidence. One example provided was the drug Dexycu, which the commenter states reduces post-operative inflammation, and therefore pain, following cataract surgery. Another commenter provided the example of IV acetaminophen and stated that the product has been used in pain management but is not specifically indicated in FDA-approved labeling for post-surgical pain management. These commenters contend that these products have been used off-label in pain management for decades and they are concerned that the statute inappropriately excludes those types of products from qualifying for separate payment. They also recommend CMS address the packaging of these products, by exempting non-opioid drugs and regional anesthesia procedures to manage pain in a surgical procedure from comprehensive APC (C–APC) packaging policies.

The manufacturer of a similar product, Caldolor, an intravenous formulation of ibuprofen, which has a general acute pain indication for the management of mild to moderate pain and the management of moderate to severe pain as an adjunct to opioid analgesics, also made similar recommendations. This commenter

stated this product is similar to several other non-opioid pain management products listed in the proposed rule, such as ketorolac tromethamine injection. This commenter cited FDA guidance where a product may be granted a general acute pain indication when supported by at least two clinical trials, each in a different pain population. This commenter believed that their more general pain indication should satisfy the statutory requirement that a qualifying drug or biological must have a label indication approved by the Food and Drug Administration to reduce postoperative pain, or produce postsurgical or regional analgesia, without acting upon the body's opioid receptors. They do not believe that the statute requires that the FDA-approved indication expressly refer to use for postoperative or postsurgical pain. They noted that their product was studied in a post-surgical population. Additionally, this commenter does not believe there is evidence that Congress intended section 4135 to exclude a non-opioid product that has a general pain indication or only include a product if the indication statement expressly refers to use for postoperative or postsurgical pain (for example, by stating that a product is used usually in a postoperative setting).

Response: Congress specifically included language requiring that drugs or biologicals have ''a label indication approved by the Food and Drug Administration to reduce postoperative pain, or produce postsurgical or regional analgesia, without acting upon the body's opioid receptors.'' We also note that many patients who receive services paid under the OPPS and ASC payment system are often in a post-surgical environment, given the nature of the procedure typically performed in an ASC or HOPD.

As there is no mention of post-operative or post-surgical use in the FDA-approved indications for the products Caldolor,[184] Dexycu,[185] or Ofirmev [186] (IV acetaminophen), we do not believe these products meet the statutory criteria and therefore do not qualify for separate payment under this policy. Additionally, we do not believe other modifications to longstanding OPPS payment policies are warranted at this time to provide separate payment for these products. We note that all other drug products proposed and finalized for separate payment have an FDA indication for reduction of postoperative pain, or production of postsurgical or regional analgesia, without acting upon the body's opioid receptors. This includes a similar product, intravenous ketorolac, that was mentioned in one comment letter, which is indicated for the short-term management of moderately severe acute pain that requires analgesia at the opioid level, usually in the postoperative setting.[187] We do not believe that products mentioned by commenters that lack an FDA-approved indication to reduce postoperative pain, or produce postsurgical or regional analgesia, without acting upon the body's opioid receptors meet the statutory requirement. We also note that those products that do meet the statutory requirements will be exempt from C–APC packaging. We are not finalizing any additional changes to our C–APC policy at this time, as we continue to believe that generally the C–APC packaging policy maintains the important packaging principles of the OPPS.

After a consideration of comments received, we are finalizing our proposal without modification, to only approve separate payment for drug or biological products with an FDA-approved indication to reduce post-operative pain or produce post-surgical or regional analgesia. Products such as those with only a general pain indication will not qualify.

(2) Indications for Medical Devices

With respect to medical devices, section 1833(t)(16)(G)(iv)(II) of the Act specifies that such a device must be used to deliver a therapy to reduce postoperative pain or produce post-surgical or regional analgesia to qualify for separate payment under section 4135. It also must have an application approved under section 515 of the Federal Food, Drug, and Cosmetic Act (FDCA), have been cleared for market under section 510(k) of the FDCA, or be exempt from the requirements of section 510(k) of the FDCA pursuant to section 510(l) or (m) or 520(g) of the FDCA. For CY 2025, for medical devices, we proposed to only approve medical devices with an indication that specifies that the device is used to deliver a therapy to reduce postoperative pain or produce post-surgical or regional analgesia and which also have FDA approval, market clearance, or an appropriate exemption from the requirements of section 510(k).

Comment: Commenters recommended CMS adhere closely to the statutory language when creating its policy. Several commenters recommended CMS clarify their proposal and the regulation text at 42 CFR 419.83(k)(2)(i) through (iv). Specifically, commenters were concerned that CMS was deviating from the statute and requiring an additional FDA-approved indication for use for medical devices that was not in statute. Commenters believed that CMS should not require medical devices to have an indication that specifies that the device is used to deliver a therapy to reduce postoperative pain or produce post-surgical or regional analgesia. Commenters believed Congress had clear and distinct intentions regarding the statutory criteria for medical devices compared to drugs and biologicals and chose not to subject medical devices to the same indications for use standard that applies to drugs and biologicals.

Response: We thank commenters for raising this issue and requesting clarification from CMS. We acknowledge the proposed rule may not have been sufficiently clear regarding the FDA-approved indications for medical devices. However, we confirm that while medical devices must be used to deliver a therapy to reduce postoperative pain, or produce postsurgical or regional analgesia, they are not required by statute to have specific language to this effect in a FDA-approved indication. Rather, the medical device must have an application approved under section 515 of the Federal Food, Drug, and Cosmetic Act (FDCA), have been cleared for market under section 510(k) of the FDCA, or be exempt from the requirements of section 510(k) of the FDCA pursuant to section 510(l) or (m) or 520(g) of the FDCA. We note that the regulation text that we proposed, and are finalizing without modification at 42 CFR 419.43(k)(2)(i) through (iv), does not require a specific FDA-approved indication for medical devices. However, one way to show that a medical device is used to deliver a therapy to reduce postoperative pain, or produce postsurgical or regional analgesia, could be through language indicating that in an FDA-approved indication.

After consideration of the public comments we received, we are finalizing without modification our proposal that a device must be used to deliver a therapy to reduce postoperative pain or produce post-

[184] Caldolor. FDA Package Insert. May 2023. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/022348s024lbl.pdf.*

[185] Dexycu. FDA Package Insert. June 2020. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/208912s002lbl.pdf.*

[186] Ofirmev. FDA Package Insert. April 2018. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/022450s011lbl.pdf.*

[187] Ketorolac tromethamine Injection. FDA Package Insert. May 2014. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/074802s038lbl.pdf.*

surgical or regional analgesia to qualify for separate payment under section 4135 for CY 2025. It also must have an application approved under section 515 of the Federal Food, Drug, and Cosmetic Act (FDCA), have been cleared for market under section 510(k) of the FDCA, or be exempt from the requirements of section 510(k) of the FDCA pursuant to section 510(l) or (m) or 520(g) of the FDCA. This is consistent with the regulation text that we are finalizing without modification at 42 CFR 419.43(k)(2)(i) through (iv). We are clarifying that medical devices are not required to have specific language in their FDA approved indication to have a specific FDA-approved indication like drugs and biologicals. However, one way to show that a medical device is used to deliver a therapy to reduce postoperative pain, or produce postsurgical or regional analgesia, could be through language indicating that it has an FDA-approved indication for one or more of those uses.

c. Amount of Payment

Section 1833(t)(16)(G)(ii)(I) of the Act provides that, for a non-opioid treatment for pain relief that is a drug or biological product, the amount of separate payment is the amount of payment for such product determined under section 1847A of the Act that exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the drug or biological, subject to a limitation, as described in the next section. Section 1833(t)(16)(G)(ii)(II) of the Act provides that, for a non-opioid treatment for pain relief that is a medical device, the amount of separate payment is the amount of the hospital's charges for the device, adjusted to cost, that exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the device, subject to a limitation, as described in the next section. As the language in section 1833(t)(16)(G)(ii)(II) of the Act is very similar to the transitional pass-through language at section 1833(t)(6)(D)(i) and (ii) of the Act, we proposed implementing a similar payment methodology for non-opioid products. A payment offset is the amount reflecting the portion of the non-opioid product in the procedure payment rate.

We proposed to assign a payment offset of zero dollars for the qualifying drugs, biologicals, and devices for CY 2025. A zero offset means that we would not offset or remove the amount that the non-opioid product represents from the procedure payment rate when setting payment rates. We proposed this would apply for CY 2025 for all non-opioid drugs, biologicals, and devices that qualify for separate payment. We proposed a zero dollar offset for the initial year of the policy as some of these products are new products or newly separately paid in the OPPS setting and their costs may not be fully reflected yet in the cost of procedures in which they may be used. Therefore, the separate payment for a drug or biological will be determined by subtracting from the amount calculated using the methodology outlined in section 1847A of the Act the portion of the otherwise applicable Medicare OPD fee schedule associated with the drug or biological, which as previously discussed, we proposed to be zero dollars for CY 2025. For the amount of payment for a medical device, the separate payment amount will be determined by subtracting from the hospital's charges for the device, adjusted to cost, the portion of the otherwise applicable Medicare OPD fee schedule amount associated with the medical device, which as previously discussed, we proposed to be zero dollars for CY 2025. These separate payment amounts will all be subject to the payment limitation, described in the subsequent section.

Section 1833(i)(10) of the Act establishes the same separate payment for the ASC setting as for hospital outpatient departments, as described in section 1833(t)(16)(G)(ii) of the Act. Both separate payments are subject to the limitation in section 1833(t)(16)(G)(iii) of the Act, which specifies that the separate payment amount shall not exceed the estimated average of 18 percent of the OPD fee schedule amount for the OPD service (or group of services) with which the non-opioid treatment for pain relief is furnished. Our final implementation of this payment limitation is discussed in further detail below. Given this statutory requirement, we proposed to pay the same separate payment amount for qualifying non-opioid products in both the HOPD and ASC settings.

As the statute requires separate payment for these non-opioid treatments for pain relief, these products cannot be packaged into the procedure payment. Under our current threshold packaging policy, if the estimated per day cost for a drug or biological is less than or equal to the applicable OPPS drug packaging threshold, we package payment for the drug or biological into the payment for the associated procedure. Similarly, under our comprehensive APC (C–APC) policy, we package all payments for services integral, ancillary, supportive, dependent, and adjunctive to the primary service into a single payment for the primary comprehensive service. For CY 2025, we proposed that non-opioid treatments for pain relief would not be subject to the threshold packaging policy in section V.B.1.a. of the CY 2025 OPPS/ASC proposed rule (89 FR 59363) and would also be separately paid when used during a comprehensive APC (C–APC) procedure in the HOPD setting. For more information on the drug packaging threshold, see section V.B.1.a of this final rule with comment period, and section II.A.b of this final rule with comment period for further information on C–APC packaging.

Comment: Most commenters strongly agreed with our proposals to provide separate payment for qualifying products. Commenters agreed that it was appropriate to assign a zero dollar offset for the initial year, CY 2025. Some commenters recommended CMS continue to assign a zero dollar offset for the duration of the 3-year separate payment policy.

Response: We thank commenters for their support. We will evaluate the need to continue to assign a zero dollar offset for future years in future rulemaking.

Comment: Some commenters recommended specific payment and payment limitation amounts be assigned for payment for certain medical devices.

Response: We note that the statute requires the additional payment for qualifying medical devices to be based on the hospital's charges for the device, adjusted to cost; therefore, we do not find it appropriate to assign a specific payment amount for a qualifying medical device.

Comment: A small number of commenters did not agree with our proposal to pay separately and unpackage qualifying non-opioid treatments for pain relief. Specifically, one commenter upheld the value and importance of the OPPS packaging policies, though they recognized that the agency was required to implement the statute and believed our proposed implementation was reasonable. Another commenter cautioned over-incentivizing non-opioid products, noting that opioids used with appropriate prescribing oversight and medical supervision remain an effective tool for pain.

Response: We thank commenters for their input.

After consideration of the public comments we received, we are finalizing our policy as proposed for CY 2025. Specifically, we are finalizing that the separate payment amount for a drug

or biological will be determined by subtracting from the amount calculated using the methodology outlined in section 1847A of the Act the portion of the otherwise applicable Medicare OPD fee schedule associated with the drug or biological, which we are finalizing to be zero dollars for CY 2025. For the amount of payment for a medical device, the separate payment amount will be determined by subtracting from the hospital's charges for the device, adjusted to cost, the portion of the otherwise applicable Medicare OPD fee schedule amount associated with the medical device, which we are finalizing to be zero dollars for CY 2025. Additionally, qualifying non-opioid treatments for pain relief will not be subject to the drug threshold packaging policy, described in section V.B.1.a. of this final rule with comment period, and will also be separately paid when used during a comprehensive APC (C–APC) procedure in the HOPD setting.

d. Payment Limitation

Section 1833(t)(16)(G)(iii) of the Act states that the separate payment amount specified in clause (ii), (which is described in the previous section) shall not exceed the estimated average of 18 percent of the OPD fee schedule amount for the OPD service (or group of services) with which the non-opioid treatment for pain relief is furnished, as determined by the Secretary.

For the non-opioid products that are currently billed under the OPPS, we conducted a claims analysis of CY 2023 OPPS claims, which are the claims available for CY 2025 rulemaking, and found that approximately 90 percent of the utilization, on average, for these non-opioid products is focused in the top five most frequently performed services for each product. Given this, we believed that using the top five services would provide a representative estimate for purposes of the payment limitation. As illustrated in Table 85 in the CY 2025 OPPS/ASC proposed rule (89 FR 59432), we proposed to use the top five services by volume associated with a drug, biological, or medical device, to determine the volume-weighted payment rate per claim and the 18 percent payment limitation specified by statute, based on the most recent claims data available for CY 2025. This payment limitation approach was also generally consistent with the comments received in response to the comment solicitation in the CY 2024 OPPS/ASC proposed rule (88 FR 49767 through 49769). For example, in response to the CY 2024 comment solicitation, several commenters supported CMS establishing a payment limitation for each non-opioid treatment item, based on a volume-weighted OPPS payment rate for the top five services that package the item into their payment rate.

We proposed to apply the 18 percent payment limitation per date of service billed, rather than per HCPCS dosage unit. This is due to the fact that there are typically multiple HCPCS dosage units, also called billing units, of each drug or biological billed per claim. Thus, the total units of a drug billed on a date of service is more reflective of the cost of the drug in that encounter. The amount of drug or biological used during an encounter, represented by a date of service for purposes of the proposal, will impact whether the separate payment for the drug or biological exceeds the payment limitation required by statute. Meaning, the same drug or biological may or may not be subject to the payment limitation, depending on the amount of drug used. For example, a drug is paid $1 per 1 mg (per billing unit) and has a payment limitation set at $100, based on 18 percent of the volume weighted average of the payment of the top 5 services associated with the use of the drug. If 50 mg (50 billing units) of this drug were to be billed during one patient encounter or one date of service, then $50 would be paid. The payment limitation would not apply as the payment for the drug did not exceed the payment limitation of $100. If 200 mg (200 billing units) of that same drug were to be billed during one patient encounter or one date of service, then the $200 payment would be limited to $100. In this case, the payment limitation would apply as the payment for the drug exceeded the payment limitation of $100. We proposed to apply this payment limitation to the date of service billed as the payment limitation applies to the total amount of separate payment, rather than the HCPCS dosage unit payment, which may only represent a small fraction of the total amount of payment.

For CY 2025, we proposed to create new status indicators for non-opioid drugs and devices to implement this payment limitation. Under the OPPS, non-opioid drugs and biologicals under this policy would be assigned a status indicator of ''K1''—Non-Opioid Drugs and Biologicals For Post-Surgical Pain Relief, while non-opioid devices would be assigned a status indicator of ''H1''—Non-opioid Medical Devices For Post-Surgical Pain Relief. Further discussion of the proposed new status indicators can be found in section X1.A of the CY 2025 OPPS/ASC proposed rule (89 FR 59404).

As discussed in section XIII.B.6.b. of the CY 2025 OPPS/ASC proposed rule (89 FR 59412), we proposed to modify the descriptor of ASC payment indicator ''L6''—''New Technology Intraocular Lens (NTIOL); special payment'' to ''Special payment; New Technology Intraocular Lens (NTIOL) or qualifying non-opioid devices'' and proposed to assign qualifying non-opioid medical devices to this payment indicator to operationalize payment of these devices. We proposed to assign qualifying drugs and biologicals to existing payment indicator ''K2''—Drugs, biologicals, and radiopharmaceuticals paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS rate.

We welcomed public comment on the methodology used to determine the payment limitation.

Comment: Most commenters agreed with CMS's rationale and methodology that using a volume weighted average of the top five procedures based on available claims data and applied per date of service was a reasonable approach in order to implement the 18 percent payment limitation requirement.

Response: We thank commenters for their support.

Comment: Commenters were supportive of utilizing new OPPS status indicators ''H1'' and ''K1'' as well as existing ASC payment indicators ''L6'' and ''K2'' in order to operationalize payment for qualifying products.

Response: We thank commenters for their support.

Comment: A few commenters recommended CMS modify its proposed payment limitation approach. For example, one commenter recommended CMS explore its discretion to provide higher payment limitations, such as by using the top 10 procedures by volume to determine a payment limitation. It believed this would increase the payment limitation for its product, Dextenza, as evidenced by independent analysis provided with its comment.

Response: We appreciate the feedback, information, and analysis provided by commenters. Based on our analysis, the vast majority of the utilization of a product occurs within the top 5 procedures in which it is used. For example, for the drug Dextenza, approximately 96 percent of the product's utilization is concentrated in the top five procedures. This is also supported by the data presented in the comment letter. We are concerned that using the top ten procedures would include unlikely procedures in the calculation of the payment limitation, which may inappropriately skew the

payment limitation. Additionally, given the overall support for using the top 5 procedures we are finalizing that methodology.

Comment: Many commenters recommended CMS update the data it used for its payment limitation calculation in the final rule. Many commenters supported CMS identifying the services with which a product would be expected to be furnished and would typically be packaged absent this policy. However, they did not believe that the procedures listed in CY 2025 OPPS/ASC proposed rule Table 85 were primary procedures. Commenters recommended that CMS use updated data for CY 2025 and only include primary procedures as the basis for calculating the payment limitation. Commenters also recommended CMS not use procedures described by unlisted codes in the payment limitation calculation. They also recommended CMS use Revenue Center Payment Method Indicators to filter the data for primary procedures only, including those HCPCS codes with a Revenue Center Payment Method Indicator of ''1'' and excluding those HCPCS codes with a Revenue Center Payment Method Indicator value of ''9''.

Response: We thank commenters for their feedback and review of our proposed methodology. Our intent is to only use primary procedures with which the qualifying non-opioid treatment for pain relief drug or device would typically be packaged. We acknowledge that in the proposed rule, some non-primary procedures were inadvertently included because they were among the most common procedures furnished with the non-opioid treatment for pain relief by volume; however, payment for the non-opioid treatment for pain relief was not always packaged into those common procedures. Therefore, consistent with the intent of our proposal and the comments received, we have updated the payment limitations accordingly with the most recent data available for this final rule and have excluded any procedures with which the payment for the non-opioid treatment was not packaged.

Using the updated final rule data and excluding non-primary procedures, the HCPCS codes identified are the primary procedure codes with which each non-opioid treatment for pain relief had its payment packaged. None of these updated top five procedures based on volume were unlisted HCPCS codes, so we are not using unlisted HCPCS codes to determine the payment limitation. We are using the CY 2025 OPPS/ASC proposed rule procedure payment rates to determine the payment limitations because we believe they are the best proxy for determining the estimated payment limitations for each product. The proposed rule procedure payment rates were the most recently available data at the time of calculation, and we expect those rates to be relatively unchanged from the final rule rates. We refer commenters to Table 157 to see the final list of primary procedures for CY 2025.

Comment: A few commenters asked for clarification regarding the payment limitation. For example, one commenter noted the payment limitation may pose challenges for use of medical devices under this policy, as the underlying procedures are also likely to be device intensive. Commenters also requested greater clarity regarding which top five services will be selected for the payment calculation process, including whether device offset costs will be included in those procedures. For ASC payments, it is also unclear whether the zero percent device offset would result in the payment being deflated by the ASC scaler, and therefore result in a lower ASC payment for procedures using these technologies. The commenter stated that this is particularly important because many non-opioid pain treatment devices are used in the ASC setting, and the decreased ASC payments may result in unintended consequences around use of these technologies.

Response: Section 1833(t)(16)(G)(ii) requires that we provide temporary additional payment for non-opioid drugs, biologicals, and medical devices, subject to a payment limitation for which the drug, biological, or medical device cost exceeds the portion of the OPPS APC payment rate that is associated with that drug, biological, or medical device. As we discussed in the CY 2025 OPPS/ASC proposed rule (89 FR 59429) we proposed to assign a payment offset of zero dollars for qualifying drugs, biologicals, and devices for CY 2025. A zero offset means that we would not offset or remove the amount that the non-opioid product represents from the procedure payment rate when setting payment rates.

We believe it is appropriate to finalize a zero dollar offset for the initial year of the policy as some of these procedures are new products or newly separately paid in the OPPS or ASC settings. For the payment limit determination, the top five services by volume into which a qualifying non-opioid treatment for pain relief has its payment packaged will be used to determine the volume-weighted 18 percent payment limitation. The existing device portions of device-intensive procedures do not contain cost and utilization data for qualifying separately payable non-opioid devices, nor can we currently identify other device costs associated with these medical devices. We anticipate we would only have cost and utilization data from claims of non-opioid medical devices or device costs associated with non-opioid medical devices when CY 2025 data becomes available. Because this data is not yet available, we believe it is appropriate to finalize a zero dollar offset for CY 2025.

Payment rates and the payment limitation for non-opioid drugs, biologicals, and medical devices are not affected by the ASC weight scalar. However, section 1833(i)(10)(A) of the Act requires that the temporary additional payments for non-opioid drugs, biologicals, and medical devices be provided in a budget neutral manner. Therefore, the ASC weight scalar calculation incorporates current and prospective ASC expenditures related to non-opioid treatments. Increases in prospective expenditures related to these non-opioid treatments will decrease the ASC weight scalar, which is applied to the payment rates for surgical procedures and ancillary procedures paid based on the OPPS relative weights and the non-device portion of device-intensive procedures. As discussed in section XIII.H.2. of this final rule with comment period, we project a decrease in prospective expenditures since the non-opioid drugs and biologicals are currently separately payable under the ASC payment system without payment limitation, and because we are unable to estimate prospective utilization and expenditures for the non-opioid medical devices for CY 2025.

After consideration of the public comments we received, we are finalizing our policy to base the 18 percent payment limitation on the volume weighted average of the CY 2025 payment rates of the top five primary procedures by volume into which a non-opioid treatment for pain relief would have their payment packaged, absent this policy. We are finalizing that we will apply the 18 percent payment limitation per date of service billed. We have updated the payment limitations for each qualifying product for CY 2025 with the 2023 claims data available for this final rule and discuss each in the following sections for each specific product. We are also finalizing our policy to create new OPPS status indicators for non-opioid drugs and devices to implement this payment limitation for CY 2025.

e. Payment Limitation With No Claims Data

For drugs, biologicals, and devices with no claims data, such as for newly FDA-approved and marketed products or products that did not previously have their own product-specific HCPCS code by which to track payment and utilization data, we solicited comment on the best approach for determining a payment limitation, as required by section 1833(t)(16)(G)(iii) of the Act. As discussed in the CY 2024 OPPS/ASC final rule with comment period (88 FR 81953), we proposed CMS could utilize the services with which a product would be expected to be furnished and would typically be packaged absent this policy, based on expected clinical use patterns. Determining the service, or group of services, to use to calculate the payment limitation could be accomplished through engagement with interested parties and a review by CMS Medical Officers and clinical staff. Absent engagement from interested parties, we proposed CMS could determine the service, or group of services, to use to calculate the payment limitation based on expected clinical use patterns. CMS could then adjust the services that are used to calculate the payment limitation as claims data becomes available in subsequent years. We welcomed comments on how to set a payment limitation for a product for which we do not have claims data on which to base a payment limitation. The proposed product was described by placeholder HCPCS code C98X4 (ON–Q Pump). We solicited comment on the top five procedures performed with this product, and the HCPCS code that describes the procedure, in order to calculate a volume weighted payment limitation for this device for CY 2025.

We noted that we may update the payment limitation amount in future rulemaking as we gather additional claims data on the utilization of and payment for this product.

Comment: The manufacturer of the ON–Q Pump responded to our comment solicitation on the procedures to use as the basis for the payment limitation for this product, given the absence specific claims data associated with that device. The commenter provided the top 5 primary procedures with which HCPCS code A4306 (Disposable drug delivery system, flow rate of less than 50 ml per hour) was packaged and recommended CMS use these top five procedures to set the payment limitation for this product. However, they noted that HCPCS code A4306 is only a proxy for their product, as this HCPCS code is not specific to the ON–Q pump system, and they also believe that many HOPDs and ASCs are likely not to report the code currently due to the C–APC packaging policy.

Response: We thank the commenter for this information. We have reviewed the commenter's recommended codes and agree with the recommendations because they align with the procedures into which HCPCS code A4306 is currently packaged in our claims data. We also agree that HCPCS code A4306 is a reasonable proxy for the utilization of the ON–Q pump, absent a product specific code with claims data. We note also that there is no available claims data for code C98X4, the proposed placeholder code for the ON–Q pump system, so we are unable to identify procedures with which this code is packaged. Based on our review, we will use the HCPCS codes recommended by the commenter, as shown in Table 157 at the end of this section, as the basis for the calculation of the payment limitation for the ON–Q pump system for CY 2025 and will use the utilization data provided by the commenter for HCPCS code A4306.

Comment: Commenters supported CMS's proposed methodology for determining the procedures used to calculate a new product's specific payment limitation when there is no claims data and encouraged engagement with manufacturers and the use of manufacturer-specific data. Commenters provided specific procedure codes and data supporting the likely use of their products in the HOPD and ASC settings.

Response: We thank commenters for their support. The specific recommendations made by commenters and our assessment of each of those recommendations are explained in the following section f. Qualifying Products.

After consideration of the public comments we received, we are finalizing a policy where CMS will utilize the services with which a product would be expected to be furnished and would typically be packaged absent this policy, to calculate the payment limitation based on expected clinical use patterns for CY 2025. CMS will determine the service, or group of services, to use to calculate the payment limitation through engagement with interested parties and a review by CMS Medical Officers and clinical staff during annual rulemaking. In the absence of engagement from interested parties, we will determine clinically appropriate procedures with which we would expect the drug or device to be frequently used in order to determine the payment limitation, including review of FDA approval materials, procedures identified in literature available to CMS, and other relevant materials. We will consider this topic further in future rulemaking if needed.

f. Qualifying Products

The following table, Table 156, lists the non-opioid alternatives of which we were aware and that we proposed would receive separate payment as a non-opioid pain management drug or device under section 4135 criteria for CY 2025.

As discussed in the CY 2025 OPPS/ASC proposed rule (89 FR 59427 through 59433), in general, CMS routinely receives comments from readers of the proposed rule with detailed rationales as to why and how they believe a particular drug, biological, medical device, or other item or service should be paid. As such, we solicited comment on whether there are any additional drugs, biologicals, or medical devices that meet the statutory requirements outlined in section 1833(t)(16)(G) and 1833(i)(10).

As discussed previously in this section, there are specific requirements with respect to FDA approval that must be met in order for the product to qualify for separate payment. For medical devices, the statute also requires that the device has demonstrated the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed in a clinical trial or through data published in a peer-reviewed journal. Interested parties that believe that a product not addressed in the proposed rule meets the statutory requirements were encouraged to submit information during the comment period that indicated that such product meets the statutory eligibility requirements. We stated that if CMS determines that such product(s) do in fact meet the statutory eligibility requirements, we would finalize separate payment for that product in the CY 2025 OPPS/ASC final rule with comment period. We stated that for drugs and biological products not addressed in the proposed rule, if no comment is submitted that outlines how that drug or biological meets the statutory criteria, then CMS would not finalize separate payment for such product for CY 2025. Additionally, we stated that for medical devices not addressed in the proposed rule, unless a comment was submitted that both outlines how that device meets the statutory criteria and included literature that demonstrates that the device has the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed in a clinical trial or through data published in a peer-reviewed journal,

then CMS would not finalize separate payment for such device for CY 2025.

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TABLE 156: PROPOSED LIST OF QUALIFYING PRODUCTS FOR SEPARATE PAYMENT UNDER SECTION 4135 OF THE CAA, 2023

Brand Name	HCPCS Code	Long Descriptor	Meets Requirements
Exparel	C9290	Injection, bupivacaine liposome, 1mg	Yes[188]
Omidria	J1097	Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml	Yes[189]
Dextenza	J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg	Yes[190]
Xaracoll	C9089	Bupivacaine, collagen-matrix implant, 1 mg	Yes[191]
Zynrelef	C9088	Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg	Yes. [192] Effective April 1, 2025
Ketorolac tromethamine Injection	J1885	Injection, ketorolac tromethamine, per 15 mg	Yes[193]
ON-Q Pump	C98X4	Elastomeric infusion pump, non-opioid pain management delivery system, including catheter and other system component(s)	Yes[194,195]

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Comment: Commenters were supportive of our proposals on the qualifying products in Table 156 for CY 2025 and they recommended that we finalize those products for separate payment for CY 2025.

Response: We thank the commenters for their support, and we are finalizing those products for separate payment, with updates to their product specific payment limitations as listed in Table 157.

Comment: The manufacturer of the medical device, ON–Q pump, recommended that CMS include the brand name ''ON–Q Pain Relief System'' in the HCPCS code descriptor to help decrease the probability that non-qualifying elastomeric infusion pumps would be reported by HOPDs and ASCs. Additionally, this commenter recommended that CMS include in the descriptor ''non-opioid anesthetic'' so that hospitals and ASCs may also include charges for the drug used with the medical device.

Response: We thank the commenter for their feedback on our proposals. We agree that the C-code descriptor should include the brand of product for better tracking purposes and the descriptors should ensure only products meeting the statutory criteria qualify for separate payment under this provision use the specific HCPCS code. Therefore, we are updating the HCPCS code descriptor accordingly for HCPCS code C98X4, replaced by HCPCS code C9804, to include the brand of the device. However, we do not agree that ''non-opioid anesthetic'' should be included in the descriptor, as the anesthetic is a separate therapeutic agent that has its own FDA approval.

Several commenters suggested additional non-opioid products that they believed qualified for separate payment under this provision. We have summarized these comments and provided our responses in the following sections.

[188] Exparel. FDA Package Insert. November 2023. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/022496s051lbl.pdf.*

[189] Omidria. FDA Package Insert. December 2017. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/205388s006lbl.pdf.*

[190] Dextenza. FDA Package Insert. October 2021. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208742s007lbl.pdf.*

[191] Xaracoll. FDA Package Insert. August 2020. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/209511s000lbl.pdf.*

[192] Zynrelef. FDA Package Insert. January 2024. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/211988s013lbl.pdf.*

[193] Ketorolac tromethamine Injection. FDA Package Insert. May 2014. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/074802s038lbl.pdf.*

[194] On-Q Pump. FDA 510K. February 2019. *https://www.accessdata.fda.gov/cdrh_docs/pdf18/K181360.pdf.*

[195] Ding DY, Manoli A 3rd, Galos DK, Jain S, Tejwani NC. Continuous Popliteal Sciatic Nerve Block Versus Single Injection Nerve Block for Ankle Fracture Surgery: A Prospective Randomized Comparative Trial. J Orthop Trauma. 2015;29(9):393–398. *https://pubmed.ncbi.nlm.nih.gov/2616525.*

SPRINT Peripheral Nerve Stimulator System (PNS)

Comment: The SPRINT PNS System was suggested by commenters as an alternative to opioids. Commenters stated that this device provides a temporary, minimally invasive solution that utilizes electrical stimulation to target peripheral nerves, offering significant pain relief while avoiding the risks associated with opioid medications. Commenters provided that this product is FDA cleared [196] and has supporting literature.[197] The manufacturer also provided the 5 procedure HCPCS codes with which they believed the SPRINT PNS device would most likely be used for post-operative pain management.

Response: Based on comments received, we believe that this medical device is used to deliver a therapy to reduce postoperative pain or produce post-surgical or regional analgesia. We confirmed that this product is FDA cleared [198] and has supporting literature demonstrating the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed in a clinical trial or through data published in a peer-reviewed journal.[199] The medical device does not currently receive transitional passthrough status and we believe it would have payment that is otherwise packaged into a payment for a covered OPD service, absent this policy.

Therefore, we believe that the SPRINT PNS System meets the statutory requirements and are finalizing that it will be paid separately under this provision. We agree that the top 5 procedures described in the comment letter are reasonable to base the payment limitation on and we will assume an equal utilization of the device with these 5 procedures for the payment limitation calculation, as shown in Table 157 at the end of this section. We note that in the absence of utilization data for the top 5 procedures, we believe it is reasonable to assume an equal utilization for purposes of calculating the payment limitation until claims data are available. Please see Table 157 for the payment limitation calculation and the new C-code used to describe the device.

IceMan Motorized Cold Therapy Device

Comment: Commenters recommended CMS evaluate and approve motorized cold therapy devices, such as the IceMan, manufactured by Enovis, under our non-opioid treatment for pain relief separate payment policy. They noted that the device is used to reduce pain after surgery. Additionally, they stated that the IceMan product is recognized by FDA as a Class 2, 510(k)-exempt device (product category ''ILO'') [200] [201] [202] and has supporting literature.[203] [204] [205] The manufacturer stated that the key studies provided on the use of continuous cold therapy include cold therapy delivered by the IceMan device.

The manufacturer also requested that CMS establish a new C-code to report use of their device and assign that code to status indicator ''H1,'' and they provided 5 HCPCS codes with which they requested CMS establish the payment limitation. These HCPCS codes are 27447 (Arthroplasty, knee, condyle and plateau; medial and lateral compartments with or without patella resurfacing (total knee arthroplasty)), 29888 (Arthroscopically aided anterior cruciate ligament repair/augmentation or reconstruction), 23472 (Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (*e.g.*, total shoulder))), 23470 (Arthroplasty, glenohumeral joint; hemiarthroplasty), and 23410 (Repair of ruptured musculotendinous cuff (*e.g.*, rotator cuff) open; acute). The manufacturer recommended CMS establish a payment limit based on the Medicare payment rate for APC 5114.

Response: Based on the comments received, we believe that the Iceman medical device is used to deliver a therapy to reduce postoperative pain or produce post-surgical or regional analgesia. We confirmed that this product is exempt from 510(k) premarket clearance by the FDA. However, the supporting literature does not demonstrate that the IceMan device specifically has the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed in a clinical trial or through data published in a peer-reviewed journal. The studies provided only broadly reference continuous cold therapy devices. We believe that the device demonstrating the ability to reduce, replace, or avoid opioid use in a clinical trial or peer-reviewed journal must be the same device as the one being studied in order to qualify for separate payment under section 4135. Therefore, we believe that the IceMan Motorized Cold Therapy Device does not meet the statutory requirements and are not finalizing separate payment for it under this provision.

CryoCuff Motorized Cold Therapy Device

Comment: Commenters recommended CMS evaluate and approve motorized cold therapy devices, such as the CryoCuff, manufactured by Enovis, under our non-opioid treatment for pain relief separate payment policy. They noted that the CryoCuff device is used to reduce pain after surgery. Additionally, they stated that the CryoCuff product is recognized by FDA as a Class 2, 510(k)-exempt devices

[196] FDA Approval Letter, July 31, 2018. *https://www.accessdata.fda.gov/cdrh_docs/pdf18/K181422.pdf.*

[197] Ilfeld BM, Plunkett A, Vijjeswarapu AM, Hackworth R, Dhanjal S, Turan A, Cohen SP, Eisenach JC, Griffith S, Hanling S, Sessler DI, Mascha EJ, Yang D, Boggs JW, Wongsarnpigoon A, Gelfand H Percutaneous, Peripheral Nerve Stimulation (Neuromodulation) for Postoperative Pain: A Randomized, Sham-controlled Pilot Study, Anesthesiology, April 2021.

[198] FDA Approval Letter, July 31, 2018. *https://www.accessdata.fda.gov/cdrh_docs/pdf18/K181422.pdf.*

[199] Ilfeld BM, Plunkett A, Vijjeswarapu AM, Hackworth R, Dhanjal S, Turan A, Cohen SP, Eisenach JC, Griffith S, Hanling S, Sessler DI, Mascha EJ, Yang D, Boggs JW, Wongsarnpigoon A, Gelfand H Percutaneous, Peripheral Nerve Stimulation (Neuromodulation) for Postoperative Pain: A Randomized, Sham-controlled Pilot Study, Anesthesiology, April 2021.

[200] See FDA Product Classification, Product Code ILO, *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm?id=5437* (identifying ILO devices as Class 2, 510(k) exempt devices, described further at 21 CFR 890.5720); see also FDA 510(k) Premarket Notification, K955057 (Mar. 8, 1996), *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K955057* (recognizing motorized cold therapy devices used for the ''application of ice after surgery or injury to reduce swelling and pain'').

[201] FDA, Product Code Database, ''ILO'', *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=5437*; see also 21 CFR 890.5720.

[202] *https://www.accessdata.fda.gov/cdrh_docs/pdf/K955057.pdf.*

[203] Jones CA et al. Opioid-sparing pain management protocol after shoulder arthroplasty results in less opioid consumption and higher satisfaction: a prospective, randomized controlled trial. J Shoulder Elbow Surg. 2022 Oct;31(10):2057–2065. doi: 10.1016/j.jse.2022.05.029. Epub 2022 Jul 5. PMID: 35803549.

[204] Barber FA, McGuire DA, Click S. Continuous-flow cold therapy for outpatient anterior cruciate ligament reconstruction. Arthroscopy. 1998 Mar;14(2):130–5. doi: 10.1016/s0749–8063(98)70030–1. PMID: 9531122.

[205] P.B. Wyatt et al., The Role of Cryotherapy After Total Knee Arthroplasty: A Systematic Review, The Journal of Arthroplasty, Volume 38, 2023, Pages 950–956.

(product category ''ILO'') [206] [207] [208] and has supporting literature.[209] [210] [211] The manufacturer stated that the key studies provided on the use of continuous cold therapy include cold therapy delivered by the Cryocuff device.

The manufacturer also requested that CMS establish a new C-code to report use of their device and assign that code to status indicator ''H1,'' and they provided 5 HCPCS codes with which they requested CMS establish the payment limitation. These HCPCS codes are 27447 (Arthroplasty, knee, condyle and plateau; medial and lateral compartments with or without patella resurfacing (total knee arthroplasty)), 29888 (Arthroscopically aided anterior cruciate ligament repair/augmentation or reconstruction), 23472 (Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (*e.g.* total shoulder))), 23470 (Arthroplasty, glenohumeral joint; hemiarthroplasty), and 23410 (Repair of ruptured musculotendinous cuff (*e.g.,* rotator cuff) open; acute). The manufacturer recommended CMS establish a payment limit based on the Medicare payment rate for APC 5114.

Response: Based on comments received, we believe that the CryoCuff medical device is used to deliver a therapy to reduce postoperative pain or produce post-surgical or regional analgesia. We confirmed that this product is exempt from 510(k) premarket clearance by the FDA. However, the supporting literature does not demonstrate that the CryoCuff device specifically has the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed in a clinical trial or through data published in a peer-reviewed journal. The studies provided only broadly reference continuous cold therapy devices. We believe that the device demonstrating the ability to reduce, replace, or avoid opioid use in a clinical trial or peer-reviewed journal must be the same device as the one being studied in order to qualify for separate payment under section 4135.

Therefore, we believe that the CryoCuff Motorized Cold Therapy Device does not meet the statutory requirements and are not finalizing separate payment for it under this provision.

ThermaZone Thermal Therapy Device

Comment: Commenters recommended CMS evaluate and approve thermal therapy devices, such as the ThermaZone manufactured by Innovative Medical Equipment, under our non-opioid treatment for pain relief separate payment policy. They noted that the device is used to reduce pain after surgery. Additionally, they stated that the product is recognized by the FDA as a Class II, 510(k)-exempt device under Product Code ''ILO'' (Pack, hot or cold, water circulating) and Regulation Number 890.5720 and has supporting literature.[212] [213] [214] [215] Data from an unpublished retrospective cohort study was also provided. The manufacturer stated that numerous studies were published in peer-reviewed journals that show that continuous cold therapy devices can replace and reduce opioids prescribed in the post-surgical setting, which applies to thermal therapy delivered by the ThermaZone device. The manufacturer also provided the top 5 procedures for which the ThermaZone is typically used, weighted by use, and calculated an approximate payment limitation of $1,924.72 based on the HPCCS codes 27447 (Arthroplasty, knee, condyle and plateau; medial and lateral compartments with or without patella resurfacing (total knee arthroplasty)), 27130 (Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft), 29888 (Arthroscopically aided anterior cruciate ligament repair/augmentation or reconstruction), 23472 (Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (*e.g.,* total shoulder))), and 23410 (Repair of ruptured musculotendinous cuff (*e.g.,* rotator cuff) open; acute)). The manufacturer of the device stated that the device is different from traditional motorized cold therapy devices in that it uses ice-less technology, offers heating and cooling technologies and provides precise temperature control for a variety of temperature settings among other benefits in the commenter's view. Many users of the ThermaZone device commented on the success they had with the device alleviating their pain and reducing their opioid use.

Response: Based on comments received, we believe that the ThermaZone medical device is used to deliver a therapy to reduce postoperative pain or produce post-surgical or regional analgesia. We confirmed that this product is recognized by the FDA as a Class II, 510(k)-exempt device. However, the supporting literature does not demonstrate that the ThermaZone device specifically has the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed in a clinical trial or through data published in a peer-reviewed journal. The studies provided only broadly reference continuous cold therapy devices. We believe that the device demonstrating the ability to reduce, replace, or avoid opioid use in a clinical trial or peer-reviewed journal must be the same device as the one being studied in order to qualify for separate payment under section 4135. Therefore, we do not believe that the ThermaZone Device meets the statutory requirements and are not finalizing separate payment for it under this provision.

Cyro Nerve Block Therapy (CryoNB)

Comment: Commenters suggested Cryo Nerve Block Therapy (CryoNB) as an alternative to opioids. Atricure, the manufacturer, stated that this therapy is

[206] See FDA Product Classification, Product Code ILO, *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm?id=5437* (identifying ILO devices as Class 2, 510(k) exempt devices, described further at 21 CFR 890.5720); see also FDA 510(k) Premarket Notification, K955057 (Mar. 8, 1996), *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K955057* (recognizing motorized cold therapy devices used for the ''application of ice after surgery or injury to reduce swelling and pain'').

[207] FDA, Product Code Database, ''ILO,'' *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=5437*; see also 21 CFR 890.5720.

[208] *https://www.accessdata.fda.gov/cdrh_docs/pdf/K955057.pdf.*

[209] Jones CA et al. Opioid-sparing pain management protocol after shoulder arthroplasty results in less opioid consumption and higher satisfaction: a prospective, randomized controlled trial. J Shoulder Elbow Surg. 2022 Oct;31(10):2057–2065. doi: 10.1016/j.jse.2022.05.029. Epub 2022 Jul 5. PMID: 35803549.

[210] Barber FA, McGuire DA, Click S. Continuous-flow cold therapy for outpatient anterior cruciate ligament reconstruction. Arthroscopy. 1998 Mar;14(2):130–5. doi: 10.1016/s0749–8063(98)70030–1. PMID: 9531122.

[211] P.B. Wyatt et al., The Role of Cryotherapy After Total Knee Arthroplasty: A Systematic Review, The Journal of Arthroplasty, Volume 38, 2023, Pages 950–956.

[212] Jones CA, Throckmorton TW, Murphy J, Eason RR, Joyce M, Bernholt DL, Azar FM, Brolin TJ. Opioid-sparing pain management protocol after shoulder arthroplasty results in less opioid consumption and higher satisfaction: a prospective, randomized controlled trial. J Shoulder Elbow Surg. 2022 Oct;31(10):2057–2065. doi: 10.1016/j.jse.2022.05.029. Epub 2022 Jul 5. PMID: 35803549.

[213] Barber FA, McGuire DA, Click S. Continuous-flow cold therapy for outpatient anterior cruciate ligament reconstruction. Arthroscopy. 1998 Mar;14(2):130–5. doi: 10.1016/s0749–8063(98)70030–1. PMID: 9531122.

[214] Muaddi H, Lillie E, Silva S, Cross JL, Ladha K, Choi S, Mocon A, Karanicolas P. The Effect of Cryotherapy Application on Postoperative Pain: A Systematic Review and Meta-analysis. Ann Surg. 2023 Feb 1;277(2):e257–e265. doi: 10.1097/SLA.0000000000004987. Epub 2023 Jan 10. PMID: 34856580.

[215] Wyatt PB, Nelson CT, Cyrus JW, Goldman AH, Patel NK. The Role of Cryotherapy After Total Knee Arthroplasty: A Systematic Review. J Arthroplasty. 2023 May;38(5):950–956. doi: 10.1016/j.arth.2022.12.004. Epub 2022 Dec 8. PMID: 36496048.

used for postoperative pain management for patients who undergo certain cardiac, thoracic, and other surgical procedures and is administered through cryoablation probes. The manufacturer stated that this device allows a surgeon to ablate nerve tips near the primary surgery incision site to block the sensory nerve from propagating a pain signal after surgery. Commenters provided that this product is FDA cleared with a 510(k) clearance (K182565,[216] K200697,[217] and K233170 [218]) and has supporting literature.[219] [220] [221] [222] The manufacturer also provided the 5 procedure HCPCS codes with which they believed the CryoNB device would most likely be used for post-operative pain management. The manufacturer also stated that the device does not receive transitional pass-through payment and currently payment is packaged within the covered hospital outpatient department service. The manufacturer also recommended that CMS establish unique C-codes for each of their commercial products and a G-code to describe the additional intraoperative time required.

Response: Based on comments received, we believe that the CryoNB medical device is used to deliver a therapy to reduce postoperative pain or produce post-surgical or regional analgesia. We confirmed that this product is FDA cleared and has supporting literature demonstrating the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed in a clinical trial or through data published in a peer-reviewed journal. The medical device is not currently receiving transitional passthrough status and we believe it would have payment that is otherwise packaged into a payment for a covered OPD service.

Therefore, we believe that the CryoNB System meets the statutory requirements and should be paid separately under this provision. We agree that the top 5 procedures described in the comment letter are reasonable to base the payment limitation on and will assume an equal utilization of the device with these 5 procedures for the payment limitation calculation. In the absence of utilization data for the top 5 procedures, we believe it is reasonable to assume an equal utilization for purposes of calculating the payment limitation until claims data are available. Please see Table 157 for the payment limitation calculation and new C-code to describe the device. Section 4135 of the CAA, 2023 statute does not address separate payment for the services associated with the provision of a medical device, and therefore we are not creating a G-code to describe the additional intraoperative time required at this time.

ambIT Electronic Pain Control System

Comment: The ambIT Electronic Pain Control System, a medical device manufactured by Avanos, was suggested by commenters as an alternative to opioids. Commenters stated that this system provides a similar benefit as the ON–Q pump, as it is a battery powered pump that delivers a local non-opioid anesthetic to a patient's surgical site or nerves to provide target pain relief while avoid systemic effects. Commenters clarified that this version of the pump is disposable. Commenters provided that this product is FDA cleared under a 510(k) [223] and has supporting literature.[224] The manufacturer also provided the 5 procedure HCPCS codes in which they believed the ambIT device would most likely be used for post-operative pain management. The manufacturer also stated that the product does not currently have pass-through payment status and currently would have its payment packaged into the payment for a covered OPD service. The manufacturer also provided suggested descriptor language for the creation of a product specific C-code.

Response: Based on comments received, we believe that the ambIT medical device is used to deliver a therapy to reduce postoperative pain or produce post-surgical or regional analgesia. We confirmed that this product is FDA cleared and has supporting literature demonstrating the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed in a clinical trial or through data published in a peer-reviewed journal. The medical device is not currently receiving transitional passthrough status and we believe would have payment that is otherwise packaged into a payment for a covered OPD service.

Therefore, we believe that the ambIT System meets the statutory requirements and should be paid separately under this provision. We agree that the top 5 procedures described in the comment letter are reasonable to base the payment limitation. Please see Table 157 for the payment limitation calculation and new C-code to describe the device.

SimplFusor Elastomeric Pump

Comment: Commenters recommended CMS consider SimplFusor, a device manufactured by Baxter, as an effective alternative to opioids. Commenters stated that this device is functionally equivalent to and interchangeable with the ON–Q elastomeric pump; therefore, the SimplFusor pump should also qualify. Commenters provided that this product is FDA cleared through a 510(k) (K151650). The commenter stated that the SimplFusor device has not specifically been studied, but that literature, specifically the literature on the ON–Q pump, demonstrates that the use of elastomeric infusion pumps to deliver pain management therapies reduces post-operative pain and opioid use. The manufacturer stated that the product is not on pass-through status and would usually have its cost packaged into the APC associated with its use.

Response: Based on the comments received, we believe that the SimplFusor medical device is used to deliver a therapy to reduce postoperative pain or produce post-surgical or regional analgesia. We confirmed that this product is FDA cleared. The medical device is not currently receiving transitional passthrough status and we believe would have payment that is otherwise packaged into a payment for a covered OPD service.

However, this product does not have literature supporting that its specific use reduced opioid use. We acknowledge that commenters provided FDA documentation that their device is substantially equivalent to a device that

[216] *https://www.accessdata.fda.gov/cdrh_docs/pdf18/K182565.pdf.*

[217] *https://www.accessdata.fda.gov/cdrh_docs/pdf20/K200697.pdf.*

[218] *https://www.accessdata.fda.gov/cdrh_docs/pdf23/K233170.pdf.*

[219] O'Connor LA, Dua A, Orhurhu V, Hoepp LM, Quinn CC. Opioid Requirements After Intercostal Cryoanalgesia in Thoracic Surgery. J Surg Res. 2022; 274:232–241.

[220] Maxwell CM, Weksler B, Houda J, Fernando HC. Intercostal Cryoablation During Video-Assisted Lung Resection Can Decrease Postoperative Opioid Use. Innovations 2023 18(4):352–356.

[221] Jaroszewski DE, Bostoros P, Farina JM, Botros MM, Aly MR, Peterson M, Lackey J, Pulivarthi KV, Smith B, Craner R, Stearns JD. Evolution of Pain Control for Adult Pectus Excavatum Repair. Ann Thorac Surg. 2024;117(4):829–837.

[222] Graves CE, Moyer J, Zobel MJ, Mora R, Smith D, O'Day M, Padilla BE. Intraoperative intercostal nerve cryoablation during the Nuss procedure reduces length of stay and opioid requirement: A randomized clinical trial. J Pediatric Surg. 2019 Nov;54(11):2250–2256.

[223] FDA 510(k) Clearance K052221; obtained in 2005 by and issued to Sorenson Medical, Inc., which was later acquired by Summit Medical Products, Inc. Avanos acquired substantially all assets of Summit Medical Products, including this FDA 510(k) Clearance K052221, in 2019.

[224] Morkos M, DeLeon A, Koeckert M, Gray Z, Liao K, Pan W, Tolpin DA. The Use of Unilateral Erector Spinae Plane Block in Minimally Invasive Cardiac Surgery. J Cardiothorac Vasc Anesth. 2023 Mar;37(3):432–436.

does demonstrate the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed in a clinical trial or through data published in a peer-reviewed journal. We believe that the device demonstrating the ability to reduce, replace, or avoid opioid use in a clinical trial or peer-reviewed journal must be the same device as the one being studied in order to qualify for separate payment under section 4135. Therefore, we believe that the SimplFusor System does not meet the statutory requirements and are not finalizing separate payment for it under this provision.

Iovera System

Comment: The Iovera System manufacturer, Pacira Biosciences, Inc., suggested that this medical device should qualify for separate payment under this provision. The manufacturer stated that this device is used to apply freezing cold to the peripheral nervous system for the treatment of pain, referred to as cyroneurolysis or cryoanalgesia. Commenters provided that this product is used to deliver a therapy to reduce postoperative pain, or produce post-surgical or reginal analgesia, is FDA cleared under a 510(k) [225] and has supporting literature.[226] [227] [228] [229] The manufacturer also provided two HCPCS codes in which the device would have its payment packaged.

Response: Based on comments received, we believe that the Iovera medical device is used to deliver a therapy to reduce postoperative pain or produce post-surgical or regional analgesia. We confirmed that this product is FDA cleared and has supporting literature demonstrating the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed in a clinical trial or through data published in a peer-reviewed journal. The medical device is not currently receiving transitional passthrough status and we believe would have payment that is otherwise packaged into a payment for a covered OPD service.

Therefore, we believe that the Iovera System meets the statutory requirements and should be paid separately under this provision. The manufacturer only provided two procedures in which the device is used, and we agree with those two procedures are likely the most common procedures in which the device is used, given the clinical nature of the device. Therefore, for this product only, we are only using these top 2 procedures as the basis for calculating the payment limitation for the device. We will assume an equal utilization of the device with these 2 procedures for the payment limitation calculation as shown in Table 157 at the end of this section. In the absence of utilization data for the top 2 procedures, we believe it is reasonable to assume an equal utilization for purposes of calculating the payment limitation until claims data are available. Please see Table 157 for the payment limitation calculation and new C-code to describe the device.

Additional Non-Qualifying Products

Comment: Commenters suggested additional products for CMS to consider under this policy. One example is the MAKO System, an FDA-cleared medical device used in hip and knee joint procedures to enable a more predictable implant placement to plan surgical experience. The system is intended to assist the surgeon in providing software-defined spatial boundaries for orientation and reference information to anatomical structures during orthopedic procedures. Another example is the PMD–200, which is a device that uses a finger probe to measure physiological signals that are elevated during surgical stimulation, and then a machine learning algorithm uses these variables to provide a clinician a continuous numerical value for pain to assist the clinician with opioid dosing.

Response: We appreciate these comments, but we do not believe these medical devices need to be evaluated under this policy because they are not directly delivering pain management therapies. The statute specifies that any device under this policy should deliver a therapy to reduce postoperative pain or produce postsurgical or regional analgesia. Both the MAKO and the PMD–200 function as supplemental tools that can assist the clinician, such as robotic assistance or machine learning assistance, in assessing the patient and planning treatment. However, the devices themselves are not medical devices that are used to deliver a therapy to reduce postoperative pain or produce postsurgical or regional analgesia. As these devices do not meet the basic definitions to be considered under this policy, we are not evaluating them further against the qualifying criteria.

Comment: Commenters also recommended other products to CMS but did not provide any supporting documentation or information on the products.

Response: For those products suggested by commenters that did not provide supplemental information, we are unable to fully evaluate the product against the statutory criteria for inclusion in this policy and therefore are not finalizing separate payment for any of these products. The final list of qualifying products can be found in Table 158.

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[225] FDA 510(k) No. K220656, available at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K220656*.

[226] Urban JA, Dolesh K, Martin E. A Multimodal Pain Management Protocol Including Preoperative Cryoneurolysis for Total Knee Arthroplasty to Reduce Pain, Opioid Consumption, and Length of Stay. Arthroplast Today. 2021 Jul 12;10:87–92. doi: 10.1016/j.artd.2021.06.008. PMID: 34286056; PMCID: PMC8280475.

[227] Mihalko WM, Kerkhof AL, Ford MC, Crockarell JR, Harkess JW, Guyton JL. Cryoneurolysis before Total Knee Arthroplasty in Patients With Severe Osteoarthritis for Reduction of Postoperative Pain and Opioid Use in a SingleCenter Randomized Controlled Trial. J Arthroplasty. 2021 May;36(5):1590–1598. doi: 10.1016/j.arth.2020.11.013. Epub 2020 Nov 14. PMID: 33279353.

[228] Ilfeld BM, Finneran JJ, Swisher MW, Said ET, Gabriel RA, Sztain JF, Khatibi B, Armani A, Trescot A, Donohue MC, Schaar A, Wallace AM. Preoperative Ultrasound-guided Percutaneous Cryoneurolysis for the Treatment of Pain after Mastectomy: A Randomized, Participant- and Observer-masked, Sham-controlled Study. Anesthesiology. 2022 Nov 1;137(5):529–542. doi: 10.1097/ALN.0000000000004334. PMID: 35929983.

[229] Dasa V, Lensing G, Parsons M, Harris J, Volaufova J, Bliss R. Percutaneous freezing of sensory nerves prior to total knee arthroplasty. Knee. 2016 Jun;23(3):523–8. doi: 10.1016/j.knee.2016.01.011. Epub 2016 Feb 10. PMID: 26875052.

TABLE 157: FINALIZED PAYMENT LIMITATIONS FOR QUALIFYING PRODUCTS FOR CY 2025

Brand Name (HCPCS Code)	Top Primary Procedures HCPCS Code	Total Units of Drugs/Device packaged into Primary Procedure	CY 2025 Procedure Rate	CY 2025 Payment Limit (Volume Weighted Average of 18 percent of Primary Procedure Payment Rate)
Claims Data Available for Volume Weighted Average				
Zynrelef (C9088)	27447	9,059.5	12,755.58	2,267.26
	27130	3,742.0	12,755.58	
	49505	335.5	3,530.16	
	23472	175.0	18,187.34	
	27446	118.0	12,755.58	
Xaracoll (C9089)	49505	336.0	3,530.16	700.48
	49507	89.0	3,530.16	
	49650	59.0	5,798.13	
	49520	34.0	3,530.16	
	47562	28.0	5,798.13	
Exparel (J0666; C9290)	27447	32,064.0	12,755.58	2,368.14
	23472	14,078.0	18,187.34	
	27130	9,259.0	12,755.58	
	49650	4,480.5	5,798.13	
	29827	3,511.0	7,090.68	
Dextenza (J1096)	66984	4,012.0	2,274.70	427.57
	66982	537.0	2,274.70	
	66991	133.0	5,124.71	
	68841	88.0	2,319.85	
	65820	59.0	4,022.80	
Omidria (J1097)	66984	7,417.5	2,274.70	425.89
	66982	1,099.5	2,274.70	
	66991	177.0	5,124.71	
	65820	98.0	4,022.80	
	66174	77.0	4,022.80	
Ketorolac tromethamine injection (J1885)	27447	119,234.5	12,755.58	1,214.30
	99284	81,714.0	438.25	
	99283	72,518.0	284.97	
	27130	65,986.5	12,755.58	
	G0463	19,509.0	128.75	
No Claims Data Available for Volume Weighted Average*				
ON-Q Elastomeric Infusion Pump** (C9804)	27447	696	12,755.58	2,284.98
	23472	149	18,187.34	
	29827	74	7,090.68	
	49505	49	3,530.16	

	27130	43	12,755.58	
ambIT Electronic Infusion Pump** (C9806)	27447	696	12,755.58	2,284.98
	23472	149	18,187.34	
	29827	74	7,090.68	
	49505	49	3,530.16	
	27130	43	12,755.58	
Cryo Nerve Block Therapy (C9808)	32601	1	5798.13	985.94
	32609	1	5798.13	
	21811	1	7090.68	
	21812	1	7090.68	
	21813	1	1609.57	
Iovera System (C9809)	64640	1	896.57	255.85
	64624	1	1946.18	
	-	-		
	-	-		
	-	-		
SPRINT Peripheral Nerve Stimulator System (C9807)	23412	1	7090.68	2,483.16
	23472	1	18,187.34	
	28705	1	18187.34	
	27130	1	12,755.58	
	27447	1	12,755.58	
*We assumed equal utilization of the qualifying product among the provided primary procedures unless otherwise advised by commenters. **Expected utilization was provided by the manufacturer.				

TABLE 158: FINALIZED QUALIFYING PRODUCTS FOR CY 2025

Brand Name	HCPCS Code	Long Descriptor	Meets Requirements
Exparel	J0666 (Previously C9290)	Injection, bupivacaine liposome, 1mg	Yes[230]
Omidria	J1097	Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml	Yes[231]
Dextenza[232]	J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg	Yes[233]
Xaracoll	C9089	Bupivacaine, collagen-matrix implant, 1 mg	Yes[234]
Zynrelef	C9088	Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg	Yes. [235] Effective April 1, 2025

[230] Exparel. FDA Package Insert. November 2023. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/022496s051lbl.pdf.*

[231] Omidria. FDA Package Insert. December 2017. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/205388s006lbl.pdf.*

[232] Payment for HCPCS Code 68841, is discussed in section III.E.6. of this final rule with comment period.

[233] Dextenza. FDA Package Insert. October 2021. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208742s007lbl.pdf.*

[234] Xaracoll. FDA Package Insert. August 2020. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/209511s000lbl.pdf.*

[235] Zynrelef. FDA Package Insert. January 2024. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/211988s013lbl.pdf.*

Brand Name	HCPCS Code	Long Descriptor	Meets Requirements
Ketorolac tromethamine Injection	J1885	Injection, ketorolac tromethamine, per 15 mg	Yes[236]
ON-Q Pump	(C98X4/ C9804)	Elastomeric infusion pump (e.g., ON-Q* Pump with Bolus), including catheter and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)	Yes[237,238]
SPRINT Peripheral Nerve Stimulator System	(C9807)	Nerve stimulator, percutaneous, peripheral (e.g., SPRINT Peripheral Nerve Stimulation System), including electrode and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)	Yes[239,240]
Cryo Nerve Block Therapy	(C9808)	Nerve cryoablation probe (e.g., cryoICE, cryoSPHERE, cryoSPHERE MAX, cryoICE cryoSPHERE, cryoICE Cryo2), including probe and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)	Yes[241,242,243,244,245,246,247]

[236] Ketorolac tromethamine Injection. FDA Package Insert. May 2014. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/074802s038lbl.pdf.*

[237] On-Q Pump. FDA 510K. February 2019. *https://www.accessdata.fda.gov/cdrh_docs/pdf18/K181360.pdf.*

[238] Ding DY, Manoli A 3rd, Galos DK, Jain S, Tejwani NC. Continuous Popliteal Sciatic Nerve Block Versus Single Injection Nerve Block for Ankle Fracture Surgery: A Prospective Randomized Comparative Trial. J Orthop Trauma. 2015;29(9):393–398. *https://pubmed.ncbi.nlm.nih.gov/2616525.*

[239] FDA Approval Letter, July 31, 2018. *https://www.accessdata.fda.gov/cdrh_docs/pdf18/K181422.pdf.*

[240] Ilfeld BM, Plunkett A, Vijjeswarapu AM, Hackworth R, Dhanjal S, Turan A, Cohen SP, Eisenach JC, Griffith S, Hanling S, Sessler DI, Mascha EJ, Yang D, Boggs JW, Wongsarnpigoon A, Gelfand H Percutaneous, Peripheral Nerve Stimulation (Neuromodulation) for Postoperative Pain: A Randomized, Sham-controlled Pilot Study, Anesthesiology, April 2021.

[241] *https://www.accessdata.fda.gov/cdrh_docs/pdf18/K182565.pdf.*

[242] *https://www.accessdata.fda.gov/cdrh_docs/pdf20/K200697.pdf.*

[243] *https://www.accessdata.fda.gov/cdrh_docs/pdf23/K233170.pdf.*

[244] O'Connor LA, Dua A, Orhurhu V, Hoepp LM, Quinn CC. Opioid Requirements After Intercostal Cryoanalgesia in Thoracic Surgery. J Surg Res. 2022; 274:232–241.

[245] Maxwell CM, Weksler B, Houda J, Fernando HC. Intercostal Cryoablation During Video-Assisted Lung Resection Can Decrease Postoperative Opioid Use. Innovations 2023 18(4):352–356.

[246] Jaroszewski DE, Bostoros P, Farina JM, Botros MM, Aly MR, Peterson M, Lackey J, Pulivarthi KV, Smith B, Craner R, Stearns JD. Evolution of Pain Control for Adult Pectus Excavatum Repair. Ann Thorac Surg. 2024;117(4):829–837.

[247] Graves CE, Moyer J, Zobel MJ, Mora R, Smith D, O'Day M, Padilla BE. Intraoperative intercostal nerve cryoablation during the Nuss procedure reduces length of stay and opioid requirement: A randomized clinical trial. J Pediatric Surg. 2019 Nov;54(11):2250–2256.

Brand Name	HCPCS Code	Long Descriptor	Meets Requirements
ambIT Electronic Infusion Pump	(C9806)	Rotary peristaltic infusion pump (e.g., ambIT Pump), including catheter and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)	Yes[248,249]
Iovera System	(C9809)	Cryoablation needle (e.g., iovera System), including needle/tip and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)	Yes[250,251,252,253,254]

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The implementation of section 4135 of the CAA, 2023, which establishes the eligibility criteria for temporary additional payments for certain non-opioid treatments for pain relief, has been finalized in this section. We note that the HCPCS codes describing the qualifying devices and drugs in Table 158 have been placed on the ASC covered ancillary procedures list. While we acknowledge HCPCS code A4306 (Disposable drug delivery system, flow rate of less than 50 ml per hour) was previously discussed as a code that could describe a general category of medical pumps in which the ON–Q pump system could have been categorized, it did not previously appear on the ASC covered ancillary procedures list. However, we also note that Medicare Administrative Contractors (MACs) determine whether a drug, device, procedure, or other service meets all program requirements and conditions for coverage and payment. HOPDs and ASC only receive payment for qualifying drugs, biologicals, and medical devices when the appropriate MAC determines that the service meets the relevant conditions for coverage and payment. As we have consistently stated in past OPPS/ASC final rules (see, *e.g.,* 87 FR 71879 and 88 FR 81660 through 81661), the fact that a drug, device, procedure or service is assigned a HCPCS code and a payment rate under the OPPS does not imply coverage by the Medicare program, but indicates only how the product, procedure, or service may be paid if covered by the program (see, *e.g.,* Pub 100–04 Medicare Claims Processing, Transmittal 11937).

We proposed revisions to 42 CFR 416.174 for the ASC payment system and § 419.43 for the OPPS to codify these policies. Specifically, we proposed revisions to § 419.174(a) to establish the eligibility for non-opioid pain management drugs and biologicals, and by adding modifications to paragraphs (a)(1) through (3) to outline drug and biological FDA approval requirements, the exclusion of drugs and biologicals with pass-through status, and the requirement that the drug or biological has payment that is packaged. We proposed new § 419.174(b) to establish the eligibility for non-opioid pain management medical devices, which includes new paragraphs (b)(1) through (4). These new paragraphs describe medical device FDA requirements, medical device clinical trial or peer-reviewed journal requirements, the exclusion of medical devices with pass-through status, and the requirement that the medical device has payment that is packaged. New paragraph (c) describes the payment amounts for qualifying drugs and biologicals in paragraph (c)(1) and medical devices in paragraph (c)(2), as well as the payment limitation for drugs, biologicals, and medical devices in paragraph (c)(3). Similarly, we also propose new § 419.43(k), which contains payment for non-opioid pain management drugs and biologicals. Specifically, new paragraph (k)(1) outlines the eligibility for separate payment for non-opioid pain management drugs and biologicals, with new paragraphs outlining (i) the drug or biological's required FDA status, (ii) the drug or biological's pass-through status, and (iii) the drug or biological's packaged status.

We also proposed to add new § 419.43(k)(2), which contains payment for non-opioid pain management medical devices. Specifically, new paragraph (k)(2) outlines the eligibility for separate payment for non-opioid pain management medical devices, with new paragraphs outlining (i) the medical device's required FDA status, (ii) the medical device clinical trial or peer-reviewed journal requirements, (iii) the medical device's pass-through status, and (iv) the medical device's packaged status. New § 419.43(k)(3) describes the separate payment amount for qualifying non-opioid treatments for pain relief. Specifically, paragraph

[248] FDA 510(k) Clearance K052221; obtained in 2005 by and issued to Sorenson Medical, Inc., which was later acquired by Summit Medical Products, Inc. Avanos acquired substantially all assets of Summit Medical Products, including this FDA 510(k) Clearance K052221, in 2019.

[249] Morkos M, DeLeon A, Koeckert M, Gray Z, Liao K, Pan W, Tolpin DA. The Use of Unilateral Erector Spinae Plane Block in Minimally Invasive Cardiac Surgery. J Cardiothorac Vasc Anesth. 2023 Mar;37(3):432–436.

[250] FDA 510(k) No. K220656, available at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K220656*.

[251] Urban JA, Dolesh K, Martin E. A Multimodal Pain Management Protocol Including Preoperative Cryoneurolysis for Total Knee Arthroplasty to Reduce Pain, Opioid Consumption, and Length of Stay. Arthroplast Today. 2021 Jul 12;10:87–92. doi: 10.1016/j.artd.2021.06.008. PMID: 34286056; PMCID: PMC8280475.

[252] Mihalko WM, Kerkhof AL, Ford MC, Crockarell JR, Harkess JW, Guyton JL. Cryoneurolysis before Total Knee Arthroplasty in Patients With Severe Osteoarthritis for Reduction of Postoperative Pain and Opioid Use in a SingleCenter Randomized Controlled Trial. J Arthroplasty. 2021 May;36(5):1590–1598. doi: 10.1016/j.arth.2020.11.013. Epub 2020 Nov 14. PMID: 33279353.

[253] Ilfeld BM, Finneran JJ, Swisher MW, Said ET, Gabriel RA, Sztain JF, Khatibi B, Armani A, Trescot A, Donohue MC, Schaar A, Wallace AM. Preoperative Ultrasound-guided Percutaneous Cryoneurolysis for the Treatment of Pain after Mastectomy: A Randomized, Participant- and Observer-masked, Sham-controlled Study. Anesthesiology. 2022 Nov 1;137(5):529–542. doi: 10.1097/ALN.0000000000004334. PMID: 35929983.

[254] Dasa V, Lensing G, Parsons M, Harris J, Volaufova J, Bliss R. Percutaneous freezing of sensory nerves prior to total knee arthroplasty. Knee. 2016 Jun;23(3):523–8. doi: 10.1016/j.knee.2016.01.011. Epub 2016 Feb 10. PMID: 26875052.

(k)(3)(i) sets the separate payment amount for a qualifying drug or biological, paragraph (k)(3)(ii) sets the separate payment amount for a qualifying medical device, and paragraph (k)(3)(iii) sets the payment limitation for drugs, biologicals, and medical devices.

We did not receive any public comments on the proposed regulation text and are finalizing as proposed with slight changes to one provision. In particular, we are clarifying the description of the payment limitation at §§ 416.174(c)(3) and 419.43(k)(3)(iii) to state that the volume weighted average for the payment limitation will be based on the most frequent 5 OPD primary procedures into which a non-opioid treatment for pain relief would be packaged. We believe the ''packaged'' language is more accurate and consistent with our proposed policy than the previous language ''furnished with.'' As previously discussed, for the payment limitation calculation, non-primary procedures will not be included in the top five procedures list, even if they are the most common procedures furnished with that non-opioid treatment for pain relief by volume. Therefore, we are modifying the proposed regulatory text to specifically state that the payment limitation will be based on the most frequent five OPD primary procedures into which payment for the non-opioid treatment for pain relief is packaged. Except for this modification, we are finalizing the regulation text as proposed. Additionally, we are revising § 416.164(a)(4) to remove ''with the exception of non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure as determined by CMS under § 416.174,'' as these drugs will be separately payable in both the OPPS and ASC under this finalized policy. Similarly, we are revising § 416.164(b)(6) to read ''Non-opioid pain management drugs, biologicals, and medical devices as determined by CMS under § 416.174,'' as now qualifying medical devices will be on the ASC covered ancillary services list under this finalized policy.

G. New Technology Intraocular Lenses (NTIOLs)

New Technology Intraocular Lenses (NTIOLs) are intraocular lenses that replace a patient's natural lens that has been removed in cataract surgery and that also meet the requirements listed in § 416.195.

1. NTIOL Application Cycle

Our process for reviewing applications to establish new classes of NTIOLs is as follows:

- Applicants submit their NTIOL requests for review to CMS by the annual deadline which is announced in the annual OPPS/ASC final rule with comment period. For a request to be considered complete, we require submission of the information requested in the guidance document titled ''Application Process and Information Requirements for Requests for a New Class of New Technology Intraocular Lenses (NTIOLs) or Inclusion of an IOL in an Existing NTIOL Class'' posted on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/new-technology-intraocular-lenses-ntiols*.
- We announce annually, in the proposed rule updating the ASC and OPPS payment rates for the following calendar year, a list of all requests to establish new NTIOL classes accepted for review during the calendar year in which the proposal is published. In accordance with section 141(b)(3) of Public Law 103–432 and our regulations at § 416.185(b), the deadline for receipt of public comments is 30 days following publication of the list of requests in the proposed rule.
- In the final rule with comment period updating the ASC and OPPS payment rates for the following calendar year, we—

++ Provide a list of determinations made as a result of our review of all new NTIOL class requests and public comments.

++ When a new NTIOL class is created, identify the predominant characteristic of NTIOLs in that class that sets them apart from other IOLs (including those previously approved as members of other expired or active NTIOL classes) and that is associated with an improved clinical outcome.

++ Set the date of implementation of a payment adjustment in the case of approval of an IOL as a member of a new NTIOL class prospectively as of 30 days after publication of the ASC payment update final rule, consistent with the statutory requirement.

++ Announce the deadline for submitting requests for review of an application for a new NTIOL class for the following calendar year.

2. Requests To Establish New NTIOL Classes for CY 2025

We did not receive any requests for review to establish a new NTIOL class for CY 2025 by March 1, 2024, the due date published in the CY 2024 OPPS/ASC final rule with comment period (88 FR 81956).

3. Payment Adjustment

The current payment adjustment for a 5-year period from the implementation date of a new NTIOL class is $50 per lens. Since implementation of the process for adjustment of payment amounts for NTIOLs in 1999, we have not revised the payment adjustment amount, and we did not propose to revise the payment adjustment amount for CY 2025.

Comment: Commenters recommended that we increase the NTIOL payment adjustment. Commenters noted that the payment adjustment has not been adjusted since CY 1999 and has significantly lagged the overall inflation rate and does not reflect the technological advancements to support continued innovation. Some commenters recommended that we establish the NTIOL payment adjustment at $91.04 while others recommended we establish the payment adjustment at $94.63 and that we increase such payment adjustment annually.

Response: We responded to this comment in last year's final rule with comment period. We refer readers to the CY 2024 OPPS/ASC final rule with comment period for our response on an increase to the NTIOL $50 per lens payment adjustment (88 FR 81955 through 81956).

4. Announcement of CY 2026 Deadline for Submitting Requests for CMS Review of Applications for a New Class of NTIOLs

In accordance with 42 CFR 416.185(a) of our regulations, CMS announces that in order to be considered for payment effective beginning in CY 2025, requests for review of applications for a new class of new technology IOLs must be received by 5 p.m. Eastern Standard Time, on March 1, 2025. Send requests via email to *outpatientpps@cms.hhs.gov* or by mail to ASC/NTIOL, Division of Outpatient Care, Mailstop C4–05–17, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850. To be considered, requests for NTIOL reviews must include information requested on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/new-technology-intraocular-lenses-ntiols*.

H. Calculation of the ASC Payment Rates and the ASC Conversion Factor

1. Background

In the August 2, 2007, ASC final rule (72 FR 42493), we established our policy to base ASC relative payment weights and payment rates under the revised ASC payment system on APC groups and the OPPS relative payment weights. Consistent with that policy and the requirement at section 1833(i)(2)(D)(ii) of the Act that the revised payment system be implemented so that it would be budget neutral, the initial ASC conversion factor (CY 2008) was calculated so that estimated total Medicare payments under the revised ASC payment system in the first year would be budget neutral to estimated total Medicare payments under the prior (CY 2007) ASC payment system (the ASC conversion factor is multiplied by the relative payment weights calculated for many ASC services in order to establish payment rates). That is, application of the ASC conversion factor was designed to result in aggregate Medicare expenditures under the revised ASC payment system in CY 2008 being equal to aggregate Medicare expenditures that would have occurred in CY 2008 in the absence of the revised system, taking into consideration the cap on ASC payments in CY 2007, as required under section 1833(i)(2)(E) of the Act (72 FR 42522). We adopted a policy to make the system budget neutral in subsequent calendar years (72 FR 42532 through 42533; § 416.171(e)).

We note that we consider the term ''expenditures'' in the context of the budget neutrality requirement under section 1833(i)(2)(D)(ii) of the Act to mean expenditures from the Medicare Part B Trust Fund. We do not consider expenditures to include beneficiary coinsurance and copayments. This distinction was important for the CY 2008 ASC budget neutrality model that considered payments across the OPPS, ASC, and MPFS payment systems. However, because coinsurance is almost always 20 percent for ASC services, this interpretation of expenditures has minimal impact for subsequent budget neutrality adjustments calculated within the revised ASC payment system.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66857 through 66858), we set out a step-by-step illustration of the final budget neutrality adjustment calculation based on the methodology finalized in the August 2, 2007, ASC final rule (72 FR 42521 through 42531) and as applied to updated data available for the CY 2008 OPPS/ASC final rule with comment period. The application of that methodology to the data available for the CY 2008 OPPS/ASC final rule with comment period resulted in a budget neutrality adjustment of 0.65.

For CY 2008, we adopted the OPPS relative payment weights as the ASC relative payment weights for most services and, consistent with the final policy, we calculated the CY 2008 ASC payment rates by multiplying the ASC relative payment weights by the final CY 2008 ASC conversion factor of $41.401. For covered office-based surgical procedures, covered ancillary radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents, as discussed in section XIII.D.2 of the CY 2023 OPPS/ASC proposed rule (87 FR 44715 through 44716)), and certain diagnostic tests within the medicine range that are covered ancillary services, the established policy is to set the payment rate at the lower of the MPFS unadjusted nonfacility PE RVU-based amount or the amount calculated using the ASC standard ratesetting methodology. Further, as discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66841 through 66843), we also adopted alternative ratesetting methodologies for specific types of services (for example, device-intensive procedures).

As discussed in the August 2, 2007 ASC final rule (72 FR 42517 through 42518) and as codified at § 416.172(c) of the regulations, the revised ASC payment system accounts for geographic wage variation when calculating individual ASC payments by applying the pre-floor and pre-reclassified IPPS hospital wage indexes to the labor-related share, which is 50 percent of the ASC payment amount based on a GAO report of ASC costs using 2004 survey data. Beginning in CY 2008, CMS accounted for geographic wage variation in labor costs when calculating individual ASC payments by applying the pre-floor and pre-reclassified hospital wage index values that CMS calculates for payment under the IPPS, using updated Core Based Statistical Areas (CBSAs) issued by OMB in June 2003.

The reclassification provision in section 1886(d)(10) of the Act is specific to acute care hospitals. We believe that using the most recently available pre-floor and pre-reclassified IPPS hospital wage indexes result in the most appropriate adjustment to the labor portion of ASC costs. We continue to believe that the pre-floor, pre-reclassified hospital wage indexes, which are updated yearly and are used by several other Medicare payment systems, appropriately account for geographic variation in labor costs for ASCs (89 FR 23424). Therefore, the wage index for an ASC is the pre-floor and pre-reclassified hospital wage index for the fiscal year under the IPPS of the CBSA that maps to the CBSA where the ASC is located.

On July 21, 2023, OMB issued OMB Bulletin No. 23–01, which provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published on July 16, 2021, in the **Federal Register** (86 FR 37770) and 2020 Census Bureau data. (A copy of this bulletin may be obtained at: *https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf*.) The pre-floor pre-reclassified IPPS hospital wage indexes for CY 2024 do not reflect OMB's new area delineations and, because the ASC wage indexes are the pre-floor and pre-reclassified IPPS hospital wages indexes, the CY 2024 ASC wage indexes do not reflect the most recent OMB changes. As discussed in the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 36139 through 36150), we proposed to use the new CBSAs delineations issued by OMB in OMB Bulletin 23–01 for the IPPS hospital wage index beginning in CY 2025. Therefore, because the ASC wage indexes for the calendar year are the pre-floor and pre-reclassified IPPS hospital wage indexes for the fiscal year, we proposed to incorporate the new OMB delineations into CY 2025 ASC wage indexes. We believe that using the revised delineations based on OMB Bulletin No. 23–01 will increase the integrity of the ASC wage index system by creating a more accurate representation of current geographic variations in wage levels.

In adopting the revised CBSA delineations from the 2010 Census data which were issued by OMB on July 15, 2015, through OMB Bulletin No. 15–01, for ASCs in counties that would see a decline in their ASC wage index for CY 2015, we adopted a blended wage index of 50 percent of the CY 2014 wage index value and 50 percent of the CY 2015 wage index value (79 FR 66937). However, we note that other Medicare payment systems incorporate a policy of capping year-to-year wage index decreases for each facility at 5 percent of the previous year's wage index value (89 FR 23431 through 23433). We believe such a policy would also be appropriate for the ASC payment system as we transition to the CBSA

delineations based on the 2020 Census data. As discussed in the IPPS/LTCH FY 2025 proposed rule, the 5-percent cap mitigates any large negative impacts of adopting the new delineations and prevents large year-to-year declines in wage index values as a means to reduce volatility (89 FR 36150). Therefore, for CY 2025, we proposed to incorporate the new OMB delineations into the CY 2025 ASC wage indexes and propose to apply a 5-percent cap on wage index decreases at the county level (or county-equivalent level) and the ASC wage index of that county would apply to all ASCs physically located in that county. We note that this 5-percent cap is applied in a budget neutral manner. The 5-percent cap reduces the wage index scalar for a calendar year which, in turn, will reduce the ASC conversion factor and the payment rates for covered ASC services in counties that are not affected by the 5-percent cap on wage index decreases. Further, we solicited comments on whether we should extend this policy after CY 2025 and permanently adopt a budget-neutral 5-percent cap on year-to-year wage index decreases.

Comment: Commenters supported our proposal to implement a 5-percent cap on year-to-year wage index decreases. However, two commenters requested that we should apply the OPPS geographic reclassifications and wage index floor policies to further align payment between the ASC payment system and the OPPS.

Response: As previously discussed in this section, the reclassification provision in section 1886(d)(10) of the Act is specific to acute care hospitals. We believe that using the most recently available pre-floor and pre-reclassified IPPS hospital wage indexes result in the most appropriate adjustment to the labor portion of ASC costs.

After consideration of the public comments we received, we are finalizing our proposal to implement a 5-percent cap on wage index decrease for CY 2025.

The final CY 2025 ASC wage indexes fully reflect the OMB labor market area delineations (including the revisions to the OMB labor market delineations discussed previously, as set forth in OMB Bulletin No. 23–01) including replacing the eight counties with the county-equivalent planning regions of Connecticut. We note that, in certain instances, there might be urban or rural areas for which there is no IPPS hospital that has wage index data that could be used to set the wage index for that area. When all of the areas contiguous to the urban CBSA of interest are rural and there is no IPPS hospital that has wage index data that could be used to set the wage index for that area, our policy has been to determine the ASC wage index by calculating the average of all wage indexes for urban areas in the State (75 FR 72058 through 72059). In other situations, where there are no IPPS hospitals located in a relevant labor market area, we apply our current policy of calculating an urban or rural area's wage index by calculating the average of the wage indexes for CBSAs (or metropolitan divisions where applicable) that are contiguous to the area with no wage index. For example, for CY 2025, we are applying a proxy wage index based on this methodology to ASCs located in CBSA 25980 (Hinesville, GA) and in CBSA 35 (Rural North Dakota).

2. Calculation of the ASC Payment Rates

a. Updating the ASC Relative Payment Weights for CY 2025 and Future Years

We update the ASC relative payment weights each year using the national OPPS relative payment weights (and PFS nonfacility PE RVU-based amounts, as applicable) for that same calendar year and uniformly scale the ASC relative payment weights for each update year to make them budget neutral (72 FR 42533). The OPPS relative payment weights are scaled to maintain budget neutrality for the OPPS. We then scale the OPPS relative payment weights again to establish the ASC relative payment weights. To accomplish this, we hold estimated total ASC payment levels constant between calendar years for purposes of maintaining budget neutrality in the ASC payment system. That is, we apply the weight scalar to ensure that projected expenditures from the updated ASC payment weights in the ASC payment system are equal to what would be the current expenditures based on the scaled ASC payment weights. In this way, we ensure budget neutrality and that the only changes to total payments to ASCs result from increases or decreases in the ASC payment update factor.

As discussed in section II.A.1.a of this final rule with comment period, we are using the CY 2023 claims data to be consistent with the OPPS claims data for the proposed rule. Consistent with our established policy, we proposed to scale the CY 2025 relative payment weights for ASCs according to the following method. Holding ASC utilization, the ASC conversion factor, and the mix of services constant from CY 2023, we proposed to compare the estimated total payment using the CY 2024 ASC relative payment weights with the estimated total payment using the CY 2025 ASC relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2024 and CY 2025.

In consideration of our policy to provide a higher ASC payment rate with ASC complexity adjustment codes for certain primary procedures when performed with add-on packaged services, we incorporated estimated total spending and estimated utilization for these codes in our budget neutrality calculation for CYs 2023 and 2024. We estimated in the CY 2023 OPPS/ASC final rule with comment period (87 FR 72094) that the impact on CY 2023 estimated total payments from our finalized CY 2023 ASC complexity adjustment codes would be $5 million in spending and we finalized our proposal to incorporate this $5 million in estimated CY 2023 total payments for the budget neutrality calculation. Based on CY 2023 utilization data, we estimated that the actual amount of spending on the new CY 2023 ASC complexity adjustment codes for CY 2023 was $24 million. We estimated that there will not be an additional increase in ASC spending related to our proposed ASC complexity adjustment codes for CY 2025.

Additionally, as discussed in section XIII.E of the CY 2025 OPPS/ASC proposed rule, section 4135(a) and (b) of the CAA, 2023, titled ''Access to Non-Opioid Treatments for Pain Relief,'' amended section 1833(t)(16) and section 1833(i) of the Act, respectively, to provides for temporary separate payments for non-opioid treatments for pain relief. As discussed in further detail in section XIII.E of the CY 2025 OPPS/ASC proposed rule, for qualifying nonopioid products, we proposed to apply an 18 percent payment limitation on the volume weighted payment average of the top 5 services associated with the use of the qualifying non-opioid product. In CY 2024, four of these qualifying nonopioid products are separately payable without the 18 percent payment limitation—HCPCS Codes C9089 (Bupivacaine implant, 1 mg), C9290 (Inj, bupivacaine liposome), J1096 (Dexametha opth insert 0.1 mg), and J1097 (Phenylep ketorolac opth soln). Therefore, to maintain budget neutrality, we estimated the total anticipated reduction as a result of the 18 percent payment limitation required by section 4135 of the CAA, 2023. Using CY 2023 utilization for these four drugs and CY 2024 ASC payment rates, we anticipated that the 18 percent payment limitation will reduce CY 2025 ASC expenditures by approximately $9 million. Therefore, we proposed to

reduce estimated CY 2025 total payments by $9 million in our weight scalar calculation as a result of section 4135 of the CAA, 2023.

We proposed to use the ratio of estimated CY 2024 to estimate CY 2025 total payments (the weight scalar) to scale the ASC relative payment weights for CY 2025. The proposed CY 2025 ASC weight scalar was 0.876. We note that we have historically displayed this figure rounded to the nearest ten thousandth; however, we believe this level of specificity is unnecessarily burdensome for an ASC payment system that is less than one-tenth the size of the OPPS (in which the weight scalar is rounded to the nearest ten-thousandth). An ASC weight scalar rounded to the nearest ten thousandth is highly sensitive to spending changes and can require the costly reissuance of new ASC payment rates from only very minor payment rate changes within the ASC Payment System, such as a revised PFS conversion factor as a result of Congressional action. Therefore, for CY 2025 and subsequent calendar years, we proposed to set the ASC weight scalar rounded to the nearest thousandth. Consistent with historical practice, we proposed to scale, using this method, the ASC relative payment weights of covered surgical procedures, covered ancillary radiology services, and certain diagnostic tests within the medicine range of CPT codes, which are covered ancillary services for which the ASC payment rates are based on OPPS relative payment weights.

We proposed that we would not scale ASC payment for separately payable covered ancillary services that have a predetermined national payment amount (that is, their national ASC payment amounts are not based on OPPS relative payment weights), such as drugs and biologicals that are separately paid or services that are contractor-priced or paid at reasonable cost in ASCs. Any service with a predetermined national payment amount would be included in the ASC budget neutrality comparison, but scaling of the ASC relative payment weights would not apply to those services. The ASC payment weights for those services without predetermined national payment amounts (that is, those services with national payment amounts that would be based on OPPS relative payment weights) would be scaled to eliminate any difference in the total payment between the current year and the update year.

For any given year's ratesetting, we typically use the most recent full calendar year of claims data to model budget neutrality adjustments. We proposed to use the CY 2023 claims data to model our budget neutrality adjustment for CY 2025.

Comment: Many commenters reiterated a longstanding recommendation that we discontinue our budget neutrality adjustment under the ASC payment system. The commenters believe this to be antiquated and preventing the migration of procedures from the more expensive hospital setting to the ASC setting. Commenters noted that the OPPS relative weights used for the ASC payment system have already been scaled for budget neutrality under the OPPS. They argued the budget neutrality adjustment under the ASC payment system could be combined with the OPPS budget neutrality adjustment thereby establishing a single OPPS and ASC weight scalar. One commenter requested more transparency in the ASC weight scalar calculation and the driving factors behind the change in the scalar.

Response: We are not accepting the commenters' recommendation to discontinue applying the ASC weight scalar. As we have stated in past rulemaking (82 FR 59421), applying the ASC weight scalar ensures that the ASC payment system remains budget neutral. We apply the ASC weight scalar to scaled OPPS relative weights to ensure that current Medicare payments under the ASC payment system do not increase as a result of newer data to determine the cost relativity between surgical procedures. The scaled prospective OPPS relative weights that are used to determine scaled prospective ASC relative weights have not, as commenters suggest, been adjusted to achieve budget neutrality within the ASC payment system prior to the application of the ASC weight scalar. We also note that no stakeholder presented empirical evidence that the budget neutrality adjustment under the ASC payment system has impacted beneficiary access to surgical procedures in the ASC setting.

In regard to the commenter's request for more transparency in the ASC weight scalar calculation, we are unclear what additional information is needed. We provide Limited Data Set files on the CMS website such that the public can use the same data the agency used in determining the ASC weight scalar for this final rule with comment period and we describe our budget neutrality adjustment process in this section of the final rule with comment period. However, to better assist the public in understanding changes in the ASC weight scalar, we have provided more context and information in the paragraph below regarding the impact of CY 2025 changes in our inputs and how they impact the ASC weight scalar. We will continue to provide this information in our OPPS/ASC proposed and final rules to enable interested parties to better understand the changes in the ASC weight scalar.

After consideration of the public comments we received, we are finalizing our proposal to use the ratio of CY 2024 to CY 2025 total payments (the weight scalar) to scale the ASC relative payment weights for CY 2025. We estimate that there will not be an additional increase in ASC spending related to our final ASC complexity adjustment codes for CY 2025. Based on the revised payment limitations from data available for this final rule with comment period, we estimate the implementation of section 4135 of the CAA, 2023 to decrease ASC spending by $5.5 million for CY 2025 as a result of the payment limitation to currently separately payable drugs qualifying nonopioid products. Therefore, we reduced estimated CY 2025 total payments by $5.5 million in our weight scalar calculation. We will monitor the utilization and will adjust our payments to maintain budget neutrality accordingly, if appropriate, through future rulemaking.

The final CY 2025 ASC weight scalar is 0.872. The final CY 2025 ASC weight scalar represents a 1.9 percent decrease from the final CY 2024 ASC weight scalar of 0.8889. We estimate that increases in the scaled OPPS relative weights as a result of relatively greater increases in the geometric mean cost of commonly-performed surgical procedures are the most significant factor causing the decline in the ASC weight scalar.

Consistent with historical practice, we are finalizing our proposal to scale the ASC relative payment weights of covered surgical procedures, covered ancillary radiology services, and certain diagnostic tests within the medicine range of CPT codes, which are covered ancillary services for which the ASC payment rates are based on OPPS relative payment weights. Additionally, we do not anticipate any budgetary impact related to our final list of ASC complexity adjustment codes for CY 2025.

b. Updating the ASC Conversion Factor

Under the OPPS, we typically apply a budget neutrality adjustment for provider-level changes, most notably a change in the wage index values for the upcoming year, to the conversion factor. Consistent with our final ASC payment policy, for the CY 2017 ASC payment

system and subsequent years, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79751 through 79753), we finalized our policy to calculate and apply a budget neutrality adjustment to the ASC conversion factor for supplier-level changes in wage index values for the upcoming year, just as the OPPS wage index budget neutrality adjustment is calculated and applied to the OPPS conversion factor.

For CY 2025, we calculated the proposed adjustment for the ASC payment system by using the most recent CY 2023 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2025 ASC wage indexes. Specifically, holding CY 2023 ASC utilization, service-mix, and the proposed CY 2025 national payment rates after application of the weight scalar constant, we calculated the total adjusted payment using the CY 2024 ASC wage indexes and the total adjusted payment using the proposed CY 2025 ASC wage indexes which included our proposed 5-percent cap on wage index declines. We used the 50 percent labor-related share for both total adjusted payment calculations. We then compared the total adjusted payment calculated with the CY 2024 ASC wage indexes to the total adjusted payment calculated with the proposed CY 2025 ASC wage indexes and applied the resulting ratio of 0.9958 (the proposed CY 2025 ASC wage index budget neutrality adjustment) to the CY 2024 ASC conversion factor to calculate the proposed CY 2025 ASC conversion factor.

Section 1833(i)(2)(D)(v) of the Act requires that the ASC conversion factor be reduced by a productivity adjustment in each calendar year. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP). We finalized the methodology for calculating the productivity adjustment in the CY 2011 PFS final rule with comment period (75 FR 73394 through 73396) and revised it in the CY 2012 PFS final rule with comment period (76 FR 73300 through 73301) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70500 through 70501). The proposed productivity adjustment for CY 2025 was projected to be 0.4 percentage point, as published in the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 36204) based on IGI's 2023 fourth quarter forecast.

Section 1833(i)(2)(C)(i) of the Act requires that, if the Secretary has not updated amounts established under the revised ASC payment system in a calendar year, the payment amounts shall be increased by the percentage increase in the Consumer Price Index for all urban consumers (CPI–U), U.S. city average, as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved. The statute does not mandate the adoption of any particular update mechanism, but it requires the payment amounts to be increased by the CPI–U in the absence of any update. Because the Secretary updates the ASC payment amounts annually, we adopted a policy, which we codified at § 416.171(a)(2)(ii)), to update the ASC conversion factor using the CPI–U for CY 2010 and subsequent calendar years.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59075 through 59080), we finalized a policy to apply the productivity-adjusted hospital market basket update to ASC payment system rates for an interim period of 5 years (CY 2019 through CY 2023), during which we would assess whether there is a migration of the performance of procedures from the hospital setting to the ASC setting as a result of the use of a productivity-adjusted hospital market basket update, as well as whether there are any unintended consequences, such as less than expected migration of the performance of procedures from the hospital setting to the ASC setting. The most recent available full year of claims data to assess the expected migration applying the productivity-adjusted hospital market basket update during the interim period would fall within the period from CY 2019 through CY 2022. However, the impact of the COVID–19 PHE on health care utilization, in particular in CY 2020, was tremendously profound, particularly for elective surgeries, because many beneficiaries avoided healthcare settings, when possible, to avoid possible infection from the SARS–CoV–2 virus. As a result, it is nearly impossible to disentangle the effects from the COVID–19 PHE in our analysis of whether the higher update factor for the ASC payment system caused increased migration to the ASC setting. To analyze whether procedures migrated from the hospital setting to the ASC setting, we need to use claims data from a period during which the COVID–19 PHE had less of an impact on health care utilization. Therefore, for CY 2024, we finalized our proposal to extend the 5-year interim period an additional 2 years, that is, through CY 2024 and CY 2025. We believed hospital outpatient and ASC utilization data from CYs 2023 and 2024 will enable us to more accurately analyze whether the application of the productivity-adjusted hospital market basket update to the ASC payment system had an effect on the migration of services from the hospital setting to the ASC setting. We revised our regulations at 42 CFR 416.171(a)(2)(iii) and (iv), which establish the annual update to the ASC conversion factor, to reflect this 2-year extension. We also revised our regulations at § 416.171(a)(2)(vi) and (vii), which establish the 2.0 percentage point reduction for ASCs that fail to meet the standards for reporting ASC quality measures, and § 416.171(a)(2)(viii)(B) and (C), which establish the productivity adjustment, to reflect this 2-year extension.

For CY 2025, we proposed to utilize the proposed hospital market basket percentage increase of 3.0 percent reduced by the proposed productivity adjustment of 0.4 percentage point, resulting in a proposed productivity-adjusted hospital market basket update of 2.6 percent for ASCs meeting the quality reporting requirements. Therefore, we proposed to apply a proposed 2.6 percent productivity-adjusted hospital market basket update factor to the CY 2024 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2025 ASC payment amounts. The ASCQR Program affected payment rates beginning in CY 2014 and, under this program, there is a 2.0 percentage points reduction to the productivity-adjusted hospital market basket update factor for ASCs that fail to meet the ASCQR Program requirements. We refer readers to section XIV.E of the CY 2019 OPPS/ASC final rule with comment period (83 FR 59138 through 59139) and section XIV.E of this final rule with comment period for a detailed discussion of our policies regarding payment reduction for ASCs that fail to meet ASCQR Program requirements. We proposed to utilize the proposed inpatient hospital market basket percentage increase of 3.0 percent reduced by 2.0 percentage points for ASCs that do not meet the quality reporting requirements and then reduced by the proposed 0.4 percentage point productivity adjustment. Therefore, we proposed to apply a 0.6 percent productivity-adjusted hospital market basket update factor to the CY 2024 ASC conversion factor for ASCs not meeting the quality reporting requirements. We also proposed that if more recent data are subsequently available (for example, a more recent estimate of the inpatient hospital market

basket percentage increase or productivity adjustment), we would use such data, if appropriate, to determine the CY 2025 ASC update for the CY 2025 OPPS/ASC final rule with comment period.

For CY 2025, we proposed to adjust the CY 2024 ASC conversion factor ($53.514) by the proposed wage index budget neutrality factor of 0.9958 in addition to the proposed productivity-adjusted hospital market basket update of 2.6 percent discussed previously, which results in a proposed CY 2025 ASC conversion factor of $54.675 (a 2.2 percent increase) for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, we proposed to adjust the CY 2024 ASC conversion factor ($53.514) by the proposed wage index budget neutrality factor of 0.9958 in addition to the proposed quality reporting/productivity-adjusted hospital market basket update of 0.2 percent discussed previously, which resulted in a proposed CY 2025 ASC conversion factor of $53.609 for ASCs not meeting the quality reporting requirements.

Comment: Many commenters supported our proposal to increase the ASC conversion factor by the productivity-adjusted hospital market basket update and recommended that we continue applying the same updated factor for both the OPPS and ASC payment system in subsequent years to align both payment systems and mitigate growing payment disparities between ASCs and HOPDs. Some commenters argued that the proposed payment rate update was insufficient when compared to the broader increases in healthcare costs. However, one commenter representing hospitals opposed our proposal and recommended that the agency collect ASC costs such that it can develop an appropriate update factor for ASCs.

Response: We appreciate the commenters' support. In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72094 through 72096), we finalized our proposal to increase the ASC conversion factor by the productivity-adjusted hospital market basket update for CYs 2024 and 2025. In the CY 2025 OPPS/ASC proposed rule (89 FR 59436 through 59437), we proposed to continue this policy and increase the proposed ASC conversion factor by the productivity-adjusted hospital market basket update for CY 2025. We intend to address commenters' recommendations regarding the most applicable and appropriate update factor for the ASC payment system in our CY 2026 OPPS/ASC proposed rule. As discussed in section XII.C of this final rule with comment period, we appreciate the thoughtful comments and responses regarding our solicitation on methods that would mitigate the burden of reporting costs on ASCs while also collecting enough data to reliably use in the determination of ASC costs. We will take these comments into consideration or future rulemaking.

With respect to commenter's concern that the hospital market basket update would insufficiently increase ASC payments, as discussed in section II.B of this final rule with comment period, section 1833(t)(3)(C)(iv) of the Act requires the OPPS OPD fee schedule increase factor for a year to equal the IPPS market basket percentage increase factor (hospital market basket update) applicable under section 1886(b)(3)(B)(iii) to hospital discharges in the fiscal year ending in such year. Accordingly, we are unable to adopt a final OPPS OPD fee schedule increase factor different than the hospital market basket update finalized in the FY 2025 IPPS/LTCH PPS final rule.

After consideration of the public comments we received, for CY 2025, we are finalizing using the hospital market basket update of 3.4 percent reduced by the productivity adjustment of 0.5 percentage point, resulting in a productivity-adjusted hospital market basket update factor of 2.9 percent for ASCs meeting the quality reporting requirements. Therefore, we apply a 2.9 percent productivity-adjusted hospital market basket update to the CY 2024 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the C Y 2025 ASC payments. We are finalizing the hospital market basket update of 3.4 percent reduced by 2.0 percentage points for ASCs that do not meet the quality reporting requirements and then reduced by the productivity adjustment of 0.5 percentage point. Therefore, we apply a 0.9 percent productivity-adjusted hospital market basket update factor to the CY 2024 ASC conversion factor for ASCs not meeting the quality reporting requirements.

For CY 2025, we are adjusting the CY 2024 ASC conversion factor ($53.514) by a wage index budget neutrality factor of 0.9969 in addition to the productivity-adjusted hospital market basket update of 2.9 percent, discussed above, which results in a final CY 2025 ASC conversion factor of $54.895 for ASCs meeting quality reporting requirements. For ASCs not meeting quality reporting requirements, we are adjusting the CY 2024 ASC conversion factor ($53.514) by the wage index budget neutrality factor of 0.9969 in addition to the reduced productivity-adjusted hospital market basket update of 0.9 percent, discussed above, which results in a final CY 2025 ASC conversion factor of $53.828 for ASCs not meeting the quality reporting requirements.

3. Display of the Final CY 2025 ASC Payment Rates

Addenda AA and BB to this final with comment period (which are available on the CMS website) display the final ASC payment rates for CY 2025 for covered surgical procedures and covered ancillary services, respectively. The final payment rates included in Addenda AA and BB to this final rule with comment period reflect the full ASC payment update and not the reduced payment update used to calculate payment rates for ASCs not meeting the quality reporting requirements under the ASCQR Program.

These Addenda contain several types of information related to the final CY 2025 payment rates. Specifically, in Addendum AA, a ''Y'' in the column titled ''To be Subject to Multiple Procedure Discounting'' indicates that the surgical procedure would be subject to the multiple procedure payment reduction policy. As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66829 through 66830), most covered surgical procedures are subject to a 50 percent reduction in the ASC payment for the lower-paying procedure when more than one procedure is performed in a single operative session.

The values displayed in the column titled ''Final CY 2025 Payment Weight'' are the final relative payment weights for each of the listed services for CY 2025. The final relative payment weights for all covered surgical procedures and covered ancillary services where the ASC payment rates are based on OPPS relative payment weights were scaled for budget neutrality. Therefore, scaling was not applied to the device portion of the device-intensive procedures; services that are paid at the MPFS nonfacility PE RVU-based amount; separately payable covered ancillary services that have a predetermined national payment amount, such as drugs and biologicals and brachytherapy sources that are separately paid under the OPPS; or services that are contractor-priced or paid at reasonable cost in ASCs. This includes separate payment for non-opioid pain management drugs.

To derive the final CY 2025 payment rate displayed in the ''Final CY 2025 Payment Rate'' column, each ASC payment weight in the ''Final CY 2025

Payment Weight'' column was multiplied by the final CY 2025 conversion factor. The conversion factor includes a budget neutrality adjustment for changes in the wage index values and the annual update as reduced by the productivity adjustment. The final CY 2025 ASC conversion factor uses the final CY 2025 productivity-adjusted hospital market basket update factor of 2.9 percent (which is equal to the inpatient hospital market basket update of 3.4 percent reduced by the productivity adjustment of 0.5 percentage point).

In Addendum BB, there are no relative payment weights displayed in the ''Final CY 2025 Payment Weight'' column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The ''Final CY 2025 Payment'' column displays the final CY 2025 national unadjusted ASC payment rates for all items and services. The final CY 2025 ASC payment rates listed in Addendum BB for separately payable drugs and biologicals are based on the most recently available data used for payment in physicians' offices.

For CY 2021, we finalized adding a new column to ASC Addendum BB titled ''Drug Pass-Through Expiration during Calendar Year'' where we flag through the use of an asterisk each drug for which pass-through payment is expiring during the calendar year (that is, on a date other than December 31st).

Addendum EE to this final rule with comment period provides the HCPCS codes and short descriptors for surgical procedures that are to be excluded from payment in ASCs for CY 2025.

Addendum FF to this final rule with comment period displays the OPPS payment rate (based on the standard ratesetting methodology), the APC device offset percentage, the device offset percentage for determining device-intensive status (based on the standard ratesetting methodology), and the device portion of the ASC payment rate for CY 2025 for covered surgical procedures.

XIV. Cross-Program Measures for the Hospital Outpatient Quality Reporting (OQR), Rural Emergency Hospital Quality Reporting (REHQR), and Ambulatory Surgical Center Quality Reporting (ASCQR) Programs

A. Background

We refer readers to sections XV, XVI, and XVII of this final rule with comment period for program specific background information, including the statutory authorities and previously finalized and newly finalized measure sets, for the Hospital Outpatient Quality Reporting (OQR), Rural Emergency Hospital Quality Reporting (REHQR), and Ambulatory Surgical Center Quality Reporting (ASCQR) Programs, respectively.

B. CMS Commitment To Advancing Health Equity Using Quality Measurement

We are committed to advancing health equity and improving health outcomes through our quality reporting programs. The CMS Framework for Health Equity acknowledges that ''addressing health and healthcare disparities and achieving health equity should underpin efforts to focus attention and drive action on our nation's top health priorities.'' CMS defines health equity as ''the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes.'' [255]

Significant and persistent disparities in healthcare outcomes exist in the United States (U.S.). Belonging to a racial or ethnic minority group, living with a disability, being a member of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community, living in a rural area, or being near or below the poverty level are often associated with worse health outcomes.[256] [257] [258] Health disparities manifest primarily as worse health outcomes in populations where access to care is inequitable.[259] [260] Such differences persist across geography and healthcare settings irrespective of improvements in quality of care over time. [261] [262] Inequities in the social determinants of health affecting these groups are interrelated and influence a wide range of health and quality of life outcomes and risks.[263]

Inequities related to the social determinants of health may affect health-related social needs (HRSNs). HRSNs are individual-level, adverse social conditions that negatively impact an individual's health or healthcare and are associated with worse health outcomes and increased healthcare utilization.[264] While HRSNs account for 50 to 70 percent of health outcomes, the mechanisms by which this connection emerges are complex and multifaceted.[265] [266] Growing evidence demonstrates that specific HRSNs are directly associated with patient health outcomes as well as healthcare utilization, costs, and performance in quality-based payment programs.[267] [268] The persistent interactions among individuals' HRSNs, medical providers' practices and behaviors, and community resources significantly impact

[255] Centers for Medicare & Medicaid Services. (2022). CMS Framework for Health Equity 2022–2032. Available at: *https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf.*

[256] Polyakova M, Udalova V, Kocks G, Genadek K, Finlay K, Finkelstein AN. (2021). Racial Disparities in Excess All-Cause Mortality During The Early COVID–19 Pandemic Varied Substantially Across States. *Health Affairs,* 40(2), 307–316. *https://doi.org/10.1377/hlthaff.2020.02142.*

[257] Rural Health Research Gateway. (2018). Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. Available at: *https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-income-health-status-recap.pdf.*

[258] Heslin KC, Hall JE. (2021). Sexual Orientation Disparities in Risk Factors for Adverse COVID–19-Related Outcomes, by Race/Ethnicity—Behavioral Risk Factor Surveillance System, United States, 2017–2019. *MMWR Morbidity Mortality Weekly Report,* 70(5), 149. *http://dx.doi.org/10.15585/mmwr.mm7005a1.*

[259] The Physicians Foundation. (2020). Survey of America's Patients, Part Three. Available at: *https://physiciansfoundation.org/wp-content/uploads/2020/10/2020-Physicians-Foundation-Survey-Part3.pdf.*

[260] Office of the Assistant Secretary for Planning and Evaluation. (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program (Second of Two Reports). Available at: *https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress.*

[261] Ibid.

[262] Khullar D, Schpero WL, Bond AM, Qian Y, Casalino LP. (2020). Association Between Patient Social Risk and Physician Performance Scores in the First Year of the Merit-based Incentive Payment System. *JAMA,* 324(10), 975–983. *https://jamanetwork.com/journals/jama/fullarticle/2770410.*

[263] Office of Disease Prevention and Health Promotion. (2021). Healthy People 2020: Disparities. Available at: *https://wayback.archive-it.org/5774/20220414003754/https://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities.*

[264] Centers for Medicare & Medicaid Services. (2021). A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. Available at: *https://www.cms.gov/priorities/innovation/media/document/ahcm-screeningtool-companion.*

[265] Kaiser Family Foundation. (2021). Racial and Ethnic Health Inequities and Medicare. Available at: *https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/.*

[266] The Physicians Foundation. (2021). Viewpoints: Social Determinants of Health. Available at: *https://physiciansfoundation.org/wp-content/uploads/2019/08/The-Physicians-Foundation-SDOH-Viewpoints.pdf.*

[267] Zhang Y, Li J, Yu J, Braun RT, Casalino LP. (2021), Social Determinants of Health and Geographic Variation in Medicare per Beneficiary Spending. *JAMA Network Open,* 4(6), e2113212. *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2780864.*

[268] Khullar D, Schpero WL, Bond AM, Qian Y, Casalino LP (2020). Association Between Patient Social Risk and Physician Performance Scores in the First Year of the Merit-based Incentive Payment System. *JAMA,* 324(10), 975–983. *https://doi.org/10.1001/jama.2020.13129.*

healthcare access, quality, and costs, as described in the CMS Equity Plan for Improving Quality in Medicare.[269] [270] Assessment of HRSNs is an essential mechanism for capturing the interaction between social, community, and environmental factors associated with health status and health outcomes.[271] [272] Studies indicate that healthcare facility leadership can positively influence culture for better quality, patient outcomes, and experience of care.[273] [274] [275]

We are committed to supporting healthcare facility leadership in building a culture of equity that focuses on eliminating health disparities to provide patients with high quality healthcare through the collection and public reporting of health equity focused measures, including in outpatient care settings.[276]

Health equity quality measurement supports the Meaningful Measures 2.0 goal to ''Leverage Quality Measures to Promote Equity and Close Gaps in Care'' as well as the objective to ''commit to a patient-centered approach in quality measure and value-based incentives programs.'' Additionally, under the CMS National Quality Strategy, adoption of health equity quality measures would support addressing the quality priority to ''advance health equity and whole-person care'' by employing a uniform approach for gathering, reporting, and analyzing health equity data across CMS quality programs.[277]

1. Adoption of the Hospital Commitment to Health Equity (HCHE) Measure for the Hospital Outpatient Quality Reporting (OQR) and Rural Emergency Hospital Quality Reporting (REHQR) Programs and the Facility Commitment to Health Equity (FCHE) Measure for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program Beginning with the CY 2025 Reporting Period/CY 2027 Payment Determination or Program Determination.[278]

a. Background

Strong and committed leadership from healthcare facility management is essential in shifting organizational culture to reduce health disparities and reach health equity goals.[279] The Agency for Healthcare Research and Quality and the Joint Commission identified that healthcare facility leadership plays an important role in promoting a culture of quality and safety.[280] [281] The Institute of Healthcare Improvement's research shows that health equity must be a priority championed by leadership teams to improve both patient access to needed healthcare services and outcomes among disadvantaged populations.[282] Based upon these findings, we believe that healthcare facility leadership is instrumental in setting specific, measurable, attainable, realistic, and time-based (SMART) goals to assess progress towards achieving equity priorities and ensuring high-quality care is equally accessible to all individuals.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25592 and 25593), we sought public comment on potential future efforts to address health equity in the Hospital Inpatient Quality Reporting (IQR) Program, particularly the inclusion of a structural measure to assess the degree of hospital leadership commitment to collecting and monitoring health equity performance data. We specifically sought feedback on (1) conceptual and measurement priorities to facilitate organizational efforts to improve health equity; and (2) an appropriate measure regarding organizational commitment to health equity and accessibility for individuals with intellectual and developmental disabilities. In response, we received support for the development and implementation of a health equity structural measure. We also received comments expressing concerns about such a health equity structural measure. We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45414 through 45416) for summaries of the comments we received related to this solicitation.

We considered this feedback with the intent that future health equity measures would align across the Medicare quality reporting programs, including the Hospital OQR, REHQR, and ASCQR Programs, to ensure equitable care across both inpatient and outpatient settings to the greatest extent possible within facilities and hospitals participating in Medicare. In addition, we believe that measuring leadership commitment to health equity should not be limited to the inpatient hospital setting but should cover the continuum of care as patients seek and receive care at various care settings.

We initially developed the HCHE and FCHE measures for use in the Hospital IQR and Inpatient Psychiatric Facility Quality Reporting (IPFQR) Programs, respectively, with the expectation of expansion into other Medicare quality reporting programs. The HCHE and FCHE measures are attestation-based structural measures that assess hospitals' and facilities' commitment to

[269] Centers for Medicare & Medicaid Services. (2021). Paving the Way to Equity: A Progress Report. Available at: *https://www.cms.gov/files/document/paving-way-equity-cms-omh-progress-report.pdf.*

[270] Centers for Medicare & Medicaid Services Office of Minority Health. (2021). The CMS Equity Plan for Improving Quality in Medicare. 2015–2021. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMSEquityPlanforMedicare_090615.pdf.*

[271] Alley DE, Asomugha CN, Conway PH, Sanghavi DM. (2016). Accountable Health Communities—Addressing Social Needs through Medicare and Medicaid. *New England Journal of Medicine,* 374(1), 8–11. Available at: *https://www.nejm.org/doi/10.1056/NEJMp1512532.*

[272] Centers for Disease Control and Prevention. (July 2020). CDC COVID–19 Response Health Equity Strategy: Accelerating Progress Towards Reducing COVID–19 Disparities and Achieving Health Equity. Available at: *https://www.cdc.gov/covid/media/pdfs/2024/07/CDC_COVID-19HealthEquityStrategy_English.pdf.*

[273] We use the term ''healthcare facility'' to refer to hospital outpatient departments (HOPDs), rural emergency hospitals (REHs), and ambulatory surgical centers (ASCs) collectively.

[274] Smith SA, Yount N, Sorra J. (2017). Exploring Relationships Between Hospital Patient Safety Culture and Consumer Reports Safety Scores. *BMC Health Services Research,* 17(1), 143. *https://doi.org/10.1186/s12913-017-2078-6.*

[275] Bradley EH, Brewster AL, McNatt Z, et al. (2018). How Guiding Coalitions Promote Positive Culture Change in Hospitals: A Longitudinal Mixed Methods Interventional Study. *BMJ Quality & Safety,* 27(3), 218–225. *https://qualitysafety.bmj.com/content/27/3/218.*

[276] Smith SA, Yount N, Sorra J. (2017). Exploring Relationships Between Hospital Patient Safety Culture and Consumer Reports Safety Scores. *BMC Health Services Research,* 17(1), 143. *https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-017-2078-6.*

[277] Centers for Medicare & Medicaid Services. (2024). CMS National Quality Strategy. Centers for Medicare and Medicaid Services. Available at: *https://www.cms.gov/medicare/quality/meaningful-measures-initiative/cms-quality-strategy.*

[278] We use the phrase ''payment determination'' for the Hospital OQR and ASCQR Programs to represent our assessment of whether the 2-percentage point reduction in payment for failing to meet program requirements is warranted. We use the phrase ''program determination'' for the REHQR Program to represent our assessment of compliance with program requirements for an applicable year because the REHQR Program does not include an associated payment adjustment.

[279] Bradley EH, Brewster AL, McNatt Z, Linnander EL, Cherlin E, Fosburgh H, Ting HH, Curry LA.(2018). How Guiding Coalitions Promote Positive Culture Change in Hospitals: A Longitudinal Mixed Methods Interventional Study. BMJ Quality & Safety, 27(3), 218–225. *https://pubmed.ncbi.nlm.nih.gov/29101290/.*

[280] Agency for Healthcare Research and Quality. (September 2019). Leadership Role in Improving Patient Safety. Patient Safety Network. Available at: *https://psnet.ahrq.gov/primer/leadership-role-improving-safety.*

[281] Joint Commission on Accreditation of Healthcare Organizations. (June 2021). The essential role of leadership in developing a safety of culture. *Sentinel Event Alert.* (57), 1–8. *https://www.jointcommission.org/-/media/tjc/newsletters/sea-57-safety-culture-and-leadership-final3.pdf.*

[282] Mate KS, Wyatt R. (2017). Health Equity Must Be a Strategic Priority. *NEJM Catalyst.* Available at: *https://catalyst.nejm.org/doi/full/10.1056/CAT.17.0556.*

health equity across the following five domains adapted from the CMS Office of Minority Health's (OMH) ''Building an Organizational Response to Health Disparities'' framework: equity as a strategic priority, data calculation, data analysis, quality improvement, and leadership engagement.[283] These measures are intended to encourage hospitals and facilities to analyze their data to understand how factors, including race, ethnicity, and the social determinants of health can contribute to the delivery of more equitable care.[284]

We believe these domains provide actionable focus areas for the assessment of healthcare facility leadership commitment because they are foundational to incentivizing hospitals and facilities to collect and utilize data to identify critical equity gaps, implement plans to address those gaps, and ensure that resources are dedicated toward healthcare equity initiatives. We also believe these measures support hospitals and facilities in quality improvement, promote efficient and effective use of resources, and leverage available data.

Adoption of these measures in the Hospital OQR, REHQR, and ASCQR Programs would support our efforts to align measures across CMS quality reporting programs, including the Hospital IQR Program (87 FR 49191 through 49201), IPFQR Program (88 FR 51100 through 51107), PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program (88 FR 59204 through 59210), and End-Stage Renal Disease Quality Incentive Program (ESRD QIP) (88 FR 76437 through 76446). We believe that alignment across the quality reporting programs is important to ensure that health equity, which impacts patients regardless of where they receive their care, is addressed in every healthcare delivery setting. Adopting these measures across quality reporting programs would incentivize quality reporting entities to collect and utilize data to identify critical equity gaps, implement plans to address said gaps, and ensure that resources are dedicated toward addressing health equity initiatives.

b. Overview of the Measures

The HCHE and FCHE measures assess a hospital's or facility's commitment to health equity by using equity-focused organizational domains aimed at advancing health equity for all patients, including but not limited to those in racial and ethnic minority groups, people with disabilities, members of the LGBTQ+ community, individuals with limited English proficiency, rural populations, religious minorities, and people facing socioeconomic challenges. Table 159 and Table 160 describe the five attestation domains and their elements for the HCHE and FCHE measures, respectively.

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[283] Centers for Medicare & Medicaid Services. (2021). Building an Organizational Response to Health Disparities [Fact Sheet]. U.S. Department of Health and Human Services. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Health-Disparities-Guide.pdf*.

[284] We note that the term ''hospital'' includes HOPDs and REHs for the purposes of this measure.

TABLE 159: HOSPITAL COMMITMENT TO HEALTH EQUITY MEASURE ATTESTATION DOMAINS

Attestation	Elements: Select all that apply (Note: Affirmative attestation of all elements within a domain would be required for the hospital to receive a point for the domain in the numerator)
Domain 1: Equity is a Strategic Priority	
Hospital commitment to reducing healthcare disparities is strengthened when equity is a key organizational priority. Please attest that your hospital has a strategic plan for advancing health equity and that it includes all the following elements.	(A) Our hospital strategic plan identifies priority populations who currently experience health disparities. (B) Our hospital strategic plan identifies health equity goals and discrete action steps to achieving these goals. (C) Our hospital strategic plan outlines specific resources which have been dedicated to achieving our equity goals. (D) Our hospital strategic plan describes our approach for engaging key stakeholders, such as community-based organizations.
Domain 2: Data Collection	
Collecting valid and reliable demographic and social determinant of health data on patients served in a hospital is an important step in identifying and eliminating health disparities. Please attest that your hospital engages in the following activities.	(A) Our hospital collects demographic information (such as self-reported race, national origin primary language and ethnicity data), and/or social determinant of health information on the majority of our patients. (B) Our hospital has training for staff in culturally sensitive collection of demographic and/or social determinant of health information. (C) Our hospital inputs demographic and/or social determinant of health information collected from patients into structured, interoperable data elements using a certified EHR technology.
Domain 3: Data Analysis	
Effective data analysis can provide insights into which factors contribute to health disparities and how to respond. Please attest that your hospital engages in the following activities.	(A) Our hospital stratifies key performance indicators by demographic and/or social determinants of health variables to identify equity gaps and includes this information on hospital performance dashboards.
Domain 4: Quality Improvement	
Health disparities are evidence that high-quality care has not been delivered equitably to all patients. Engagement in quality improvement activities can improve quality of care for all patients.	(A) Our hospital participates in local, regional, or national quality improvement activities focused on reducing health disparities.
Domain 5: Leadership Engagement	
Leaders and staff can improve their capacity to address disparities by demonstrating routine and thorough attention to equity and setting an organizational culture of equity. Please attest that your hospital engages in the following activities.	(A) Our senior leadership, including chief executives and the entire board of trustees, annually reviews our strategic plan for achieving health equity. (B) Our senior leadership, including chief executives and the entire board of trustees, annually reviews key performance indicators stratified by demographic and/or social factors.

TABLE 160: FACILITY COMMITMENT TO HEALTH EQUITY MEASURE ATTESTATION DOMAINS

Attestation	Elements: Select all that apply (Note: Affirmative attestation of all elements within a domain would be required for the facility to receive a point for the domain in the numerator)
Domain 1: Equity is a Strategic Priority	
Facility commitment to reducing healthcare disparities is strengthened when equity is a key organizational priority. Please attest that your facility has a strategic plan for advancing health equity and that it includes all the following elements.	(A) Our facility strategic plan identifies priority populations who currently experience health disparities. (B) Our facility strategic plan identifies health equity goals and discrete action steps to achieving these goals. (C) Our facility strategic plan outlines specific resources which have been dedicated to achieving our equity goals. (D) Our facility strategic plan describes our approach for engaging key stakeholders, such as community-based organizations.
Domain 2: Data Collection	
Collecting valid and reliable demographic and social determinant of health data on patients served in a facility is an important step in identifying and eliminating health disparities. Please attest that your facility engages in the following activities.	(A) Our facility collects demographic information (such as self-reported race, national origin primary language and ethnicity data), and/or social determinant of health information on the majority of our patients. (B) Our facility has training for staff in culturally sensitive collection of demographic and/or social determinant of health information. (C) Our facility inputs demographic and/or social determinant of health information collected from patients into structured, interoperable data elements using an EHR technology.
Domain 3: Data Analysis	
Effective data analysis can provide insights into which factors contribute to health disparities and how to respond. Please attest that your facility engages in the following activities.	(A) Our facility stratifies key performance indicators by demographic and/or social determinants of health variables to identify equity gaps and includes this information on facility performance dashboards.
Domain 4: Quality Improvement	
Health disparities are evidence that high-quality care has not been delivered equitably to all patients. Engagement in quality improvement activities can improve quality of care for all patients.	(A) Our facility participates in local, regional, or national quality improvement activities focused on reducing health disparities.
Domain 5: Leadership Engagement	
Leaders and staff can improve their capacity to address disparities by demonstrating routine and thorough attention to equity and setting an organizational culture of equity. Please attest that your facility engages in the following activities.	(A) Our facility senior leadership, such as chief executives and the entire facility board of trustees, annually reviews our strategic plan for achieving health equity. (B) Our facility senior leadership, such as chief executives and the entire facility board of trustees, annually reviews key performance indicators stratified by demographic and/or social factors.

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The HCHE measure is currently used in the Hospital IQR and PCHQR Programs. As further discussed below, we proposed to adopt the HCHE measure for the Hospital OQR and REHQR Programs. The FCHE measure is currently used in the IPFQR Program and ESRD QIP. As further discussed below, we proposed to adopt the FCHE measure for the ASCQR Program.

We note that there are two measure specification variations between the HCHE and FCHE measures, as reflected in Tables 159 and 160. First, Table 159 references hospitals (such as HOPDs and REHs) in connection with HCHE; Table 160 references facilities (such as ASCs, which are not hospitals) in

connection with FCHE. Second, Domain 2C of the HCHE measure requires hospitals to use a certified electronic health record (EHR) technology (CEHRT) [285] in order to attest ''yes''; Domain 2C of the FCHE measure requires facilities to use EHR technology, but does not require the use of CEHRT, in order to attest ''yes.'' We recognize that ASCs have governance structures and operational circumstances that are distinct from hospitals. We also recognize that many non-hospital facilities, including ASCs, have not adopted CEHRT, but may use some EHR technology,[286] justifying this variation in Domain 2C between the HCHE and FCHE measures.[287]

c. Pre-Rulemaking Measure Review

As required under section 1890A of the Act, the Consensus-Based Entity (CBE), currently Battelle, established the Partnership for Quality Measurement (PQM), comprised of clinicians, patients, measure experts, and health information technology specialists, to participate in the pre-rulemaking process and the measure endorsement process and provide input on the selection of quality and efficiency measures. The pre-rulemaking process, which we refer to as the Pre-Rulemaking Measure Review (PRMR), includes a review of measures published on the publicly available list of Measures Under Consideration (MUC List) by one of several committees convened by the PQM for the purpose of providing multi-stakeholder input to the Secretary on the selection of quality and efficiency measures under consideration for use in certain Medicare quality programs, including the Hospital OQR, REHQR, and ASCQR Programs. More details regarding the PRMR process may be found in the PQM Guidebook of Policies and Procedures for Pre-Rulemaking Measure Review and Measure Set Review, including details of the measure review processes in Chapter 3.[288]

As part of the PRMR process, the Hospital Recommendation Group reviewed and voted on the HCHE and FCHE measures during their meeting on January 18 and 19, 2024.[289] [290] The voting results of the HCHE measure for the Hospital OQR and REHQR Programs were ''recommend with conditions,'' and the voting results of the FCHE measure were ''recommended without conditions'' for the ASCQR Program. The conditions for the HCHE measure for the Hospital OQR and REHQR Programs were: (1) obtaining CBE endorsement; (2) additional specificity around attestation requirements; and (3) ongoing data collection for further measure testing, particularly with regard to smaller entities.[291] We have taken these conditions into account, as follows, and proposed both of these measures for adoption. We discuss CBE endorsement in section XIV.B.1.d of this final rule with comment period below.

Regarding the condition to provide additional specificity around attestation requirements, we note that these domains were developed based on the recommendations from a technical expert panel (TEP) that informed our initial selection and development of this measure.[292] We also addressed this concern during the January 18–19, 2024 PRMR meeting by sharing that there are accompanying guidance documents available to provide information and examples of qualifying activities for the HCHE measure (which can also be applied to the FCHE measure).[293] [294]

With respect to the condition related to ongoing data collection for further measure testing due to concerns that smaller entities may face challenges regarding data collection and analysis, we reiterate that HCHE is an attestation measure only in Hospital OQR, a pay-for-reporting program, and REHQR, a program with no associated payment adjustment.[295] While we acknowledge the limitations in testing structural measures, we believe this measure captures useful information regarding providers' commitment to promoting health equity to inform patient choice. We have therefore considered the Hospital Recommendation Group's concerns and determined that they are adequately addressed.

d. CBE Endorsement

Section 1833 (t)(17)(C)(i) of the Act provides that the Hospital OQR Program, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities (not necessarily the CBE). Under section 1833(i)(7)(B) of the Act, this requirement at section 1833(t)(17)(C) applies to the ASCQR Program except as the Secretary may otherwise provide. For the Hospital OQR Program and ASCQR Program, we note that 1833(t)(17) of the Act does not require that each measure we adopt for these programs be CBE-endorsed (75 FR 72064 and 72065 for the Hospital OQR Program and 76 FR 74494 for the ASCQR Program).

Section 1833(t)(17)(C)(i) of the Act provides that the Hospital OQR Program, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities (not necessarily the CBE). Under section 1833(i)(7)(B) of the Act, this requirement at section 1833(t)(17)(C) applies to the ASCQR Program except as the Secretary may otherwise provide. For the Hospital OQR Program and ASCQR Program, we note that section 1833(t)(17) of the Act

[285] CEHRT refers to the certified health IT requirements established by CMS. ONC health IT certification criteria referenced in the CEHRT definition can be found at 45 CFR 170.315. Please refer to the following for more details on CEHRT requirements: *https://www.cms.gov/medicare/regulations-guidance/promoting-interoperability-programs/certified-ehr-technology*. Please refer to the Measure Calculation section for more details on CEHRT and the HCHE Measure.

[286] We define the term ''EHR technology'' as ONC's definition for Electronic Health Record, ''a real-time patient health record with access to evidence-based decision support tools that can be used to aid clinicians in decision making. The EHR can automate and streamline a clinician's workflow, ensuring that all clinical information is communicated. It can also prevent delays in response that result in gaps in care. The EHR can also support the collection of data for uses other than clinical care, such as billing, quality management, outcome reporting, and public health disease surveillance and reporting,'' at *https://www.healthit.gov/topic/health-it-and-health-information-exchange-basics/glossary*.

[287] Taira A. (June 2021). ASCA Survey Shows Mixed Usage of EHR among ASCs. ASC Focus. Available at: *https://www.ascfocus.org/ascfocus/content/articles-content/articles/2021/digital-debut/asca-survey-shows-mixed-usage-of-ehr-among-ascs*.

[288] Partnership for Quality Measurement. (September 2023). Guidebook of Policies and Procedures for Pre-Rulemaking Measure Review and Measure Set Review. Available at: *https://p4qm.org/sites/default/files/2023-09/Guidebook-of-Policies-and-Procedures-for-Pre-Rulemaking-Measure-Review-%28PRMR%29-and-Measure-Set-Review-%28MSR%29-Final_0.pdf*.

[289] Partnership for Quality Measurement. 2023 Pre-Rulemaking Measure Review (PRMR) Meeting Summary: Hospital Committee. Available at: *https://p4qm.org/sites/default/files/2024-02/PRMR-Hospital-Recommendation-Group-Meeting-Summary-Final.pdf*.

[290] Partnership for Quality Measurement. Pre-Rulemaking Measure Review Measures Under Consideration: 2023 Recommendations Report. Available at: *https://p4qm.org/sites/default/files/2024-02/PRMR-2023-MUC-Recommendations-Report-Final.pdf*.

[291] Ibid.

[292] Centers for Medicare & Medicaid Services. (February 2022). Summary of Technical Expert Panel (TEP) Meeting #1, November 16, 2021: Health Equity Quality Measurement, Hospital Commitment to Health Equity Measure. Available at: *https://mmshub.cms.gov/sites/default/files/HealthEquityQualityMeasurementTEP1SumReport.pdf*.

[293] Centers for Medicare & Medicaid Services (January 2024). Attestation Guidance for the Hospital Commitment to Health Equity Measure (v 1.2). Available at: *https://qualitynet.cms.gov/files/659c609eca7fd3001b35edab?filename=AttstGdnceHCHEMeas_v1.2.pdf*.

[294] Centers for Medicare & Medicaid Services (January 2024). Frequently Asked Questions Hospital Commitment to Health Equity, HIQR. Available at: *https://qualitynet.cms.gov/files/659c60afd4b704001df0af51?filename=FAQ_HCHE_HIQR.pdf*.

[295] Partnership for Quality Measurement. (2023). 2023 PRMR Final MUC Recommendation Spreadsheet. Available at: *https://p4qm.org/PRMR*.

does not require that each measure we adopt for these programs be CBE-endorsed (75 FR 72064 and 72065 for the Hospital OQR Program and 76 FR 74494 for the ASCQR Program).

Section 1833(t)(17)(C)(i) of the Act also requires measures developed for the Hospital OQR Program to reflect consensus among affected parties. Under section 1833(i)(7)(B) of the Act, this requirement also applies to the ASCQR Program except as the Secretary may otherwise provide. As we have noted in previous rulemaking, consensus among affected parties can be reflected in ways other than CBE endorsement, including through the measure development process, through broad acceptance and use of the measure(s), and through public comment (75 FR 72064 and 72065 for the Hospital OQR Program and 76 FR 74494 for the ASCQR Program).

For the REHQR Program, section 1861(kkk)(7)(C)(i) of the Act generally requires that quality measures specified by the Secretary for the REHQR Program be endorsed by a CBE; however, section 1861(kkk)(7)(C)(ii) of the Act provides an exception to the general CBE-endorsement requirement, stating that in the case of a specified area or medical topic determined appropriate by the Secretary for which a measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures on this topic, and therefore we believe the exception in section 1861(kkk)(7)(C)(ii) of the Act applies for purposes of this measure for the REHQR Program.

At this time, we find no other feasible and practicable measures set forth by a national consensus building entity on the topic of a hospital's or facility's leadership commitment to health equity. While we recognize the value of measures undergoing CBE endorsement review and prefer to use endorsed measures, there are currently no CBE-endorsed measures that address hospital or facility commitment to health equity. Given the urgency of achieving health equity, it is important to implement this measure as soon as possible. As previously noted, the HCHE measure was developed based on the consensus of a TEP whose recommendations informed the initial selection, development, and emphasis of the importance of this measure and subsequently the FCHE measure, which, as noted in section XIV.B.1.b of this final rule with comment period above, is a similar measure with only two measure specification variations to accommodate setting-specific realities with regard to CEHRT adoption.[296] We will consider submitting the HCHE and FCHE measures to the CBE for endorsement in the future.

e. Measure Calculation

The proposed HCHE and FCHE measures each consist of the same five attestation-based domains as shown in Table 159 and Table 160 respectively, subject to variations noted above.

The numerator of both the HCHE and FCHE measures would capture the total number of domains to which the hospital or facility is able to attest affirmatively, up to a maximum of five domains. We proposed that a hospital or facility would only receive a point for a domain if it attested ''yes'' to all the elements within that domain. We would not accept an attestation whereby a hospital or facility attests ''yes'' to some, but not all, of the elements; in the event a hospital or facility would not be able to attest ''yes'' to one or more elements within a domain, or the entirety of a domain, they would respond ''no.'' For example, for Domain 1, if the hospital or facility's strategic plan meets elements (A) and (B), but not (C) and (D) of Domain 1, then the hospital or facility would not be able to affirmatively attest ''yes'' and would receive zero points for Domain 1.

The denominator of both the HCHE and FCHE measures would constitute a total of five points (that is, one point per domain).

We also refer readers to the measure specifications, available on our QualityNet website.[297]

As noted above, Domain 2C of the HCHE measure requires the use of CEHRT, while Domain 2C of the FCHE measure requires the use of EHR technology, which is not required to be certified by ONC in accordance with ONC's requirements. We made this distinction because we recognize that many non-hospital facilities, including ASCs, currently have not adopted CEHRT and instead use non-certified EHR technology,[298] while a majority of hospitals have adopted CEHRT.[299] Although REHs are a new Medicare provider type, the majority of REH-eligible facilities, as noted in the CY 2024 OPPS/ASC final rule (88 FR 82069), have met requirements for the reporting of electronic clinical quality measures (eCQMs), which require CEHRT, under the Medicare Promoting Interoperability Program.

f. Data Submission Requirements

In the CY 2025 OPPS/ASC proposed rule, we proposed to require hospitals, REHs, and ASCs to submit their yes/no attestation responses on these structural measures in all three programs by an annual deadline using the CMS-designated information system (currently, the Hospital Quality Reporting (HQR) system) consistent with the data submission requirements of these measures in the Hospital IQR, IPFQR and PCHQR Programs. We refer readers to sections XV.E.2.a, XVI.E.3.b, and XVII.E.2.a of this final rule with comment period for additional details regarding data submission deadlines for web-based measure reporting such as the HCHE and FCHE measures for the Hospital OQR, REHQR, and ASCQR Programs, respectively.

We invited public comment on our proposal to adopt the HCHE measure for the Hospital OQR Program beginning with the CY 2025 reporting period/CY 2027 payment determination, to adopt the HCHE measure for the REHQR Program beginning with the CY 2025 reporting period/CY 2027 program determination, and to adopt the FCHE measure for the ASCQR Program beginning with the CY 2025 reporting period/CY 2027 payment determination.

The following comments and responses are applicable to both the HCHE and FCHE measures for the Hospital OQR, REHQR, and ASCQR Programs. Program-specific comments and responses are addressed subsequently.

Comment: Many commenters expressed support for our proposal to adopt the HCHE and FCHE measures. Many commenters stated that these measures will align quality

[296] Centers for Medicare & Medicaid Services. (February 2022). Summary of Technical Expert Panel (TEP) Meeting # 1 November 16, 2021: Health Equity Quality Measurement Hospital Commitment to Health Equity Measure. Available at: *https://mmshub.cms.gov/sites/default/files/HealthEquityQualityMeasurementTEP1SumReport.pdf.*

[297] Measure specifications are posted at *https://qualitynet.cms.gov/outpatient/oqr/proposedmeasures2#tab2* for the Hospital OQR and REHQR Programs, and *https://qualitynet.cms.gov/asc/ascqr/proposedmeasures2#tab2* for the ASCQR Program and may be moved to other pages on QualityNet upon publication of the final rule.

[298] Taira A. (June 2021). ASCA Survey Shows Mixed Usage of EHR among ASCs. ASC Focus. Available at: *https://www.ascfocus.org/ascfocus/content/articles-content/articles/2021/digital-debut/asca-survey-shows-mixed-usage-of-ehr-among-ascs.*

[299] Office of the National Coordinator for Health Information Technology. (2023). National Trends in Hospital and Physician Adoption of Electronic Health Records. Available at: *https://www.healthit.gov/data/quickstats/national-trends-hospital-and-physician-adoption-electronic-health-records.*

measurement across quality reporting programs as well as across hospitals and systems. Commenters expressed that this alignment would provide important measurable data to reduce health disparities and work towards a more equitable healthcare system. A few commenters stated that systematic data collection is an important first step hospitals must take to identify and work to prevent health inequities. A commenter specifically stated that these measures can serve as a foundation to address inequities in HIV care and outcomes across racial/ethnic minorities, sexual orientation and gender identity, and other social factors.

Response: We thank commenters for their support.

Comment: Several commenters recommended that CMS include voluntary reporting or delay mandatory reporting for these measures to allow hospitals and facilities adequate time to expand health equity improvement initiatives to the outpatient areas, as well as create the appropriate structure for consistent communication and build and deploy processes, such as utilizing EHR technology. A few commenters recommended phasing in measure domains incrementally to allow hospitals and facilities time to familiarize themselves with the measure. Commenters also suggested that delaying mandatory reporting would provide CMS with more time to work with stakeholders to better define each domain, and to continue to evolve and potentially respecify the measures to reduce burden on providers.

Response: We appreciate commenters' concerns about the timing of mandatory reporting; however, achieving health equity is a pressing issue which deserves serious focus and rapid action. We emphasize that this is an annual measure that was proposed for adoption beginning with the CY 2025 reporting period/CY 2027 payment or program determination, which will allow hospitals, REHs, and ASCs more than a year before the submission deadline of May 15, 2026, at which time these healthcare facilities would submit attestations regarding the identified domains during the CY 2025 reporting period. Hospitals, REHs, and ASCs can spend the remainder of CY 2024 and CY 2025 addressing potential barriers to positive attestations for the HCHE/FCHE measure before December 31, 2025. We additionally consider this measure to be a building block for a more comprehensive suite of measures that would assess progress in providing high-quality healthcare for all patients regardless of social risk factors or demographic characteristics. We also reiterate that this is an attestation measure intended to assess the capacity and commitments of the HOPD, REH, or ASC in regard to health equity and help these healthcare facilities identify potential gap areas on this topic to improve quality of care.

We also note that hospitals that participate in the Hospital IQR Program will already have 1 year of experience reporting data on the HCHE measure for the FY 2025 payment determination (that is, data submitted in FY 2024 representing the FY 2023 performance period) (87 FR 49191 through 49201). Given the timing of this measure's implementation in the Hospital IQR Program, hospitals, REHs, and ASCs will have had the opportunity to learn from the experiences of hospitals participating in the Hospital IQR Program, including best practices for minimally burdensome assessment of performance on the required domains. We will monitor measure implementation and data reporting as part of standard program and measure review and will consider updates to the measure if we identify implementation strategies to reduce burden.

Comment: A few commenters recommended CMS develop an audit function to ensure the accuracy of self-reported data and to ensure that a facility's or hospital's stated commitments to health equity are being implemented in a way that creates meaningful change.

Response: We understand commenters' concerns regarding the accuracy of self-reported data. While we do not have a specific means to validate hospital and facility attestation to these measures at this time, we have provided an Attestation Guidance document and a FAQ document, which clearly define what constitutes an affirmative attestation and provide answers to frequently asked questions, for the HCHE measure in Hospital IQR Program.[300] [301] We intend to provide specific guidance for the Hospital OQR, REHQR, and ASCQR Programs, consistent with the specifications described in Tables 159 and 160 and requirements being finalized in this section of the final rule, in the future. Hospitals, REHs, and ASCs may also refer to the measure specifications for additional attestation guidance.[302]

Comment: A few commenters recommended that CMS communicate with stakeholders to refine its portfolio of health-equity related measures while creating a streamlined measure set that is applicable and standardized across settings. A commenter recommended collaborating with stakeholders toward the development of a measure that is meaningful for hospitals as they design interventions to address HRSNs in partnership with their communities. Another commenter recommended that CMS evaluate the results of these measures in conjunction with stakeholder communication before expanding measure requirements.

Response: We thank the commenters for this feedback. We reiterate that stakeholders convened by the PRMR entity previously reviewed the HCHE and FCHE measures and provided feedback during the PRMR process. We refer readers to section XIV.B.1.c of this final rule with comment period for a discussion of the PRMR process. The purpose of the PRMR process is to solicit and provide multi-stakeholder input to the Secretary on the selection of quality and efficiency measures under consideration for use in CMS quality programs, including the Hospital OQR, REHQR, and ASCQR Programs. We will continue identifying opportunities for collaboration with all stakeholders to align assessment of social health drivers across CMS programs. The HCHE and FCHE measures are foundational additions to our programs, and we plan to identify additional health equity measures for development and potential subsequent adoption. We will continue to seek stakeholder input through the pre-rulemaking process, as required under section 1890A of the Act, as well as through notice-and-comment rulemaking, before modifying the HCHE and FCHE measures or adding new measures to ensure meaningful outcomes.

Comment: Several commenters recommended strategies to best implement the HCHE and FCHE measures. Commenters recommended additional factors to include in these measures to make them more meaningful, including the collection of demographics other than race and ethnicity (such as age, gender, and

[300] Centers for Medicare & Medicaid Services (January 2024). Attestation Guidance for the Hospital Commitment to Health Equity Measure (v 1.2). Available at: *https://qualitynet.cms.gov/files/659c609eca7fd3001b35edab?filename=AttstGdnceHCHEMeas_v1.2.pdf.*

[301] Centers for Medicare & Medicaid Services (January 2024). Frequently Asked Questions Hospital Commitment to Health Equity, HIQR. Available at: *https://qualitynet.cms.gov/files/659c60afd4b704001df0af51?filename=FAQ_HCHE_HIQR.pdf.*

[302] Measure specifications are posted at *https://qualitynet.cms.gov/outpatient/oqr/proposedmeasures2#tab2* for the Hospital OQR and REHQR Programs, and *https://qualitynet.cms.gov/asc/ascqr/proposedmeasures2#tab2* for the ASCQR Program and may be moved to other pages on QualityNet upon publication of the final rule.

health literacy). A commenter recommended using a community needs assessment and implementing regulatory flexibilities to explore additional ways to support hospitals in addressing health equity. Another commenter recommended that CMS create a plan of action prior to measure implementation to meet the equity intention behind these measures.

Several commenters recommended the adoption of quality reporting measures to supplement the HCHE and FCHE measures. A commenter specifically recommended the adaptation and inclusion of the Age Friendly Hospital measure in the outpatient setting, as it is currently included in the Hospital IQR measure set.

Several commenters recommended that CMS consider alternative approaches to address health equity. A few commenters recommended that CMS further refine or develop alternative measure concepts, while incorporating a more holistic view of the hospital or facility, to accurately evaluate leadership commitment to health equity. A commenter suggested the adoption of measures with numerical results instead of yes or no answers. This commenter stated that structural measures do not always drive action since they are not linked to direct quality outcomes and do not have a sound validation process. The commenter further recommended that it would be more impactful for CMS to develop new outcome measures related to health equity that drive action and measurable change. Another commenter suggested that CMS revisit its current definition of ''health equity'' to instead focus on the absence of disparities in the processes or outcomes of hospital care, leading to a more narrow and actionable definition. Additionally, a commenter recommended that CMS explore developing measures using data that CMS already collects through claims or could be collected through other digital measurement sources.

Response: We thank commenters for their recommendations. Adoption of the HCHE and FCHE measures in the Hospital OQR, REHQR, and ASCQR programs would lay the groundwork for a more comprehensive suite of measures that would assess progress in providing high-quality healthcare for all patients regardless of social risk factors or demographic characteristics. We will consider this feedback in future rulemaking and measure development.

Comment: A few commenters expressed concern about hospital and facility penalization. A commenter cautioned that these measures penalize providers rather than incentivize them to comply with data collection and implementation that advances health equity. Another commenter recommended sensitivity and a formulaic coefficient when evaluating under-resourced facilities to ensure congruency on quality performance relative to facilities with more resources. This commenter also recommended adjusting programmatic requirements to ensure that reporting on quality measures is feasible for all facilities and that under-resourced facilities do not face undue difficulty or burdensome penalties that could affect access to care for vulnerable populations.

Response: We acknowledge commenters' concerns regarding resources, including increased data collection burden. The benefits of encouraging hospital and facility commitment to health equity outweigh the burden of attestation under this measure. We will consider the concept of a single streamlined health equity measure at the organizational level in future rulemaking. We remind commenters that the Hospital OQR and ASCQR Programs are pay-for-reporting programs. Participants are only penalized for failure to submit required data on quality measures as specified; their payments are not affected based on their performance on measures. Additionally, the REHQR Program does not include a financial incentive or penalty for REHs.

As described in the CY 2025 OPPS/ASC proposed rule (89 FR 59516, 59522, 59526), the estimated burden for HOPDs and REHs is 10 minutes annually for the HCHE measure, and the estimated burden for ASCs is 10 minutes annually for the FCHE measure, which is a reasonable expectation for quality reporting data submission. Finally, we would also like to note that the HCHE and FCHE measures are not meant to compare facilities with one another, but rather for facilities to identify and address structural gaps within their strategic planning, data collection and analysis, quality improvement, and leadership engagement.

Comment: Several commenters opposed to the adoption of the HCHE and FCHE measures expressed concern that, without additional requirements for facilities to make changes based on identified health equity gaps, the HCHE and FCHE measures may only serve as a checklist measure rather than incentivizing actionable change at the systemic level. A few commenters recommended CMS provide more timely and actionable data to hospitals to yield more prompt advancements in safety and quality. Another commenter expressed concern that there is no published clinical evidence to link hospital measurement of social determinants of health to improvements in quality of care or outcomes.

Response: We thank commenters for their feedback and acknowledge their concerns. Hospitals and facilities are responsible for ensuring the best outcomes possible for the patients that they serve, including identifying potential barriers to optimal health and helping patients identify resources to address those barriers. These measures are important, foundational measures for improving health equity among those that have been disadvantaged or underserved by the healthcare system. Adoption of the HCHE and FCHE measures will incentivize hospitals and facilities to collect and utilize data across the five domains to identify critical equity gaps, implement plans to address these gaps, and ensure that resources are dedicated toward addressing health equity initiatives, therefore resulting in actionable initiatives and change. These measures aim to support hospitals and facilities in leveraging available data, pursuing focused quality improvement activities, and promoting efficient and effective use of resources. Leadership commitment to health equity can foster organizational competencies aimed at achieving health equity for the facility's patients.

Regarding the commenter's concern regarding published clinical evidence to link hospital measurement of social determinants of health to improvements in quality of care or outcomes, as we discussed in section XIV.B of the CY 2025 OPPS/ASC proposed rule, there is substantial research showing differences in care and experiences among these populations (89 FR 59437 and 59438). We also refer readers to HHS' Healthy People 2030 Framework's website for social determinants of health, which includes literature summaries of the latest research related to social determinants of health and how it affects health outcomes and health disparities: *https://health.gov/healthypeople/priority-areas/social-determinants-health/literature-summaries.* Although the HCHE and FCHE measures are not clinical measures, they aim to improve hospital and facility awareness of the tie between its structural practices and patient outcomes, which will lead to improved clinical outcomes for patients. Advancing health equity helps foster a healthcare system that benefits all and

the delivery of more equitable care will, in turn, improve patient outcomes.[303]

We appreciate the commenter's recommendation to provide more timely and actionable data to hospitals to yield more prompt advancements in safety and quality and will consider this input throughout these measures' implementation.

Comment: A few commenters that did not support adoption of the HCHE and FCHE measures expressed concern about the ''one size fits all'' approach to implementing these measures and stated that the measures are not appropriately tailored to the hospital outpatient, REH, or ASC settings.

Response: We acknowledge that this measure was initially developed for the general acute care setting. The inclusion of the HCHE and FCHE measures in other care settings, including inpatient hospitals, PPS-Exempt cancer hospitals, and dialysis facilities, demonstrate broad applicability of the measure concept and specifications for different healthcare facility types, including in HOPDs, REHs, and ASCs. Hospitals and facilities of every type could benefit from these commitment to health equity measures, as they serve to incentivize the collection and utilization of data across the five domains to identify critical equity gaps, implement plans to address these gaps, and ensure that resources are dedicated toward addressing health equity initiatives, therefore resulting in actionable initiatives and change. These measures aim to support hospitals and facilities in leveraging available data, pursuing focused quality improvement activities, and promoting efficient and effective use of resources. We also reiterate the modifications to Domains 2 and 5 of the FCHE measure (compared to the HCHE measure), which were constructed to address nuances within non-hospital settings. Strong and consistent facility leadership can be instrumental in establishing specific, measurable, and attainable goals to advance equity priorities and improve care for all patients in any care setting, including patients who receive care in HOPDs, REHs, or ASCs. Leaders of health services organizations across the healthcare system are likely to encounter the same challenges and use the same types of strategies to achieve organizational goals related to improving health equity within their respective organizations and patient populations. We note that health equity is a critical focus area for all hospitals and facilities, including those that treat a disproportionate share of patients with health disparities. We will monitor measure implementation and data reporting as part of standard program and measure review and will consider updates to the measure if improvements are identified through this process.

Comment: A few commenters that did not support adoption of the HCHE and FCHE measures stated concerns that collecting and publicly reporting the attestation domains for assessing organizational-level leadership involvement in healthcare equity could be misleading to the public and may further underscore disparity without the necessary context. This commenter stated that, without a holistic view of organizational culture, internal policies, specialties, and community demographics, it may not be possible to accurately and fairly evaluate organizations under these measures.

A few commenters further recommended the public display of attestations for each element in a domain as well as additional language stating what hospitals and facilities are doing to achieve health equity. A few commenters recommended that CMS allow for ''partial credit,'' if hospitals and facilities meet the requirements of only a few elements in a specific domain.

Response: We acknowledge commenters' concern about public reporting of this measure and interpretation by the public. Public reporting of these measures will provide insightful information to healthcare providers and the public on the number of hospitals and facilities currently participating in health equity strategic planning, collecting data, using these data to identify equity gaps, establishing key performance indicators, and reviewing indicators with hospital and facility senior leaders. We intend to provide educational materials as part of our outreach and public reporting of this measure to ensure understanding and interpretation of publicly reported data.

Regarding commenter request for partial credit, the five domains of this measure are actionable focus areas, and assessment of hospital and facility leadership commitment to them is foundational. As stated in the CY 2025 OPPS/ASC proposed rule, the five domains of this measure were adapted from the CMS Office of Minority Health's Building an Organizational Response to Health Disparities framework, which focuses on data collection, data analysis, culture of equity, and quality improvement, and we encourage its use for data analysis to further understand the factors we have highlighted (89 FR 59439). All elements within each domain are necessary for a hospital or facility to indicate that they are committed to advancing health equity for their patients. Each domain represents a core principle in a hospital or facility's commitment to health equity. Achieving credit for each overarching domain, as this data will be publicly displayed by overall score and by domain, rather than by element, should be an incentive for each hospital or facility to work towards and can be used to track a facility or hospital's progress within a particular focus area from year to year. We recognize that hospitals, REHs, and ASCs may be unable to positively attest to every element and domain in this measure as reporting begins. With time, we anticipate hospitals and facilities will be able to positively attest to more domains as they continue to establish their compliance with each element within each domain. This measure will incentivize providers to collect and utilize data to identify critical equity gaps, implement plans to address said gaps, and ensure that resources are dedicated toward addressing healthcare equity initiatives. We encourage providers to analyze their own data to understand the many factors that may influence health outcomes, including various drivers of health, such as housing stability and food security, to deliver more equitable care in their communities and in turn improve patient outcomes for all patients.

Additionally, we note that hospitals and facilities will receive credit for the reporting of their measure results regardless of their responses to the attestation questions. The Hospital OQR Program and the ASCQR Programs are pay-for-reporting programs, and hospitals and ASCs are not scored based on their performance on measures. The REHQR Program does not include a financial incentive or penalty for REHs.

The following comment and response section is applicable to only the HCHE measure for the Hospital OQR and REHQR Programs.

Comment: Several commenters that did not support adoption of the HCHE measure in the Hospital OQR and REHQR Programs expressed concern that the measure has not been endorsed by a consensus-based entity (CBE) and that it has not been reviewed or validated specifically for the outpatient rural emergency setting.

Response: While we recognize the value of measures undergoing review for potential CBE endorsement, measures of health equity are a priority for CMS, and

[303] CMS Framework for Health Equity 2022–2032. (n.d.). *https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf.*

it is important to implement this measure as soon as possible.

For the Hospital OQR Program, we note that section 1833(t)(17) of the Act does not require that each measure we adopt is CBE-endorsed, but states that the Hospital OQR Program, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities. We reviewed measures endorsed by consensus organizations and were unable to identify any other measures on this topic endorsed by a consensus organization, so the inclusion of such a measure is not feasible or practicable. Section 1833(t)(17)(C)(i) also requires measures included in the Hospital OQR Program to reflect consensus among affected parties. As we have stated in previous rulemaking (75 FR 72064), consensus among affected parties can be reflected in ways other than CBE endorsement, including through the measure development process, through broad acceptance and use of the measure(s), and through public comment. As stated previously, the HCHE measure was developed based on the consensus of a TEP whose recommendations informed the initial selection, development, and emphasis of the importance of this measure and subsequently the FCHE measure.[304] Additionally, these measures have been adopted through rulemaking with public comment periods in other care settings, including inpatient hospitals, PPS-Exempt cancer hospitals, and dialysis facilities, which demonstrate broad applicability and acceptability of the measure concept and specifications for different healthcare facility types, including in HOPDs, REHs, and ASCs.

For the REHQR Program, we note that under section 1861(kkk)(7)(C)(ii) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed measures endorsed by consensus organizations and were unable to identify any other measures on this topic endorsed by a consensus organization, and therefore, the exception in section 1861(kkk)(7)(C)(ii) of the Act applies.

Comment: Several commenters expressed concerns regarding duplicative reporting of attestations for the HCHE measure in the Hospital OQR Program, noting that this measure has already been adopted into the Hospital IQR Program. These commenters requested the ability to submit one single submission jointly for both programs.

Response: We appreciate commenter input on mechanisms to reduce burden and reporting duplication and will incorporate this input into future rulemaking. We acknowledge that the HCHE measure has been adopted into the Hospital IQR Program, and the importance of prioritizing resources and streamlining hospital-wide system processes to promote administrative efficiency. However, because hospital inpatient departments and hospital outpatient departments treat different patient populations and employ different staff, we are requiring that hospitals participating in both the Hospital IQR and Hospital OQR Program submit their HCHE measure data separately. We will monitor implementation of the HCHE measure and will address any modifications in future rulemaking.

Comment: Another commenter stated that many of the priorities included in this measure are currently addressed by hospitals and health systems and urged CMS to catalogue what hospitals are already doing before establishing new measures or requirements to reduce burden and redundancy. A commenter recommended conducting an environmental scan, listening sessions, focus groups, and a technical expert panel (TEP) to reduce instances of redundant measures.

Response: We would like to clarify to commenters that we review environmental scans, which include a review of current hospital and health system activities, and frequently consult with stakeholders before adopting measures. We refer readers to section XIV.B.1.c of this final rule with comment period for a discussion of PRMR process, which holds the purpose of providing multi-stakeholder input to the Secretary on the selection of quality and efficiency measures under consideration for use in quality reporting programs. We will continue to adhere to these practices and will continue to evaluate current practices to reduce redundancy.

Comment: A commenter cited a concern that it will be difficult to implement a performance improvement project that can provide meaningful change as described in Domain 1, given the patient's limited contact with an outpatient department.

Response: We acknowledge the commenters' concerns. We recognize that hospitals are responsible for ensuring the best outcomes possible for the patients that they serve, even within short patient interactions. Ensuring the best possible outcomes requires treating the whole patient, which includes identifying potential barriers to optimal health, and helping patients identify resources to address those barriers. We encourage hospitals to refer vulnerable patients to appropriate resources.

Comment: A commenter recommended the inclusion of a patient experience measure(s) as a means of ensuring quality of care and equitable care in the REHQR program. Additionally, specifically related to the Hospital OQR Program, a commenter recommended that CMS build upon these equity measures with additional equitable care practices such as the Health Equity Report Card (HERC), a useful tool for hospitals seeking to meet the requirements of the HCHE measure, to provide best practice recommendations and ensure accountability for health systems.

Response: We thank these commenters for their recommendations and will consider this input in future rulemaking.

The following comment and response section is applicable to only the FCHE measure for the ASCQR Program.

Comment: Several commenters that did not support adoption of the FCHE measure expressed concern about the lack of testing of the FCHE measure in the ASC setting, and their belief that this measure will not be feasible to implement in ASCs due to differences between ASCs and inpatient hospitals. These commenters suggested that this measure not be adopted until it has been tested for validity and reliability in the ASC setting. A commenter stated that the technical expert panel (TEP) which informed the selection and development of the measure did not include any ASC representatives. The commenter further stated that the TEP only reviewed the hospital version of the measure. The commenter mentioned that there is a difference in ASCs' operational infrastructure compared to hospitals, stating that ASCs do not have the same data collection and analysis capabilities, nor the same technological tools as hospitals. The commenter further added that ASCs do not have immediate access to subject matter experts in culturally sensitive collection of demographic or social determinant of health information and do not have the same resources to properly outsource patients to local and national resources. Commenters stated their concerns about ASCs' lack of long-term relationships with patients, inability to follow-up on interventions,

[304] Centers for Medicare & Medicaid Services. (February 2022). Summary of Technical Expert Panel (TEP) Meeting # 1 November 16, 2021: Health Equity Quality Measurement Hospital Commitment to Health Equity Measure. Available at: *https://mmshub.cms.gov/sites/default/files/HealthEquityQualityMeasurementTEP1SumReport.pdf*.

and limited staff. These commenters added that ASCs do not have the same extensive leadership organization as hospitals, which they believe will make implementation of this measure difficult for ASCs.

Response: We acknowledge that this measure was initially developed for the general acute care setting. We understand commenter concern regarding a lack of input from ASC representatives within the TEP. The inclusion of the FCHE measures in other care settings, including inpatient psychiatric facilities, PPS-Exempt cancer hospitals, and dialysis facilities, demonstrates the broad applicability of the measure concept and specifications for different healthcare facility types, including ASCs. Healthcare facilities of every type can benefit from this measure, as it serves to incentivize facilities to collect and utilize data across the five domains to identify critical equity gaps, implement plans to address these gaps, and ensure that resources are dedicated toward addressing health equity initiatives, therefore resulting in actionable initiatives and change. This measure aims to support healthcare facilities in leveraging available data, pursuing focused quality improvement activities, and promoting efficient and effective use of resources, which applies to all settings of care.

Strong and consistent facility leadership can be instrumental in establishing specific, measurable, and attainable goals to advance equity priorities and improve care for all patients in any care setting, including patients who receive care in ASC facilities. Leaders of health services organizations across the healthcare system, including both ASCs and acute care hospitals, are likely to encounter the same challenges and use the same types of strategies to achieve organizational goals related to improving health equity within their respective organizations and patient populations.

Relating to commenter concerns regarding the difference in ASC resources, the FCHE measure accounts for differences in EHR technology in ASCs as compared to hospital settings, as we are not requiring the use of CEHRT. Additionally, if all ASCs have similar issues with attesting ''yes'' to specific elements within a domain, that will be reflected in public reporting.

Leadership commitment to health equity in all healthcare facilities, including ASCs, is important to addressing health disparities. We will monitor measure implementation and data reporting as part of standard program and measure review and will consider updates to the measure if improvements are identified through this process. We have provided an Attestation Guidance document and a FAQ document, which clearly define what constitutes an affirmative attestation and provide answers to frequently asked questions, for the HCHE measure in Hospital IQR Program.[305] [306] We intend to provide specific guidance for the ASCQR Program, consistent with the specifications described in Table 160 and requirements being finalized in this section of the final rule, in the future. Facilities may also refer to the measure specifications for additional attestation guidance.[307]

Comment: A few commenters that did not support adoption of the FCHE measure stated that this measure is not actionable as it is not linked to clinical outcomes and there is not sufficient evidence proving that this measure will impact quality of care. A commenter stated that evidence of health equity gaps in ASCs has not been clearly conveyed as previous analyses performed on ASCQR program's claims-based measures did not show racial or socioeconomic disparities.

Response: We thank commenters for their concerns. ASCs are responsible for ensuring the best outcomes possible for the patients that they serve, including identifying potential barriers to optimal health, and helping patients identify resources to address those barriers. This measure is an important foundational measure for improving health equity among those that have been disadvantaged or underserved by the healthcare system.

As discussed in section XIV.B of CY 2025 OPPS/ASC proposed rule, there is substantial research showing differences in care and experiences among these populations (89 FR 59437 and 59438). Regarding the commenter's concern about the lack of evidence of equity gaps among ASCs, research indicate disparities in access to ASCs and a need for more data collection to ensure patient appropriateness and to be able to track quality outcomes.[308] [309] The FCHE measure ensures facilities are collecting and evaluating patient data in light of demographic considerations and challenges, which is the first step in identifying equity gaps at the facility level, justifying its use in the ASC setting.

Adoption of the FCHE measure will incentivize ASCs to collect and utilize data across the five domains to identify critical equity gaps, implement plans to address these gaps, and ensure that resources are dedicated toward addressing health equity initiatives, therefore resulting in actionable initiatives and change. This measure aims to support ASCs in leveraging available data, pursuing focused quality improvement activities, and promoting efficient and effective use of resources. A commitment to health equity by facility leadership can foster organizational competencies aimed at achieving health equity for the facility's patients. Although the FCHE measure is not a clinical measure, the measure aims to improve facility awareness of the tie between its structural practices and its patient outcomes, which could lead to improved clinical outcomes for patients.

Comment: A few commenters that did not support adoption of the FCHE measure raised concern that this measure is not CBE endorsed.

Response: While we recognize the value of measures undergoing review for potential CBE endorsement, measures of health equity are a CMS priority. We reviewed measures endorsed by consensus organizations and were unable to identify any other measures on this topic endorsed by a consensus organization, so the inclusion of such a measure is not feasible or practicable. For the ASCQR Program, under section 1833(i)(7)(B) of the Act, the requirement that measures be endorsed at section 1833(t)(17)(C) of the Act applies to the ASCQR Program except as the Secretary may otherwise provide. We note that section 1833(t)(17) of the Act does not require that each measure we adopt for the program is CBE-endorsed (76 FR 74494). Section 1833(t)(17)(C)(i) states that the ASCQR Program, to the extent feasible and practicable, shall include measures set forth by one or more

[305] Centers for Medicare & Medicaid Services (January 2024). Attestation Guidance for the Hospital Commitment to Health Equity Measure (v 1.2). Available at: *https://qualitynet.cms.gov/files/659c609eca7fd3001b35edab?filename=AttstGdnceHCHEMeas_v1.2.pdf*.

[306] Centers for Medicare & Medicaid Services (January 2024). Frequently Asked Questions Hospital Commitment to Health Equity, HIQR. Available at: *https://qualitynet.cms.gov/files/659c60afd4b704001df0af51?filename=FAQ_HCHE_HIQR.pdf*.

[307] Measure specifications are posted at: *https://qualitynet.cms.gov/asc/ascqr/proposedmeasures2#tab2* for the ASCQR Program and may be moved to other pages on QualityNet upon publication of the final rule.

[308] Witiw, C. D., Wilson, J. R., Fehlings, M. G., & Traynelis, V. C. (2020). Ambulatory Surgical Centers: Improving quality of operative spine care? *Global Spine Journal, 10*(1_suppl). *https://doi.org/10.1177/2192568219849391*.

[309] Chatterjee, A., Amen, T. B., & Khormaee, S. (2022b). Trends in geographic disparities in access to ambulatory surgery centers in New York, 2010 to 2018. JAMA Health Forum, 3(10). *https://doi.org/10.1001/jamahealthforum.2022.3608*.

national consensus building entities. Section 1833(t)(17)(C)(i) also requires measures included in the ASCQR Program to reflect consensus among affected parties. As we have stated in previous rulemaking (76 FR 74494), consensus among affected parties can be reflected in ways other than CBE endorsement, including through the measure development process, through broad acceptance and use of the measure(s), and through public comment. The FCHE measure achieved the aim of seeking consensus among affected parties by garnering stakeholder input during measure development. We refer readers to section XIV.B.1.c of this final rule with comment period for a discussion of PRMR process, which holds the purpose of providing multi-stakeholder input to the Secretary on the selection of quality and efficiency measures under consideration for use in quality reporting programs.

Comment: Several commenters that did not support adoption of the FCHE measure raised concern that many ASCs do not have an EHR, and therefore, would not be able to attest 'yes' to Domain 2. The commenters stated that EHRs are costly to implement and maintain. A commenter stated that a more realistic estimate of ASCs owning and operating an EHR is around 20 percent. The commenter further stated that ASCs do not have the technology or personnel to develop patient-level data, stratify this data, identify equity gaps, and produce performance dashboards. The commenter stated that most ASCs do not have the technological tools and data analysis skills needed to ''identify priority populations who experience health disparities'' within the communities they serve.

Response: We acknowledge that some ASCs may face challenges adopting EHR technology. We reiterate that the ASCQR Program is a pay-for-reporting program, not a pay-for-performance program. ASCs that do not have EHR technology can attest that they satisfy the other domains, as applicable, and receive a score of 0–4 out of 5 without any financial penalties. We understand the commenters' concern that the public may misinterpret ASCs' reported results as a lack of commitment to health equity. To reduce the likelihood of misinterpretation, we intend to provide educational materials as part of our outreach and public reporting of this measure to ensure understanding and appropriate interpretation of publicly reported data.

We encourage ASCs to allocate resources towards EHR adoption if they are able. Adoption of EHR technology within ASCs will lead to more positive outcomes, as EHR usage has been shown to have positive impacts on care quality, coordination, efficiency, patient care safety, documentation accuracy, and cost reduction.[310] Although initial EHR adoption has associated costs, it is expected that, over time, ASCs will experience a decrease in financial and operational burden. By purchasing an EHR, an ASC will save costs previously spent on maintaining and managing patient charts.[311] EHRs additionally decrease duplicative testing and interventions. Furthermore, EHRs ensure all required patient information is included in the operative note, leading to accurate reimbursements.[312] We continue to encourage ASCs to consider EHR adoption to streamline documentation of patient health information, including demographic characteristics and social determinants of health, which will support ASCs in collecting and utilizing data to identify critical equity gaps, implementing plans to address these gaps, and ensuring that resources are dedicated toward addressing health equity initiatives.

Comment: A few commenters recommended the development of a new health equity measure or the adaptation of the FCHE measure to be better suited to address the differences between ASCs and hospitals. A commenter advocated for a measure to be developed which assesses whether an ASC's quality program addresses equitable care and outcomes for the surgical services provided at the ASC.

A commenter stated that the measure must be adapted for small facilities to prevent biased scores that favor large facilities with greater resources. The commenter recommended that CMS assess current capabilities of the ASC industry through an environmental scan before additional rulemaking action around this measure. The commenter stated that the results of the scan could inform a restructuring of the measure and allow for a reasonable time frame for implementation. The commenter recommended delaying this measure's implementation by 5 years if an environmental scan is not conducted.

Response: We appreciate commenter recommendations surrounding the development of new equity measures tailored to ASC specific needs. We reiterate our awareness that this measure was initially developed for the general acute care setting. Our environmental assessments indicate that there are currently no other existing measures that address facility commitment to health equity. Therefore, it is important to implement this measure as soon as feasible. We would like to remind commenters that this measure addition serves as a foundation for a suite of future equity-focused measures. We see inclusion of such measures in the ASCQR Program as informing efforts to advance and achieve health equity among ASCs by allowing for the recognition and tracking of disparities for the population they serve. Our approach to developing equity-focused measures is incremental and will evolve over time to capture healthcare equity outcomes, as well as align as closely as possible with the measure's respective healthcare setting.

We understand commenter concern regarding the compatibility of the FCHE measure with small ASCs. We would like to note that the FCHE measure is not meant to compare facilities with one another, but rather for facilities to identify structural gaps within their strategic planning, data collection and analysis, quality improvement, and leadership engagement. We remind facilities that the ASCQR Program is a pay-for-reporting program, not a pay-for-performance program. Upon reporting this attestation-based measure, ASCs that do not meet all domain criteria will not be financially penalized.

We appreciate the commenter recommendation to use environmental scans to inform measure development. We include evidence extracted from environmental scans to inform our measure development and will continue to incorporate this critical step in our quality measure development processes for future measures.

Comment: Commenters raised concerns that the rule does not explain how or if CMS will provide financial or administrative support to implement these measures. A commenter recommended that reimbursements should be provided for time spent implementing this measure. A commenter further recommended that CMS engage with hospitals and facilities to better understand the reporting burden of quality measures before their finalization. A few commenters raised concern that ASCs have a lower reimbursement rate than hospitals, making this measure more difficult to implement.

Response: We have provided an Attestation Guidance document and an FAQ document, which clearly define what constitutes an affirmative attestation and provide answers to frequently asked questions, for the HCHE measure in Hospital IQR

[310] Geier, A., & Smith, D. (2019). The role of electronic documentation in Ambulatory Surgery Centers. AORN Journal, 109(4), 444–450. *https://doi.org/10.1002/aorn.12636.*

[311] Ibid.

[312] Ibid.

Program.[313] [314] We intend to provide specific guidance for the ASCQR Program, consistent with the specifications described in Table 160 and requirements being finalized in this section of the final rule, in the future. ASCs may also refer to the measure specifications for additional attestation guidance.[315]

We reiterate that the ASCQR program is statutorily limited to reduce the ASC fee schedule increase factor by 2-percentage points in the event the ASC fails to meet program requirements as established by the Secretary (section 1833(i)(7) of the Act). The ASCQR program statute does not provide authority for CMS to provide financial incentives. Regarding commenters' concern that ASCs have a lower reimbursement rate than hospitals, we reiterate that this is an attestation-based measure of a facility's commitment to addressing health equity. Additionally, medical procedures can cost up to 58 percent more when performed in an HOPD, rather than an ASC, justifying the disparity in Medicare reimbursement rates.[316] We disagree that this attestation measure would be more difficult to implement due to differing reimbursement rates.

Comment: A commenter that did not support adoption of the FCHE measure expressed concern that, when this measure was reviewed during the 2021–2022 Measures Application Partnership (MAP) process for the Hospital IQR Program, the measure received a ''do not support'' recommendation, as the group believed there was insufficient evidence proving that this measure will influence patient outcomes.

Response: We understand the commenter's concern. We note that during the more recent 2023 MAP process as previously discussed, 78.95 percent of committee voters recommended the FCHE measure for inclusion in the ASCQR Program without conditions.[317] The committee expressed support for a measure that captures commitment to health equity consistently across settings.

Comment: Several commenters that did not support adoption of the FCHE measure expressed concern over reporting burden, as this timeline coincides with OAS CAHPS and THA/TKA PRO–PM measure compliance. A few commenters expressed that there would not be sufficient time to implement processes, technology, and training needed to successfully report this measure.

A commenter recommended that CMS weigh the burden of a finalized measure with the value it provides. A few commenters suggested delaying the implementation of this measure or allowing for voluntary reporting.

Response: We acknowledge commenters' concerns regarding resources, including increased data collection burden; however, achieving health equity is an issue which deserves serious focus and rapid action for improvement. Therefore, we do not find it appropriate to delay the implementation of this measure. The benefits of encouraging ASC commitment to health equity outweigh the burden of attestation under this measure.

We understand commenter concerns related to timing of mandatory reporting of the FCHE measure. We emphasize that this measure was proposed for adoption beginning with the CY 2025 reporting period/CY 2027 payment or program determination, which will allow ASCs more than a year before the submission deadline of May 15, 2026, at which time ASCs would submit attestations regarding the identified domains during the CY 2025 reporting period. ASCs can spend the remainder of CY 2024 and CY 2025 establishing processes and addressing potential barriers to positive attestations for the FCHE measure before December 31, 2025, enabling the possibility to report ''yes'' on each domain by the end of CY 2025.

We note that hospitals participating in the Hospital IQR Program will have already reported data on the similar Hospital Commitment to Health Equity measure for the FY 2025 payment determination (that is, data submitted in FY 2024 representing the FY 2023 performance period) (87 FR 49191 through 49201) before required reporting of the Facility Commitment to Health Equity measure begins within the ASCQR Program, as reporting for this measure would begin with the CY 2027 payment determination. Given the timing of this similar measure's implementation in the Hospital IQR Program, ASCs will have had the opportunity to learn from the experiences of acute care hospitals, including best practices for minimally burdensome assessment of performance on the required domains.

We will also monitor measure implementation and data reporting as part of standard program and measure review and will consider updates to the measure if we identify implementation strategies to reduce burden.

Comment: A few commenters that did not support adoption of the FCHE measure expressed concern about potential unintended consequences that may result from the adoption of this measure, including a reduction in patient safety investments due to funding being instead allocated towards FCHE measure reporting.

Response: We appreciate the commenter's concern and will monitor this measure, as we do all ASCQR measures, for any unintended or adverse outcomes associated with implementation. The ability of medical providers to contextualize a facility's commitment to health equity through the five attestation domains is important and could strengthen referrals to and partnerships with community-based service providers for patients with the most complex needs.

Comment: A commenter recommended that ASCs should be able to rely on the inpatient HCHE measure to meet the ASCQR FCHE reporting requirement in cases where hospital-based ASCs have the same leadership and board members as the inpatient hospital.

Response: We appreciate commenter concerns regarding duplicative reporting. We would like to note that a sizeable portion of ASCs are specialized facilities and may have different health equity goals than hospitals.[318] Therefore, it is important that the FCHE measure is reported independently from the HCHE measure.

[313] Centers for Medicare & Medicaid Services (January 2024). Attestation Guidance for the Hospital Commitment to Health Equity Measure (v 1.2). Available at: *https://qualitynet.cms.gov/files/659c609eca7fd3001b35edab?filename=AttstGdnceHCHEMeas_v1.2.pdf.*

[314] Centers for Medicare & Medicaid Services (January 2024). Frequently Asked Questions Hospital Commitment to Health Equity, HIQR. Available at: *https://qualitynet.cms.gov/files/659c60afd4b704001df0af51?filename=FAQ_HCHE_HIQR.pdf.*

[315] Measure specifications are posted at *https://qualitynet.cms.gov/outpatient/oqr/proposedmeasures2#tab2* for the Hospital OQR and REHQR Programs, and *https://qualitynet.cms.gov/asc/ascqr/proposedmeasures2#tab2* for the ASCQR Program and may be moved to other pages on QualityNet upon publication of the final rule.

[316] Newitt, P. (n.d.). HOPDs vs. ASCS: 10 considerations for 2024. Becker's ASC Review. *https://www.beckersasc.com/asc-coding-billing-and-collections/hopds-vs-ascs-10-considerations-for-2024.html.*

[317] PRMR final MUC recommendation spreadsheet. PRMR Final MUC Recommendation Spreadsheet | Partnership for Quality Measurement. (n.d.). *https://p4qm.org/prmr-final-muc-reco.*

[318] ASCA. (September 2024). What is an ASC? Ambulatory Surgery Center Association (ASCA). Available at: *https://www.ascassociation.org/asca/about-ascs/surgery-centers#:~:text=Ambulatory%20surgery%20centers%2C%20or%20ASCs,including%20diagnostic%20and%20preventive%20procedures.*

After consideration of the public comments we received, we are finalizing adoption of the HCHE measure for the Hospital OQR Program and the REHQR Program as proposed. Additionally, we are finalizing the FCHE measure for the ASCQR Program, as proposed.

2. Adoption of the Screening for Social Drivers of Health (SDOH) Measure for the Hospital Outpatient Quality Reporting (OQR), Rural Emergency Hospital Quality Reporting (REHQR), and Ambulatory Surgical Center Quality Reporting (ASCQR) Programs Beginning with Voluntary Reporting for the CY 2025 Reporting Period Followed by Mandatory Reporting for the CY 2026 Reporting Period/CY 2028 Payment or Program Determination

a. Background

SDOH is an umbrella term that refers to community-level factors that impact health and well-being, while HRSNs are social and economic needs that individuals experience that affect their ability to maintain their health and well-being.[319] Consistent screening of patients for potential HRSNs helps healthcare facilities identify individuals who have historically been underserved by the healthcare system and could support ongoing quality improvement initiatives at the population level by providing data to stratify patient risk and organizational performance to address SDOH.[320] [321] While widespread interest exists in addressing SDOH at community, State, and national levels and in supporting HRSNs for patients who experience one or more HRSNs, action is inconsistent, with 92 percent of hospitals screening for one or more of the five HRSNs listed in Table 161 but only 24 percent of hospitals screening for all five of these HRSNs.[322] Additionally, pilot studies screening for HRSNs have been conducted in the HOPD and ASC settings, with clinicians and staff agreeing that HRSN data are important and relevant to collect in these settings to improve patient care and communication as well as to connect patients with social-related services.[323] [324] We believe that it is essential for healthcare facilities to screen for patient-level HRSN data to support the improvement of patient outcomes and their identified social needs.

In 2017, the CMS Center for Medicare and Medicaid Innovation (CMMI) launched the Accountable Health Communities (AHC) Model, which tested whether systematically identifying and addressing the HRSNs of Medicare and Medicaid beneficiaries through screening, referral, and community navigation services impacted their health outcomes and related healthcare utilization and costs.[325] [326] Evaluation of the AHC Model's standard 10-item AHC Health-Related Social Needs Screening Tool (AHC HRSN Screening Tool) found a reduction in emergency department (ED) visits among Medicaid and Medicare fee-for-service (FFS) beneficiaries.[327]

Under the AHC Model, the following five core domains were selected to screen for HRSNs among Medicare and Medicaid beneficiaries: (1) food insecurity; (2) housing instability; (3) transportation needs; (4) utility difficulties; and (5) interpersonal safety. These domains were chosen based upon literature review and expert consensus utilizing the following criteria: (1) availability of high-quality scientific evidence linking a given HRSN to adverse health outcomes and increased healthcare utilization, including hospitalizations and associated costs; (2) ability for a given HRSN to be screened and identified prior to discharge, be addressed by community-based services, and potentially improve healthcare outcomes, including reduced readmissions; and (3) evidence that a given HRSN is not systematically addressed by healthcare providers.[328] In addition to established evidence of their association with health status, risk, and outcomes, these five domains were selected for the AHC Model because they can be assessed across the broadest spectrum of individuals in a variety of settings.[329]

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[319] Assistant Secretary for Planning and Evaluation. (November 2023). Call to Action: Addressing Health-Related Social Needs in Communities Across the Nation. Available at: *https://aspe.hhs.gov/sites/default/files/documents/3e2f6140d0087435cc6832bf8cf32618/hhs-call-to-action-health-related-social-needs.pdf.*

[320] Assistant Secretary for Planning and Evaluation. (September 2022). Reflections Accompanying a Report on Addressing Social Drivers of Health: Evaluating Area-level Indices. Available at: *https://aspe.hhs.gov/sites/default/files/documents/474a62378abf941f20b3eaa74ca5721c/Area-level-Indices-ASPE-Reflections.pdf.*

[321] American Hospital Association. (December 2020). Health Equity, Diversity & Inclusion Measures for Hospitals and Health System Dashboards. Available at: *https://ifdhe.aha.org/system/files/media/file/2020/12/ifdhe_inclusion_dashboard.pdf.*

[322] Fraze TK, Brewster AL, Lewis VA, Beidler LB, Murray GF, Colla, CH. (2019). Prevalence of Screening for Food Insecurity, Housing Instability, Utility Needs, Transportation Needs, and Interpersonal Violence by US Physician Practices and Hospitals. *JAMA Network Open,* 2(9), e1911514. *https://doi.org/10.1001/jamanetworkopen.2019.11514.*

[323] Berkowitz RL, Bui L, Shen Z, Pressman A, Moreno M, Brown S, Nilon, A Miller-Rosales, Azar KM. (2021). Evaluation of a social determinants of health screening questionnaire and workflow pilot within an adult ambulatory clinic. *BMC Family Practice,* 22(1), 256. *https://doi.org/10.1186/s12875-021-01598-3.*

[324] Schickedanz A, Hamity C, Rogers A, Sharp AL, Jackson A. (2019). Clinician Experiences and Attitudes Regarding Screening for Social Determinants of Health in a Large Integrated Health System. *Medical Care,* 57, S197–S201. *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6721844/.*

[325] Centers for Medicare & Medicaid Services. (2021). A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. Available at: *https://innovation.cms.gov/media/document/ahcm-screeningtool-companion.*

[326] Centers for Medicare & Medicaid Services. (2021). Accountable Health Communities Model. Accountable Health Communities Model. Available at: *https://www.cms.gov/priorities/innovation/innovation-models/ahcm.*

[327] Centers for Medicare & Medicaid Services. (2023). Accountable Health Communities (AHC) Model Evaluation: Second Evaluation Report. CMS Innovation Center. Available at: *https://www.cms.gov/priorities/innovation/data-and-reports/2023/ahc-second-eval-rpt.*

[328] Billioux A, Verlander, K, Anthony S, Alley D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. *NAM Perspectives,* 7(5). *https://doi.org/10.31478/201705b.*

[329] Centers for Medicare & Medicaid Services. (2021). Accountable Health Communities Model. Accountable Health Communities Model. Available at: *https://innovation.cms.gov/innovation-models/ahcm.*

TABLE 161: THE FIVE CORE HRSN DOMAINS SCREENED UNDER THE AHC MODEL

Domain	Description
Food Insecurity	Food insecurity is defined as limited or uncertain access to adequate quality and quantity of food at the household level. It is associated with diminished mental and physical health and increased risk for chronic conditions.[330] Individuals experiencing food insecurity often have inadequate access to healthier food options which can impede self-management of chronic diseases like diabetes and heart disease, and require individuals to make personal trade-offs between food purchases and medical needs, including prescription medication refills and preventive health services.[331,332] Food insecurity is associated with high-cost healthcare utilization including emergency department (ED) visits and outpatient visits.[333,334]
Housing Instability	Housing instability encompasses multiple conditions ranging from inability to pay rent or mortgage, frequent changes in residence including temporary stays with friends and relatives, living in crowded conditions, and actual lack of sheltered housing in which an individual does not have a personal residence.[335] Population surveys consistently show that people from some racial and ethnic minority groups constitute the largest proportion of the U.S. population experiencing housing instability.[336] Housing instability is associated with higher rates of chronic illnesses, injuries, and complications and more frequent utilization of high-cost healthcare services.[337]
Transportation Needs	Unmet transportation needs include limitations that impede transportation to destinations required for all aspects of daily living.[338] Groups disproportionately affected include older adults (aged >65 years), people with lower incomes, people with impaired mobility, residents of rural areas, and people from some racial and ethnic minority groups. Transportation needs contribute to postponement of routine medical care and preventive services which ultimately lead to chronic illness exacerbation and more frequent utilization of high-cost healthcare services.[339,340] Patients with serious mental
	illness often lack access to transportation with many Medicaid eligible patients relying on Medicaid's non-emergency medical transportation (NEMT) to access needed healthcare, though this does not provide access to transportation to other aspects of daily living.[341]
Utility Difficulties	Inconsistent availability of electricity, water, oil, and gas services is directly associated with housing instability and food insecurity.[342] Specifically, interventions that increase or maintain access to such services have been associated with individual and population-level health improvements.[343]
Interpersonal Safety	Interpersonal safety affects individuals across the lifespan, from birth to old age, and is directly linked to mental and physical health. Assessment for this domain includes screening for exposure to intimate partner violence, child abuse, and elder abuse.[344] Exposure to violence and social isolation are reflective of individual-level social relations and living conditions that are directly associated with injury, psychological distress, and death in all age groups.[345]

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[330] Berkowitz SA, Seligman HK, Meigs JB, Basu S. (2018). Food Insecurity, Healthcare Utilization, and High Cost: A Longitudinal Cohort Study. *The American Journal of Managed Care,* 24(9), 399–404. *http://www.ncbi.nlm.nih.gov/pmc/articles/pmc6426124/.*

[331] Seligman HK, Berkowitz, SA. (2019). Aligning Programs and Policies to Support Food Security and Public Health Goals in the United States. *Annual Review of Public Health,* 40(1), 319–337. *https://www.annualreviews.org/doi/10.1146/annurev-publhealth-040218-044132.*

[332] National Academies of Sciences, Engineering, and Medicine. (2006). Executive Summary: Cost-Benefit Analysis of Providing Non-Emergency Medical Transportation. Washington, DC: The National Academies Press. Available at: *https://nap.nationalacademies.org/catalog/23285/executive-summary-cost-benefit-analysis-of-providing-non-emergency-medical-transportation.*

[333] Berkowitz SA, Seligman HK, Meigs JB, Basu S. (2018). Food Insecurity, Healthcare Utilization, and High Cost: A Longitudinal Cohort Study. *The American Journal of Managed Care,* 24(9), 399–404. *http://www.ncbi.nlm.nih.gov/pmc/articles/pmc6426124/.*

[334] Dean EB, French MT, Mortensen, K. (2020). Food insecurity, health care utilization, and health care expenditures. *Health Services Research,* 55(S2), 883–893. Available at: *https://doi.org/10.1111/1475-6773.13283.*

[335] Hill-Briggs, F. (2020). Social Determinants of Health and Diabetes: A Scientific Review. *Diabetes Care,* 44(1), 258–279. *https://pubmed.ncbi.nlm.nih.gov/33139407/.*

[336] Henry M, de Sousa T, Roddey C, Gayen S, Bednar T, Abt Associates. (January 2021). The 2020 Annual Homeless Assessment Report (AHAR) to Congress; Part 1: Point-in-Time Estimates of Homelessness. U.S. Department of Housing and Urban Development. Available at: *https://www.huduser.gov/portal/sites/default/files/pdf/2020-AHAR-Part-1.pdf.*

[337] Baxter A, Tweed E, Katikireddi S, Thomson H. (2019). Effects of Housing First approaches on health and well-being of adults who are homeless or at risk of homelessness: systematic review and meta-analysis of randomized controlled trials. *Journal of Epidemiology and Community Health,* 73; 379–387. *https://doi.org/10.1136/jech-2018-210981.*

[338] Centers for Medicare and Medicaid Services. (2023) Addressing Transportation Barriers: A User Case in Leveraging the Value-Based Insurance Design (VBID) Model. Available at: *https://www.cms.gov/priorities/innovation/innovation-models/vbid.*

[339] Billioux A, Verlander, K, Anthony S, Alley D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. *NAM Perspectives,* 7(5). *https://doi.org/10.31478/201705b.*

[340] Shier G, Ginsburg M, Howell J, Volland P, Golden R. (2013). Strong Social Support Services, Such as Transportation And Help For Caregivers,

These five evidence-based HRSN domains described in Table 161 informed our development of the Screening for SDOH and Screen Positive Rate for SDOH measures. We used these five HRSN domains to inform the development of the SDOH measure we proposed to adopt in this final rule because the AHC Model's HRSN Screening Tool allows healthcare facilities to quickly screen for patients' core health-related social needs and was designed to work in a variety of clinical settings, making it ideal for implementing across quality reporting programs, including the Hospital OQR, REHQR, and ASCQR Programs, with minimal burden to healthcare facilities.[346]

We recognize that patient interaction with the healthcare system may be limited by setting. For example, a patient receiving care in an HOPD, REH, or ASC may not have recently received care in an acute care hospital paid under IPPS, inpatient psychiatric facility cancer hospital, or dialysis facility, and therefore would not have the opportunity to benefit from being screened for SDOHs despite this measure's prior adoption in other quality programs. By adopting aligned Screening for SDOH measures within the Hospital OQR, REHQR, and ASCQR Programs, we expect to increase the likelihood that these settings will screen patients and provide contextualized care and any necessary relevant referrals to address their patient's needs.

Screening for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety in HOPDs, REHs, and ASCs can help identify and provide appropriate referrals for patients who may benefit from greater support in one or more of those areas. Adoption of the Screening for SDOH measure in the Hospital OQR, REHQR, and ASCQR Programs would continue to support our priority of identifying risk factors for inadequate healthcare access and adverse health outcomes among patients.

b. Measure Overview

The Screening for SDOH measure is a process measure that assesses the total number of patients, who were 18 years or older on the date of service, screened for social risk factors (specifically, the five HRSNs of food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety) as they receive care from a HOPD, REH, or ASC.

c. Pre-Rulemaking Measure Review

As part of the PRMR process, the Hospital Recommendation Group reviewed and voted on the Screening for SDOH measure during their meeting on January 18 and 19, 2024.[347] The Hospital Recommendation Group ''recommended with conditions'' the Screening for SDOH measure for all three programs (that is, the Hospital OQR, REHQR, and ASCQR Programs).

The committee recommended a condition specific to the Hospital OQR Program, which was to allow hospitals to report this measure one time each year for both the Hospital IQR Program and Hospital OQR Program if applicable.[348] We note that we considered allowing hospitals to report this measure jointly for the Hospital IQR and Hospital OQR Programs (if applicable); however, as the patient populations represented by the programs are different, as is the measure calculation due to this difference in the denominator, we proposed to require a separate data submission for each program. More importantly, patients and consumers would likely find useful Compare tool information on screening rates separated for inpatient and outpatient departments of the same hospital.

d. CBE Endorsement

Section 1833(t)(17)(C)(i) of the Act provides that the Hospital OQR Program, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities (not necessarily the CBE). Under section 1833(i)(7)(B) of the Act, this requirement at section 1833(t)(17)(C) applies to the ASCQR Program except as the Secretary may otherwise provide. For the Hospital OQR Program and ASCQR Program, we note that section 1833(t)(17) of the Act does not require that each measure we adopt for these programs be CBE-endorsed (75 FR 72064 and 72065 for the Hospital OQR Program and 76 FR 74494 for the ASCQR Program).

Section 1833(t)(17)(C)(i) of the Act also requires measures developed for the Hospital OQR Program to reflect consensus among affected parties. Under section 1833(i)(7)(B), this requirement also applies to the ASCQR Program except as the Secretary may otherwise provide. As we have stated in previous rulemaking, consensus among affected parties can be reflected in ways other than CBE endorsement, including through the measure development process, through broad acceptance and use of the measure(s), and through public comment (75 FR 72064 and 72065 for the Hospital OQR Program and 76 FR 74494 for the ASCQR Program).

For the REHQR Program, section 1861(kkk)(7)(C)(i) of the Act generally requires that quality measures specified by the Secretary for the REHQR Program be endorsed by a CBE; however, section 1861(kkk)(7)(C)(ii) of the Act provides an exception to the general CBE-endorsement requirement, stating that in the case of a specified area or medical topic determined appropriate by the Secretary for which a measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed CBE endorsed measures and were unable to identify any other CBE-endorsed measures on this topic, and therefore we believe the exception in section 1861(kkk)(7)(C)(ii) of the Act applies for purposes of this measure for the REHQR Program.

Can Lead To Lower Health Care Use And Costs. *Health Affairs,* 32(3), 544–551. *https://www.healthaffairs.org/doi/10.1377/hlthaff.2012.0170.*

[341] National Alliance on Mental Illness. Medicaid: Non-Emergency Medical Transportation (NEMT). Available at: *https://www.nami.org/Advocacy/Policy-Priorities/Supporting-Community-Inclusion-and-Non-Discrimination/Medicaid-Non-Emergency-Medical-Transportation.*

[342] Baxter A, Tweed E, Katikireddi S, Thomson H. (2019). Effects of Housing First approaches on health and well-being of adults who are homeless or at risk of homelessness: systematic review and meta-analysis of randomized controlled trials. *Journal of Epidemiology and Community Health,* 73; 379–387. *https://doi.org/10.1136/jech-2018-210981.*

[343] Wright BJ, Vartanian KB, Li HF, Royal N, Matson JK (2016). Formerly Homeless People Had Lower Overall Health Care Expenditures After Moving into Supportive Housing. *Health Affairs,* 35(1), 20–27. *https://www.healthaffairs.org/doi/10.1377/hlthaff.2015.0393.*

[344] Billioux A, Verlander K, Anthony S, Alley D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. *NAM Perspectives,* 7(5). *https://doi.org/10.31478/201705b.*

[345] Henry M, de Sousa T, Roddey C, Gayen S, Bednar T, Abt Associates. (January 2021). The 2020 Annual Homeless Assessment Report (AHAR) to Congress; Part 1: Point-in-Time Estimates of Homelessness. U.S. Department of Housing and Urban Development. Available at: *https://www.huduser.gov/portal/sites/default/files/pdf/2020-AHAR-Part-1.pdf.*

[346] Centers for Medicare & Medicaid Services. (2021). A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. Available at: *https://innovation.cms.gov/media/document/ahcm-screeningtool-companion.*

[347] The Screening for SDOH measure is identified on the MUC List as MUC2023–156.

[348] Partnership for Quality Measurement. 2023 Pre-Rulemaking Measure Review (PRMR) Meeting Summary: Hospital Committee. Available at: *https://p4qm.org/sites/default/files/2024-02/PRMR-Hospital-Recommendation-Group-Meeting-Summary-Final.pdf.*

At this time, we find no other feasible and practicable measures set forth by a national consensus building entity on the topic of screening for SDOH. While we recognize the value of measures undergoing CBE endorsement review and prefer to use endorsed measures, there are currently no CBE-endorsed measures that address screening for SDOH in the outpatient setting. Given the urgency of achieving health equity, it is important to implement this measure as soon as possible. We note that the five domains for which patients would be screened were chosen based upon literature review and expert consensus, and that these five domains informed development of the Screening for SDOH measure. We will consider submitting the Screening for SDOH measure to the CBE for endorsement in the future.

e. Data Sources

For data collection of the Screening for SDOH measure, we proposed that healthcare facilities would use a self-selected screening tool to collect these data. We proposed to allow healthcare facilities to select their screening tool to reduce burden and in recognition of the fact that some healthcare facilities may already be screening their patients for HRSNs. If a healthcare facility is not already doing so, many screening tools for HRSNs already exist. While we acknowledge the potential benefits of requiring all healthcare facilities to use the same screening instrument or a prescribed set of standards around the number or types of screening questions used, we also recognize the benefits of providing healthcare facilities with flexibility to customize screening and data collection to their patient populations and individual needs.

One example of a screening tool that healthcare facilities could consider using is the AHC HRSN Screening Tool, which providers used in the AHC Model to screen for HRSNs in their Medicare, Medicaid, and dually eligible beneficiary populations.[349] We have tested the AHC HRSN Screening Tool across many care delivery sites in diverse geographic locations and determined that it demonstrates evidence of both reliability and validity.[350] The AHC HRSN Screening Tool can be implemented in a variety of healthcare settings, including HOPDs, REHs, and ASCs. While the AHC Model focused on HRSNs among community-dwelling Medicare and Medicaid beneficiaries, the AHC HRSN Screening Tool can be used to screen patients with any insurance status or type, including commercially insured and uninsured individuals. The AHC HRSN Screening Tool has broad applicability in settings outside of the AHC Model as it screens for a range of five HRSN domains while also being concise, limited to only ten questions. We believe this promotes manageable integration into clinical workflow settings and provides greater accessibility and application to diverse patient populations.[351] [352]

For additional screening tools for healthcare facilities to consider using to collect data for this Screening for SDOH measure, we refer readers to evidence-based resources like the Social Interventions Research and Evaluation Network (SIREN) website, for example, which provides comprehensive information about the most widely used HRSN screening tools.[353] [354] SIREN contains descriptions of the content and characteristics of various tools, including information about intended populations, completion time, and number of questions.

We also encourage healthcare facilities to consider digital standardized screening tools. We refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49207 through 49208), where we discuss how the use of certified health information technology (IT), including but not limited to CEHRT,[355] can support capture of HRSN information in a standardized, interoperable fashion. We also encourage healthcare facilities to learn about the United States Core Data for Interoperability (USCDI) standard used in certified health IT and how this standard can support interoperable exchange of health and HRSN assessment data.[356]

In alignment with the Hospital IQR Program, we proposed that HOPDs, REHs, and ASCs could confirm the current status of any previously reported HRSNs in another care setting and inquire about others not previously reported, in lieu of re-screening a patient within the reporting period. In addition, if this information has been captured in the EHR in another outpatient setting or the inpatient setting during the same reporting period, we proposed that the HOPD, REH, and ASC could use that information for purposes of reporting the measure in lieu of screening the patient. We intend to monitor and evaluate the measure screening requirements, including frequency, in these outpatient settings to ensure balance between quality of care for patients and facility burden.

f. Measure Calculation

The Screening for SDOH measure is calculated as a percentage equal to the numerator over the denominator. The numerator is defined as the number of patients admitted to an HOPD, REH, or ASC, who are 18 years or older on the date of admission and are screened for all five HRSNs described in Table 161 during their receipt of services in the HOPD, REH, or ASC, as applicable.[357] The denominator is defined as the number of patients who are admitted to a HOPD, REH, or ASC, as applicable, and who are 18 years or older.

The measure excludes patients who: (1) opt-out of screening; or (2) are themselves unable to complete the screening and have no legal guardian or caregiver able to do so on the patient's behalf.

g. Data Submission and Reporting

In the CY 2025 OPPS/ASC proposed rule, we proposed to allow healthcare facilities to voluntarily submit to CMS aggregate data for this measure for the CY 2025 reporting period and then to require mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment or program determination. Specifically, we

[349] Centers for Medicare and Medicaid Services. The Accountable Health Communities Health-Related Social Needs Screening Tool. Available at: *https://www.cms.gov/priorities/innovation/files/worksheets/ahcm-screeningtool.pdf.*

[350] Centers for Medicare and Medicaid Services. (2023). A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. Available at: *https://www.cms.gov/priorities/innovation/media/document/ahcm-screeningtool-companion.*

[351] Ibid.

[352] Billioux A, Verlander, K, Anthony S, Alley D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. *NAM Perspectives,* 7(5). *https://doi.org/10.31478/201705b.*

[353] Social Interventions Research & Evaluation Network. (2019). Social Needs Screening Tool Comparison Table. Available at: *https://sirenetwork.ucsf.edu/tools-resources/resources/screening-tools-comparison.*

[354] The Social Interventions Research and Evaluation Network (SIREN) at University of California San Francisco was launched in the spring of 2016 to synthesize, disseminate, and catalyze research on SDOH and healthcare delivery.

[355] CEHRT refers to certified health IT requirements defined by CMS for certain programs which incorporate health IT certification criteria established by the Office of the National Coordinator for Health Information Technology (ONC) at 45 CFR 170.315.

[356] Office of the National Coordinator for Health IT (ONC). United States Core Data for Interoperability. Available at: *https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi.*

[357] The term ''admitted patients'' appears in the measure specifications and MUC documentation and is intended to refer to a person who receives ambulatory care in these designated settings.

proposed that healthcare facilities would aggregate data they collect for the numerator and the denominator to CMS (as described in section XIV.B.2.f of this final rule with comment period), and that they would not be required to submit patient-level data. We proposed to require aggregate data because we believe patient-level reporting is unnecessary and would cause undue burden due to the transfer of large quantities of data. However, in the future, we may consider requiring the reporting of patient-level information. This measure aims to encourage healthcare facilities to screen for and identify HRSNs in order to identify and address social needs among their patient populations.

We also proposed that healthcare facilities would be required to submit data on this measure annually using the CMS-designated information system (currently, the HQR system) consistent with the data submission requirements for this measure in the Hospital IQR, IPFQR and PCHQR Programs. We refer readers to sections XV.E.2.a, XVI.E.3.b, and XVII.E.2.a of this final rule with comment period for additional details regarding data submission using the CMS-designated information system in the Hospital OQR, REHQR, and ASC Programs, respectively.

We proposed to adopt this measure beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment or program determination. We proposed to begin with 1 year of voluntary reporting to provide a transition period for healthcare facilities to select and integrate screening tools into their clinical workflow processes.

We invited public comment on our proposal to adopt the Screening for SDOH measure for the Hospital OQR, REHQR, and ASCQR Programs beginning with voluntary reporting for the CY 2025 reporting period, and to require mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment or program determination, as described above.

The following comments and responses are applicable for the Hospital OQR, REHQR, and ASCQR Programs unless noted otherwise.

Comment: Many commenters supported the Screening for SDOH measure as well as CMS's efforts to align measures across programs and increase screening for SDOH in outpatient, rural, and ambulatory settings. Several commenters expressed support for adopting the Screening for SDOH measure in the outpatient programs because they believe the measure helps better identify patients with food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety concerns, and they appreciate CMS's commitment to improving health outcomes for all patients with higher health-related needs. A few commenters expressed support for screening for food insecurity specifically, because it can help provide appropriate referrals for patients who may benefit from additional nutrition, identify malnutrition risk across outpatient settings, facilitate access to appropriate and timely nutrition interventions, and connect patients to community-based nutrition programs and services that address ongoing needs. A commenter supported the adoption of the Screening for SDOH measure across the Hospital OQR, ASCQR, and REHQR programs because the measure provides structured support that healthcare providers need to better support patients who have SDOH needs and help providers acknowledge how SDOH impact patient outcomes. Another commenter expressed appreciation for CMS's indication that the patient screening in the outpatient setting can leverage information that the patient has already provided in a prior encounter in the performance year.

Response: We thank commenters for their support of the Screening for SDOH measure. We agree with commenters that availability of SDOH data will potentially identify innovative opportunities to support enhanced availability of community resources to meet the needs identified by the Screening for SDOH measure. We agree with the commenters' statement that this measure could support efforts to connect patients in need with community resources.

Comment: Many commenters supported the adoption of the Screening for SDOH measure but offered specific recommendations, including that CMS provide a mechanism to confirm that referrals to appropriate services resulted in actual service delivery since the actual services, not the referrals, are the goal. These commenters recommended that CMS continue to take steps towards measuring prompt action to connect patients to a community-based organization, interventions to address the HRSN, the resolution of the need, and efforts to ensure that providers are able and incentivized to connect patients with necessary clinical, mental, behavioral, and social services as seamlessly as possible.

Response: We thank the commenters for their broad support and recommendations. We will take into consideration as appropriate the recommendations to ensure that referrals of patients to various support services are addressing needs and resulting in actual services.

Comment: Many commenters supported the adoption of the Screening for SDOH measure in the Hospital OQR Program because it affirms that any patient entering the care of the hospital undergoes an HRSN screen. Several commenters expressed support for the Screening for SDOH measure specifically in the Hospital OQR program noting that robust data collection on patient demographics and SDOH enables more accurate analysis of health equity and improves the quality of care for all beneficiaries in the Medicare program, and that the addition of the health equity measures HOPDs will allow for more consistency between the outpatient and inpatient space and will aid in identifying and assisting patients who are struggling with one of the five domains. A commenter supported the measure because it will allow for 1 year of voluntary reporting to support implementation in the outpatient setting and appreciated that HOPD staff could confirm the current status of any previously reported HRSNs in another care setting and inquire about others not previously reported. The commenter also supported that CMS would allow hospitals to use SDOH screening information that is recorded in the EHR in another health setting during the same reporting period to report data on the measures. A commenter supported that CMS emphasized a limited number of universal health-related domains and strongly supported CMS allowing health systems flexibility to use their preferred screening tool. Another commenter supported the measure because collecting SDOH data allows HOPDs to refer patients to care that can address their SDOH and connect patients to community-based resources based on their needs. Additionally, a commenter supported CMS's commitment to advancing health equity and improving health outcomes because occupational therapy (OT) practitioners can address SDOH at the person, group, and population level by assessing and addressing both the social needs of the individual clients and the structural challenges that impact the ability to meet these social needs. This commenter further stated that addressing SDOH within OT interventions can improve health outcomes, increase health equity, expand occupational engagement, and contribute to wellness. A commenter appreciated the decision to allow

inpatient screenings in the same reporting period to also be considered for measuring screening rates in the outpatient setting but requested clarification on whether non-office, procedural visits such as imaging or lab services in the outpatient department would be considered ''admissions'' to an HOPD subject to screening in the measure calculation. A commenter recommended that outpatient lab tests and X-Rays be included in the proposed outpatient requirements, and that clarification be provided on qualifying outpatient hospital encounters and on the types of HOPD environments SDOH screening requirements will cover.

Response: We thank the commenters for their support of the Screening for SDOH measure in the Hospital OQR Program. We agree that HRSNs are critical factors that impact patient outcomes, and increased knowledge about patients' HRSNs will help hospitals shape goals associated with health equity. We agree with commenters that availability of SDOH quality data will support the identification of innovative opportunities to enhance availability of community resources to meet the needs identified by the Screening for SDOH measure. Further, we share the commenters' belief that this measure could support efforts to connect patients in need with community resources. We thank commenters for their questions regarding the technical specifications of the measure. We agree that screening for SDOH is most appropriate when administered so that the patient's information can be used by the patient's care team. As we stated in the proposed rule, screening for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety can help identify and provide appropriate referrals for patients who may benefit from greater support in one or more of those areas. As such, we are clarifying that while outpatient care can refer to numerous types of health services, such as emergency department (ED) services, observation services, outpatient surgical services, lab tests, and X-rays, for purposes of this measure in the Hospital OQR Program, REHQR, and ASCQR programs, patients receiving services that are limited to specific medical tests are not included in the denominator cohort. These services include imaging, laboratory, and pharmacy services, which are typically specific types of auxiliary services to a patient's more comprehensive care, where such screenings and referrals should be provided.

Comment: Several commenters supported the adoption of the Screening for SDOH measure and offered recommendations about the data in the Screening for SDOH measure, including that CMS should publish the standards on how SDOH data will be protected, and that CMS should require disaggregated collection of the measures at the individual level to allow providers to assess the factors impacting an individual patient's health to better meet their needs. These commenters also supported the expansion of the SDOH reporting and the changes to the transportation element, but recommended CMS focus on ensuring the data are collected rather than on the specific vendor or tool used for the collection.

Response: We thank the commenters for their support and recommendations. We have given this significant consideration to ensuring data is protected in development of the SDOH measures. The combination of existing privacy laws and the measure specifications (requiring submission of aggregated data) address the concerns relative to patient rights and transparency. HOPDs, REHs, and ASCs generally must comply with applicable laws governing the confidentiality, privacy, and security of patient information. We have also specified the measure to allow patients to opt-out of screening. We thank the commenter for their recommendation to ensure that data are collected rather than focusing on a vendor or tool. We note that we do not require HOPDs, REHs or ASCs to report this measure using a specific vendor or tool. As previously discussed, outpatient settings are provided the flexibility to choose their own screening tool to eliminate redundancy, utilize interoperable systems, and reduce burden. We have provided suggestions for validated screening tools, such as the AHC HRSN Screening Tool, that HOPDs, REHs and ASCs may use if they choose, but we do not require outpatient settings to use these tools to maintain this flexibility.

Comment: A few commenters supported the Screening for SDOH measure and recommended that CMS continue engaging with stakeholders to ensure that the measure remain relevant. A few commenters supported the Screening for SDOH measure but recommended additional efforts, including that CMS consider opportunities to implement higher level holistic SDOH screening approaches and accompany the SDOH screening with responsive care models that provide effective interventions to address patients' unmet needs, that CMS consider adopting the Social Need Screening and Intervention measure in its quality reporting programs as an alternative, and that CMS make the question related to interpersonal violence (IPV) optional.

A commenter agreed with HOPDs having the flexibility to choose their own screening tool to measure HRSNs and recommended that we incorporate this flexibility across existing and future quality measures to eliminate redundancy, utilize interoperable systems, and reduce burden. A commenter appreciated that CMS allows HOPDs to utilize previous screens to avoid the burden of re-screening but recommended that CMS work with measure developers to develop a measure that focuses on the actions that were taken following a positive screen and evaluate the impact of SDOH on health outcomes to adjust the domains for social drivers. The commenter also recommended that CMS share the roadmap for moving the healthcare system beyond screening towards effectively closing gaps for social needs of patients and a plan to evaluate the link between identifying a social need and utilization of services to address the patients' needs. They also recommended expanding the measure and metric to include additional SDOH such as access to education, employment opportunities, digital connectivity, and environmental factors which can have significant impacts on health outcomes.

A commenter recommended finalizing the Screening for SDOH measure with flexibility to allow HOPDs to use different screening tools and increasing support for safety net hospitals' ability to respond to SDOH needs, and another commenter recommended enhanced transparency because consumers should be able to identify the screening rate a facility attains for each domain and the reporting of more granular level results for each measure will contribute to driving improvement where the largest deficits are identified. A commenter recommended that CMS require disaggregated collection of the measures at the individual level to allow providers to assess the factors impacting an individual patient's health to better meet their needs. A commenter supported the adoption of the Screening for SDOH measure as an important first step but recommended that CMS increase funding to ensure that patients who screen positive for SDOH are able to receive resources including things like transportation, housing, and food security. The commenter also recommended that CMS align with

other organizations and national initiatives that are establishing coding and documentation standards in this space, simplifying the process to remove ambiguity, and supporting easy integration into providers' current workflow. Another commenter recommended that efforts to address SDOH ensure that providers are able and incentivized to connect patients with necessary clinical, mental, behavioral, and social services as seamlessly as possible.

Response: We thank the commenters for the recommendations to engage in further efforts to implement holistic screening approaches, alternative measures, and expansion of additional social drivers of health and we will consider these recommendations in future rulemaking. However, in response to the recommendation to make the interpersonal safety domain optional, we note that we have prioritized selection of the proposed five HRSN domains based on existing evidence from both the AHC Model that informed the initial selection, and emerging evidence of correlations between given social drivers of health and worse health outcomes and SDOH for which interventions have shown marked improvements in health outcomes and healthcare utilization.

It is imperative that HOPDs, REHs, and ASCs screen for all five domains established in this measure. We understand the sensitive nature of screening for risk of interpersonal violence and that patient safety must remain the hospital's, REH's, and ASC's principal concern. We recommend that hospitals, REHs, and ASCs ensure that patients feel that they are safe answering questions and remind patients that they may opt out of the screening for any reason. We note that the measure specifications exclude patients: (1) who opt-out of screening; and (2) are themselves unable to complete the screening and have no legal guardian or caregiver able to do so on the patient's behalf (89 FR 59447). We also note that while individual responses to the SDOH survey may constitute protected health information (PHI) under the HIPAA Privacy Rule (45 CFR parts 160 and 164, subparts A and E), the information HOPDs, REHs, and ASCs must provide CMS to meet the requirements of the SDOH measure consist of aggregated, de-identified data only. Information that does not identify the individual that is the subject of the health information and for which there is no reasonable basis to believe it could be used to identify an individual, is not individually identifiable health information (IIHI) and is therefore not PHI (45 CFR 160.103). HIPAA covered entities must comply with requirements to use and disclose PHI only as permitted or required by the HIPAA Privacy Rule, but the HIPAA Privacy Rule does not place restrictions on the use or disclosure of information that is not PHI (45 CFR 164.502). While HOPDs, REHs, and ASCs that begin to collect SDOH information will be creating additional PHI that they did not previously create, the SDOH quality measure will not require them to disclose any PHI or IIHI to CMS. We remind HOPDs, REHs, and ASCs that as covered entities, they must ensure the confidentiality, integrity, and availability of all electronic PHI, including any electronic PHI generated in the course of collecting responses to any SDOH survey (45 CFR 164.306).

In response to the recommendation to align with other organizations and national initiatives, this data collection will inform meaningful and sustainable solutions for other provider types through similar collections in other quality reporting programs and note that we will continue identifying opportunities for collaboration with other stakeholders to align SDOH assessment across CMS programs. We commend additional stakeholder efforts currently underway to expand capabilities to capture additional drivers of health data elements. We will continue building the overarching strategy for integrating social drivers of health screening into quality improvement and future rulemaking. We also note that we will continue identifying opportunities for collaboration with other stakeholders to ensure the measure remains relevant in future years.

As to commenters' request for additional information on CMS's work on health equity, we refer commenters to the CMS Framework for Health Equity 2022–2032 available at: *https://www.cms.gov/priorities/health-equity/minority-health/equity-programs/framework*.

Comment: A few commenters expressed their support for the Screening for SDOH measure but requested clarifications including that CMS clarify any restrictions on what tools, modified or not, a hospital or facility can use to screen patients for the HRSNs. A commenter also requested clarification on the outpatient population in the denominator of this measure for use in the Hospital OQR program because not all outpatient interactions involve an office visit where screening would be appropriate. A commenter requested clarification on qualifying outpatient hospital encounters and further defining of the types of HOPD environments SDOH screening requirements will cover.

Response: We appreciate the commenters' support and requests for clarification. We note that we are not mandating use of a specific screening tool, and we therefore defer to providers to make the appropriate determination regarding how to collect the data. We also note that, while outpatient care can refer to numerous types of health services, such as emergency department (ED) services, observation services, outpatient surgical services, lab tests, and X-rays, for purposes of this measure in the Hospital OQR, REHQR, and ASCQR Programs, patients receiving services that are limited to specific medical tests are not included in the denominator cohort. These services include imaging, laboratory, and pharmacy services, which are typically specific types of auxiliary services to a patient's more comprehensive care, where such screenings and referrals should be provided.

Comment: A few commenters fundamentally supported the SDOH screening measure but expressed concerns that the data required for the measure may not currently be reliably documented using discrete data fields that can be captured electronically. A commenter recommended adding economic insecurity as a social risk factor for screening as it can lead to many other social determinants of health.

Response: We thank the commenters for their broad support of the Screening for SDOH measure. We appreciate the commenter's concerns about the limits of the discrete data fields. The data collected by the measure captures critical information about SDOH, and we note that this measure does not restrict hospitals or facilities from documenting more qualitative data about SDOH. Hospitals and facilities are not restricted to the data fields provided if they wish to gather more qualitative data on their patients. We appreciate the recommendation to include economic insecurity and will consider adding it to the measure in future rulemaking.

Comment: A few commenters recommended that CMS work with stakeholders on the best ways to gather more granular data while maintaining strong privacy and patient safeguards so researchers and other stakeholders can evaluate how hospitals are evaluating HRSNs as well as whether hospitals and large hospital systems are adequately evaluating HRSNs because it is important to understand how HRSNs contribute to healthcare spending, quality, and outcomes at the individual

and community levels. A commenter supported the use of Z-codes to inform social risk adjustment and recommended that CMS continue to use Z-codes as a proxy for social risk and to maintain a broad viewpoint on how social risk is identified. The commenter also recommended that CMS avoid leveraging SDOH screening data as if it were epidemiologic data rather than data intended to understand patients' needs and optimize their health and well-being. Another commenter recommended that CMS include the Distress Thermometer as a useful tool for providers seeking free resources to meet these measures. Another commenter noted that the measure is a welcome addition to the measure set but recommended that CMS develop a stronger audit function because without an adequate auditing function, the measures remain highly susceptible to subjectivity.

The commenter also recommended keeping the Hospital IQR Program reporting separate from the Hospital OQR Program reporting because it will ensure a more accurate picture allowing for improved consistency in data collection over time. Another commenter recommended that CMS continue to make important changes to the Hospital OQR program by strengthening requirements for hospitals to report on a more comprehensive set of quality and equity measures. A commenter supported the inclusion of health equity and also recommended consolidating the reporting of HRSNs at the organizational level rather than separately for inpatient and outpatients to align human and technological resources. Another commenter supported CMS's work to identify and address social drivers of health in all patient care settings but recommended additional guidance from CMS and additional time to operationalize the screenings during outpatient visits.

Response: We thank the commenters for the recommendation to engage with stakeholders and we will continue identifying opportunities for collaboration with stakeholders to ensure the measure is gathering granular data and adequately evaluating HRSNs. We agree with commenters that the intention of the measure is to understand patients' needs, rather than to provide epidemiologic information. We will also consider including references to the Distress Thermometer in our resources for this measure. Additionally, in response to the recommendation to keep the Hospital IQR Program reporting and the Hospital OQR Program reporting separate, we note that, as previously stated in the CY 2025 OPPS/ASC proposed rule, the populations represented by the Hospital IQR and Hospital OQR programs are distinct, resulting in a different denominator calculation of the measure for each program (89 FR 59446). We will continue to require a separate data submission for each program in the HQR system.

We appreciate the recommendations to consolidate the reporting of HRSNs at the organizational level, and to strengthen the requirements for hospitals to report on a more comprehensive set of equity measures. Additionally, regarding the recommendation to evaluate the initial metrics from the measure, we note that we will monitor measure implementation and data reporting as part of standard program and measure review and will consider updates to the measure if improvements are identified through this process. Regarding the use of Z codes, we appreciate commenters' recommendations; however, adoption of Z codes across healthcare systems has been slow and unstandardized, and the Screening for SDOH measure will be beneficial to clinicians in addressing patient social needs while provider uptake of Z codes improves.

Comment: A few commenters supported the inclusion of the Screening for SDOH measure in the REHQR Program noting that they support the broad effort to evaluate and promote health equity and SDOH within the REH model and commended CMS for focusing on measures related to health equity for REHs because they play a vital role in ensuring healthcare access in rural and remote communities. They stated that inclusion of the measure will help ensure a focus on health-related social needs and address health equity across facilities. A commenter recommended that CMS prioritize inclusion of a patient experience measure in future rulemaking because they believe such measurement is currently missing from the REHQR program and is an important reflection of providing culturally relevant care.

Response: We thank the commenters for their support of the inclusion of the Screening for SDOH measure in the REHQR Program, and we agree that HRSNs are critical factors that impact patient outcomes, and increased knowledge about patients' HRSNs will help REHs shape goals associated with health equity. Further, we agree that collecting these data will help REHs improve coordination with outpatient and community resources to better deliver patient-centered care. We thank the commenter for the recommendation and will consider inclusion of a patient experience measure in the REHQR Program in future rulemaking.

Comment: A few commenters expressed specific support for the adoption of the Screening for SDOH measure in the ASCQR Program because it aligns with the measure as adopted in inpatient settings, reflects important priorities in safety and health equity, and will ensure that quality reporting is consistent across different healthcare settings. A commenter expressed support for CMS's efforts to improve health equity with the Screening of SDOH measure in the Hospital OQR and ASCQR Programs but recommended that CMS begin with voluntary reporting to allow HOPDs and ASCs time to implement the screening tools and workflows needed. The commenter also requested guidance on the cadence of required screenings such as if a patient is screened every visit or once every 6 months, or if a patient receives a HRSN screening in the emergency department and is then admitted, if they would need an additional screening to satisfy Hospital IQR Program reporting.

Response: We appreciate the commenters' support and recommendation. We agree that the measure ensures alignment across quality programs and will help shape our goals associated with health equity. We thank the commenter for their recommendation to implement this measure with a voluntary reporting period. We remind readers that we proposed this measure with an initial voluntary reporting period beginning with the CY 2025 reporting period and proposed to require mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment or program determination.

Regarding the commenter's request to clarify the cadence of screening we note that outpatient settings would not be required to re-screen patients in the same reporting period if the data are already captured in the EHR. HOPDs, REHs and ASCs could confirm the current status of any previously reported HRSNs in another care setting and inquire about others not previously reported in lieu of re-screening a patient for all HRSN domains within the reporting period.

Additionally, as previously discussed in the CY 2025 OPPS/ASC proposed rule, the populations represented by the Hospital IQR and other outpatient quality reporting programs are distinct, resulting in a different denominator calculation of the measure for each program (89 FR 59446). Therefore, inpatient and outpatient settings will be unable to accurately report this measure

if data are combined for inpatient and outpatient programs. We will therefore continue to require a separate data submission for each program in the HQR system.

In addition, as we stated in the proposed rule, screening for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety can help identify and provide appropriate referrals for patients who may benefit from greater support in one or more of those areas. As such, we are clarifying that while outpatient care can refer to numerous types of health services, such as emergency department (ED) services, observation services, outpatient surgical services, lab tests, and X-rays, for purposes of this measure in the Hospital OQR, REHQR, and ASCQR Programs, patients receiving services that are limited to specific medical tests are not included in the denominator cohort. These services include imaging, laboratory, and pharmacy services, which are typically specific types of auxiliary services to a patient's more comprehensive care, where such screenings and referrals should be provided.

The following comments and responses are broadly applicable to the Hospital OQR, REHQR, and ASCQR Programs, unless noted otherwise.

Comment: Many commenters expressed concerns about the administrative burden and insufficient reimbursement rate associated with the work required to collect data and report this measure for outpatient settings that are already under-resourced. These commenters recommended that CMS consider the administrative burden of the measure to ensure that new reporting processes do not place undue strain on entities. A few commenters recommended working with stakeholders to develop an electronic clinical quality measure to reduce burden. A few commenters recommended increased reimbursement due to the reporting burden of this measure. A commenter recommended removing other quality reporting requirements if there are no additional financial incentives.

Response: We acknowledge commenters' concerns regarding resource constraints, including increased administrative burden; however, achieving health equity is an issue that deserves serious focus and rapid action for improvement. The benefits of screening patients for SDOH outweigh the minimal burden under this measure. As discussed in the CY 2025 OPPS/ASC proposed rule (89 FR 59516 and 59517, 89 FR 59522 and 59523, and 89 FR 59526, respectively) and in sections XXVI.A.c, XXVI.B.c, and XXVI.C.c of this final rule with comment period, we estimated the collection burden for this measure to be 2 minutes per patient screening and 10 minutes annually per HOPD, REH, and ASC to report the measure data. We note that there are ongoing reevaluation efforts that aim to improve the Screening for SDOH measure through the development of the Addressing Social Needs (ASN) eCQM for introduction to the Hospital IQR Program and eventually the Merit-based Incentive Payment System (MIPS) and Hospital OQR Programs.[358] As we move toward interoperability, we will consider this recommendation in future rulemaking. We will continue to identify opportunities for collaboration with stakeholders to align screening for SDOH assessment across CMS programs.

We seek to reduce reporting burden in all our quality reporting programs and value-based purchasing programs. As an example of our commitment to reducing burden in the ASCQR Program, we refer readers to our RFI on the Specialty-Select and the Specialty-Threshold frameworks as detailed in section XVII.G of this final rule with comment period, in an effort to decrease reporting burden by ensuring that ASCs are reporting on measures most meaningful to their facilities.

Regarding commenters' recommendations for increased reimbursement, we reiterate that the Hospital OQR and ASCQR Programs are statutorily limited to reduce the fee schedule increase factor by 2-percentage points in the event the HOPD or ASC fails to meet program requirements as established by the Secretary (section 1833(i)(7) of the Act). The Hospital OQR, REHQR and ASCQR Program statutes do not provide authority for CMS to provide financial incentives. For the REHQR Program, there is no financial penalty or incentive for quality reporting (section 1861(kkk)(7)); however, REHs will be paid for furnishing covered REH services at a rate that includes an additional five percent increase over the OPPS payment rate.

To support implementation of the Screening for SDOH measure within HOPDs, REHs and ASC, we refer readers to the Hospital IQR Program's FAQ document regarding this measure in the Hospital IQR Program, available at: *https://www.qualityreportingcenter.com/globalassets/2024/04/iqr/17.-sdoh-measure--faqs_april-2024_vfinal508.pdf.*

We will develop a similar Frequently Asked Questions document for the Hospital OQR, REHQR, and ASCQR Programs as part of providing educational and outreach materials; this document will be conveyed through routine communication channels.

Comment: Many commenters expressed concern about this Screening for SDOH measure under the ASCQR Program, stating that ASCs have insufficient resources, are likely understaffed, and have a lower reimbursement rate than hospitals, making this measure more difficult to implement given the increased reporting and operational burden required. A commenter stated that this measure expands the role of ASCs beyond their scope, without additional funding or resources. A commenter stated that ''we recently finalized a new standalone HCPCS G code describing a SDOH Risk Assessment'' and stated that providers can be paid for performing this service. This commenter further stated that this measure requires the ''same resource use in ASCs'' and recommended that CMS allow ASCs to receive reimbursement for the SDOH Risk Assessment. A commenter recommended implementing measures that only provide the greatest value to patient safety and quality of care in ASCs, as additional mandatory measures may divert revenue away from other patient safety investments.

A few commenters expressed concern about the burden associated with aggregating and reporting results of existing screening for SDOH among HOPDs. A commenter expressed concern that the addition of this measure in the Hospital OQR Program may significantly increase burden on Emergency Departments (EDs), which are often resource strained.

Response: We thank commenters for their concern that this measure is out of scope for ASCs; however, we respectfully disagree as ASCs are responsible for ensuring the best outcomes possible for the patients that they serve. Ensuring the best possible outcomes requires treating the whole patient, which includes identifying potential barriers to optimal health, and helping patients identify resources to address those barriers. Under the AHC Model, the five core domains selected to screen HRSNs (food insecurity, housing instability, transportation needs, utility difficulties and interpersonal safety) were chosen based upon literature

[358] Centers for Medicare & Medicaid Services. (2023). Addressing Social Needs (ASN) Electronic Clinical Quality Measure (eCQM) Specifications Document for Public Comment. Available at: *https://mmshub.cms.gov/sites/default/files/Yale-CORE-ASN-measure-specs-for-public-comment.pdf.*

review and expert consensus utilizing the availability of scientific evidence linking a given HRSN to adverse health outcomes and increased healthcare utilization, including hospitalizations and associated costs (89 FR 59444). ASCs that have successfully connected patients to community resources may show a decrease in readmission rates and in cost savings associated with healthcare delivery over time.[359] [360] This may be beneficial for the health of the communities ASCs serve. We encourage ASCs to refer vulnerable patients to appropriate resources wherever possible or feasible.[361]

Additionally, we appreciate the commenter's concern that this measure may divert revenue away from other patient safety investments among facilities and note the minimal burden of collecting data (estimated at 2 minutes per patient screening and 10 minutes annually per HOPD to report the measure data). We will monitor this measure, as we do all ASCQR measures, for any unintended or adverse outcomes associated with potential future implementation. The ability for medical providers to screen for social drivers of health through the five HRSN domains is important and will help patients with the most complex needs.

We acknowledge commenters' concerns that this measure may place increased burden on HOPDs and reiterate that the benefits of screening patients for SDOH outweigh the minimal burden of collecting data (estimated at 2 minutes per patient screening and 10 minutes annually per HOPD to report the measure data) under this measure as achieving health equity requires swift action for improvement. We also note that hospitals participating in the Hospital IQR Program that choose to voluntarily report this measure will have experience screening patients for SDOH under the Hospital IQR Program, and HOPDs would not be required to re-screen the same patients for the Hospital OQR Program if the data are already captured in the EHR.

Comment: Many commenters that did not support the Screening for SDOH measure expressed concern about the additional burden that would be created by implementing EHR systems to collect SDOH data. These commenters recommended additional time for measure implementation.

Several commenters expressed concern that implementation of this measure under the ASCQR Program lacks feasibility and creates additional burden as a large portion of ASCs have not integrated EHRs into current workflow processes and would have limited resources to finance this technology due to the investments required for this quality reporting measure. A commenter recommended conducting additional research on how this measure can be applied to the ASC setting, especially for ASCs that are under-resourced and unable to implement EHR systems.

Response: We thank the commenters for their feedback and note that the Screening for SDOH measure does not require EHRs for healthcare facilities that have not yet acquired one. We disagree that this concern is applicable to the adoption of the Screening for SDOH measure in the Hospital OQR and REHQR Programs. We note that, as of 2021, 96 percent of hospitals have already integrated EHRs into their workflow processes.[362] Further, hospitals that participate in the Hospital OQR Program are required to utilize health information technology modules certified to the 2015 Edition Cures Update, which was a specific edition of ONC health IT certification criteria, beginning with the CY 2023 reporting period/CY 2025 payment determination to report eCQMs (86 FR 63868 through 63869).[363] We note that this rule with comment period finalizes a requirement at § 419.46(j)(1) that hospitals participating in the Hospital OQR Program ''utilize certified technology updated to be consistent with the Office of the National Coordinator for Health Information Technology's health IT certification criteria, as adopted and updated in 45 CFR 170.315,'' which is consistent with ONC's current ''edition-less'' approach to the ONC health IT certification criteria (89 FR 1207). We also note that, for clarity, this finalized requirement differs from our proposal by the removal of an acronym and its replacement by the full agency name. Additionally, many REHs reported under the Medicare Promoting Interoperability and Hospital IQR Programs prior to conversion, and thus are likely to also have EHR systems already embedded in their workflows.

Adoption of EHR technology will lead to more positive outcomes in ASC settings, as EHR usage has been shown to have positive impacts on care quality, coordination, efficiency, patient care safety, documentation accuracy, and cost reduction.[364] Although initial EHR adoption has associated costs, we expect that, over time, ASCs will experience less financial and operational burden. By purchasing an EHR, an ASC will save costs previously spent on maintaining and managing patient charts.[365] EHRs additionally decrease duplicative testing and interventions and ensure all required patient information is included in the operative note, leading to accurate reimbursements.[366] We continue to encourage ASCs to consider EHR adoption to streamline documentation of patient health information, including demographic characteristics and SDOH, which will incentivize ASCs to collect and utilize data to identify critical equity gaps, implement plans to address these gaps, and ensure that resources are dedicated toward addressing health equity initiatives.

Comment: Many commenters recommended delaying voluntary implementation of the measure by at least 1 year and extending voluntary reporting to provide outpatient settings enough time to prepare and build the needed infrastructure and community networks or add a phased approach to mandatory reporting that allows flexibility for organizations to not burden their administrative tasks in ways that may hinder day-to-day operations. These commenters, across all programs, stated that the measure requires significant time and financial resources to integrate into workflows.

A commenter recommended delaying implementation in the Hospital OQR Program until a comprehensive measure review has been performed. Another commenter specifically recommended that CMS delay voluntary reporting for the Hospital OQR Program until CY

[359] Bensken WP, Alberti PM, Koroukian SM. (2021) Health-related social needs and increased readmission rates: findings from the nationwide readmissions database. *J Gen Intern Med.* 2021;36:1173–1180. *https://doi.org/10.1007/s11606-021-06646-3.*

[360] Weaver RH, Bolkan C, Robbins SL, et al. (2021). Caring beyond health care: lessons learned from a community-based partnership to reduce hospital readmission among high-risk adults. *J Comm Engag Scholarship.* 2021;14(1). *https://doi.org/10.54656/NWMT3812.*

[361] We refer ASCs to the following resource that match patients with community resources based on geographic location: *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/CMLN%20Social%20Determinants%20of%20Health%20Relevance%20and%20Resources%20Guide.pdf.*

[362] Office of the National Coordinator. National Trends in Hospital and Physician Adoption of Electronic Health Records. Available at: *https://www.healthit.gov/data/quickstats/national-trends-hospital-and-physician-adoption-electronic-health-records.*

[363] On July 29, 2024, notice was posted in the **Federal Register** that ONC would be dually titled to the Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (89 FR 60903).

[364] Geier, A., & Smith, D. (2019). The role of electronic documentation in Ambulatory Surgery Centers. AORN Journal, 109(4), 444–450. *https://doi.org/10.1002/aorn.12636.*

[365] Ibid.

[366] Ibid.

2027 and begin mandatory reporting in CY 2029.

Response: We thank the commenters for their feedback, and we acknowledge their concerns about the operational complexity of introducing new quality measures into existing clinical workflows and EHR systems. Beginning data collection remains imperative as we continue to build on our strategic pillar to advance health equity by addressing the health disparities that underlie our health system, and the proposed voluntary and mandatory reporting periods prioritize the urgency of capturing SDOH data and taking actionable steps towards closing health equity gaps.

We acknowledge commenters' concerns regarding the financial resources needed to integrate this measure into workflows; however as previously noted, achieving health equity is an issue that deserves serious focus and rapid action for improvement. The benefits of screening patients for SDOH outweigh the minimal burden under this measure (estimated at 2 minutes per patient screening and 10 minutes annually per HOPD, REH, and ASC to report the measure data).

Additionally, hospitals participating in the Hospital IQR Program that choose to voluntarily report this measure will have already reported data in FY 2024 (87 FR 49207 through 49208), and the Hospital IQR Program finalized mandatory reporting of this measure for the FY 2026 payment determination (that is data submitted in FY 2025 representing the FY 2024 performance period) (87 FR 49207 through 49208). Given the timing of reporting this measure in the Hospital IQR Program, outpatient settings will have the opportunity to learn from the experiences of hospitals participating in the Hospital IQR Program, including best practices for collecting HRSN data, prior to mandatory reporting for the Hospital OQR, REHQR, and ASCQR Programs for the CY 2026 Reporting Period/CY 2028 Payment or Program Determination.

Comment: Many commenters that did not support adoption of the Screening for SDOH measure expressed concern that it has not been tested in the HOPD, REH or ASC settings. Many commenters urged CMS to continue testing the measure in these outpatient settings to demonstrate feasibility, reliability, validity, and to address challenges endured in the inpatient setting prior to expanding it as mandatory in the outpatient setting.

Several commenters did not support adoption of the Screening for SDOH measure in the ASCQR Program based on their belief that there is insufficient evidence that this measure leads to improved patient outcomes among ASCs. A commenter expressed concern that the burden of implementation of this measure in the ASCQR Program and the potential for skewed results due to lack of testing outweighs the benefit of screening for SDOH due to the lack of evidence-based research and inaccuracy of non-risk adjusted data. A commenter expressed concern that without testing in the ASC setting, there are many unknowns regarding requirements for implementation such as determining the full-time equivalent (FTE) impact of staffing the screening and referral processes. A commenter recommended first conducting screenings for SDOH in a smaller outpatient population to provide lessons learned.

Response: We acknowledge that this measure was initially developed for the acute care setting. We recognize the value of measures undergoing testing and evaluation of validity and feasibility in the setting for which they are being adopted. As part of the PRMR process, the measure underwent an assessment of the measure's testing data and appropriateness for the outpatient setting, including a review of the measure's scientific acceptability, feasibility, and usability. Additionally, we will continue to test the performance of this measure in the HOPD, REH, and ASC settings throughout the voluntary reporting period. Given the urgency of achieving health equity, and as there are currently no other existing measures that address screening of HRSNs, it is important to implement this measure as soon as feasible. This measure is not specific to any particular setting of care and is equally applicable to the outpatient setting as to general acute care settings. Identifying the HRSNs of HOPD, REH, and ASC patients will be equally valuable in understanding patients' needs, improving care coordination with outpatient and community resources, increasing the dignity and respect with which patients are treated, and supporting development of patient-centered treatment plans. Additionally, outpatient settings are encouraged to prioritize screening tools that have undergone adequate testing to ensure they are accurate and reliable. For example, the AHC HRSN Screening Tool has been tested across many care delivery settings in diverse geographic locations and has demonstrated evidence of both reliability and validity.[367] We thank the commenters for their recommendations and will monitor measure implementation and data reporting as part of standard program and measure review and will consider updates to the measure if improvements are identified through this process.

Comment: Many commenters did not support the Screening of SDOH measure due to their beliefs that the lack of standardized screening approach could introduce inaccuracies in data collection. These commenters recommended that CMS require outpatient settings to take a standardized screening approach for implementing this measure, including providing set screening tools, as this would allow for more valid comparisons between HOPDs, REHs, and ASCs and would reduce ambiguity.

A few commenters recommended working with stakeholders to develop consistent survey questions while maintaining the flexibility for how and when facilities screen patients. A commenter expressed concern that not all tools compiled on the SIREN website have been validated or ''vetted through all steps of gold standard measure development.'' This commenter recommended that CMS provide a list of screening tools that are adequately tested and validated to reduce potential burden that may occur if CMS were to mandate a standardized tool at a later time. A commenter expressed their belief that standardized measure definitions within and across programs, coupled with more timely performance data provided to facilities will greatly support the advancement of patient safety and quality improvement by creating consistent and actionable goals and results. The commenter recommended providing more timely actionable data to promote immediate advancements in patient safety and quality.

Response: We thank the commenters for their feedback. We agree that allowing outpatient settings flexibility with tool selection is a tradeoff, but, as we discussed previously, this flexibility aims to reduce burden for HOPDs, REHs and ASCs, by allowing these settings to continue to use screening tools that they may already use for greater customization of screening and data collection for each settings' patient population and individual needs. This is the first time we will be collecting SDOH data in these settings as part of quality performance measurement and

[367] Centers for Medicare and Medicaid Services. (2023). A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. Available at: *https://www.cms.gov/priorities/innovation/media/document/ahcm-screeningtool-companion.*

we want to ensure that all HOPDs, REHs, and ASCs are working towards initial screening, in a form and manner that works for them. We anticipate that for HOPDs, REHs, and ASCs associated with other healthcare settings where this measure has been adopted, such as the Hospital IQR Program, an organic alignment of screening tools will emerge and generate a degree of industry-led standardization. We also anticipate additional emphasis on standardized and validated screening instruments in future versions of these measure. Outpatient settings are encouraged to prioritize screening tools that have undergone adequate testing to ensure they are accurate and reliable. As we indicated previously, health equity is a key priority, and we intend to continue to develop relevant measures. We are taking commenters' recommendations under consideration as appropriate to inform potential future notice-and-comment rulemaking.

In response to the commenter's recommendation to provide more timely actionable data, we intend to publicly display data for the Screening for SDOH measure on the first available refresh of Care Compare. Typically, this would occur in October of the year following data submission. For example, for the CY 2026 Reporting Period/2028 Payment Determination or Program year, the data would be displayed on Care Compare in October 2027. This is as soon as technically feasible for data collected during the CY 2026 performance period and submitted between January 1 and May 15, 2027.

Comment: Many commenters that did not support adoption of the Screening for SDOH measure stated that the measure is not appropriate for the outpatient setting where there is little to no patient follow-up. A few of these commenters noted that outpatient settings would need to hire staff such as case managers and social workers to conduct screening in advance of a patient visit and make any needed workflow changes.

For the ASCQR Program specifically, many commenters stated their belief that the measure does not capture the essence of the work currently done by ASCs, the measure falls outside of the primary ASC function, the questions asked are inappropriate for the ASC setting, and the data should be collected by primary care physicians or hospitals.

For the Hospital OQR Program, a commenter expressed concern that HOPDs that focus on diagnostic testing are not suited to conduct screening for SDOH due to the absence of specialized staff to conduct this screening. A commenter recommended a more targeted approach to screening that only requires screening under the Hospital OQR Program in HOPDs with long-term patient and provider relationships, adequate staff, and resources to respond to results from screening. This commenter recommended convening a TEP with representation from the hospital community to determine how to identify HOPDs that have the resources to implement this measure.

Response: We thank the commenters for their concerns. However, we disagree with the commenters' assertion that the measure is not appropriate for outpatient settings. HOPDs, ASCs, and REHs are responsible for treating the whole patient and ensuring the best outcomes possible for the patients that they serve, including identifying potential barriers to optimal health, and helping patients identify resources to address those barriers. One of the benefits of collecting data from screening for HRSNs will be identification of opportunities to enable meaningful action, including prioritizing and investing in such resources. As part of the PRMR process, the measure underwent an assessment of the measure's testing data and appropriateness for the outpatient setting, including a review of the measure's scientific acceptability, feasibility, and usability. We are taking commenters' recommendations under consideration as appropriate to inform future potential rulemaking.

Additionally, as previously noted, while outpatient care can refer to numerous types of health services, such as emergency department (ED) services, observation services, outpatient surgical services, lab tests, and X-rays, for purposes of this measure in the Hospital OQR, REHQR, and ASCQR Programs, patients receiving services that are limited to specific medical tests are not included in the screening cadence of this measure. These services include imaging, laboratory, and pharmacy services, which are typically specific types of auxiliary services to a patient's more comprehensive care, where such screenings and referrals should be provided.

Comment: Many commenters that did not support adoption of the Screening for SDOH measure cited concerns about whether the data would be meaningful, accurately and fairly evaluate organizations, and lead to progress or change. A commenter questioned the efficacy and validity of the AHC Model and whether the testing of universal HRSN screening demonstrated meaningful impact on health outcomes and health equity. A commenter expressed concern about the required author permissions when using the AHC tool and noted that healthcare facilities would need to ''reach out to the screening question author to notify them of their plan to use it.''

Several commenters noted other factors to include in the measure to make it more meaningful, including demographics across communities other than race and ethnicity (such as age, gender, and health literacy, accessibility of services, etc.). A commenter recommended using a community needs assessment and implementing regulatory flexibilities to help providers effectively act on social determinants of health and gaps in access to care.

A commenter urged CMS to develop a more meaningful measure for Hospital OQR Program that captures a granular scale of data and differentiates patients with the greatest need for follow-up.

Response: We thank the commenters for their input. The intent of this measure is to promote adoption of screening patients for HRSNs by healthcare providers as well as taking action to connect patients who identify one or more HRSNs with available resources. Evaluation of the AHC Model concluded that universal screening may identify needs that would otherwise remain undetected.[368] While broad availability of community-based resources that address patients' HRSNs would be ideal, one of the benefits of collecting data from screening for HRSNs will be identification of opportunities to enable meaningful action, including prioritizing and investing in such resources. Beginning to collect the data remains imperative and such data collection has already allowed some entities to reallocate resources to address HRSNs that disproportionately affect a given patient population or geographic region, as noted in the FY 2023 IPPS/LTCH PPS final rule, in which the Hospital IQR Program adopted this measure (87 FR 49213). This input is valuable in the continuing development of the CMS health equity quality measurement efforts and supports our aims to acknowledge the impact of HRSNs on healthcare access, utilization, outcomes, and costs. We will continue to take all concerns, comments, and suggestions into account for any potential future development and expansion of our health equity quality measurement efforts.

Regarding the commenter's concern about using the AHC Screening tool, we

[368] Centers for Medicare and Medicaid Services. (2020). Accountable Health Communities Mode (AHC) First Evaluation Report. Available at: *https://www.cms.gov/priorities/innovation/data-and-reports/2020/ahc-first-eval-rpt-perspective.*

note that use of this tool is not required, but if healthcare facilities would like to use it, they can follow the guidance provided in the ''Accountable Health Communities Health-Related Social Needs Screening Tool Citation and Notification Information'' document, which requires citing the authors and in some instances, notifying the authors of intended use.[369] Beyond notification and citation, there are no restrictions on use of the AHC screening tool questions. Furthermore, healthcare facilities may create or choose other tools to use for implementing this measure.

Comment: Several commenters that did not support adoption of the Screening for SDOH measure expressed concern that this measure has not received endorsement by the CBE. Some of these commenters noted that this was a previous condition placed by the MAP when the Screening for SDOH measure was adopted in other quality reporting programs. Several commenters recommended submitting the measure for endorsement by a CBE. A commenter also suggested using a different measure for achieving health equity that is endorsed by the National Quality Forum (NQF).

Response: While we recognize the value of measures undergoing review for potential CBE endorsement, measures of health equity are a priority for CMS, and it is important to implement this measure as soon as possible, beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting for the CY 2026 reporting period. We note that section 1833(t)(17) of the Act requires measures developed for the Hospital OQR Program to reflect consensus among affected parties. Under section 1833(i)(7)(B), this requirement also applies to the ASCQR Program except as the Secretary may otherwise provide. Under section 1833(t)(17)(C)(i), the Hospital OQR Program is only required to include measures set forth by a national consensus building entity ''to the extent feasible and practicable.'' We have been unable to identify any measures on this topic set forth by a consensus building entity and it is not feasible and practicable to include such a measure at this time. As we have noted in previous rulemaking, consensus among affected parties can be reflected in ways other than CBE endorsement, including through the measure development process, through broad acceptance and use of the measure(s), and through public comment (75 FR 72064 and 72065 for the Hospital OQR Program and 76 FR 74494 for the ASCQR Program). As stated previously, this measure has been adopted through rulemaking with public comment periods in other care settings, including inpatient hospitals, PPS-Exempt cancer hospitals, and dialysis facilities, which evidence broad applicability and acceptability of the measure concept and specifications for different healthcare facility types, both inpatient and outpatient.

For the REHQR Program, we note that under section 1861(kkk)(7)(C)(ii) of the Act, the Secretary may specify a measure that is not endorsed if due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed measures endorsed by consensus organizations and were unable to identify any other measures that assess screening for SDOH and are endorsed by a consensus organization, and therefore, the exception in section 1861(kkk)(7)(C)(ii) of the Act applies.

We note further that the Screening for SDOH measure has been adopted in four other CMS quality reporting programs (Hospital IQR Program, IPFQR Program, PCHQR Program, and ESRD QIP), and that this measure establishes an important foundation to prioritize the achievement of health equity among outpatient settings.

Regarding the commenter's recommendation that we implement measures endorsed by the NQF, we wish to clarify that the CBE is currently Battelle. Battelle administers the PQM in the pre-rulemaking and measure endorsement processes. As previously discussed in section XIV.B.1.c of this final rule with comment period, this measure has been reviewed during the Pre-Rulemaking Measure Review (PRMR) process, where the committee recommended this measure with conditions. We will consider submitting the Screening for SDOH measure to the CBE for endorsement in the future.

Additionally, we note that our approach to developing health equity measures is incremental and intended to evolve over time to capture social drivers of health in the Hospital OQR, REHQR and ASCQR Programs. We will continue to take all concerns, comments, and suggestions into account for any potential future development and expansion of our health equity quality measurement efforts. As with all Hospital OQR, REHQR and ASCQR measures, we will monitor the data and any unintended consequences of the measure as part of standard measure maintenance.

Comment: Several commenters recommended CMS use consistent terminology when describing social risk factors related to health outcomes to ensure consistency with other quality reporting programs and prevent unintended consequences that may negatively impact patients. A few commenters recommended that CMS work with stakeholders to clearly define terms and domains related to this measure to improve processes and data collection.

Response: We thank the commenters for their feedback. HRSNs, which we have previously defined as individual-level, adverse social conditions that negatively impact a person's health or healthcare, are significant risk factors associated with worse health outcomes as well as increased healthcare utilization.[370] As previously mentioned, SDOH is an umbrella term that refers to community-level factors that impact health and well-being, while HRSNs are social and economic needs that individuals experience that affect their ability to maintain their health and well-being.[371] Conceptually, HRSNs exist along a continuum with other equity-related terms—such as ''social determinants of health'' and ''social risk factors''—used to describe upstream factors that can adversely affect the health of individuals and communities. We agree these terms are often conflated and even used interchangeably, and the variety of terms has created both confusion as well as concern, prompting leaders in the field to adopt ''social drivers of health'' instead. In the future, we intend to utilize ''social drivers of health'' terminology to more holistically capture aforementioned and related concepts, while minimizing potential misinterpretation or negative connotation. We thank commenters for their recommendations and will continue identifying opportunities for collaboration with stakeholders to determine the most appropriate terminology for screening for social drivers of health.

[369] Centers for Medicare and Medicaid Services. (2021). Accountable Health Communities Health-Related Social Needs Screening Tool Citation and Notification Information. Available at: *https://www.cms.gov/priorities/innovation/media/document/ahcm-screening-tool-citation.*

[370] Centers for Medicare & Medicaid Services. (2021). A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. Available at: *https://www.cms.gov/priorities/innovation/media/document/ahcm-screeningtool-companion.*

[371] Assistant Secretary for Planning and Evaluation. (November 2023). Call to Action: Addressing Health-Related Social Needs in Communities Across the Nation. Available at: *https://aspe.hhs.gov/sites/default/files/documents/3e2f6140d0087435cc6832bf8cf32618/hhs-call-to-action-health-related-social-needs.pdf.*

Comment: Several commenters expressed concerns regarding the measure specifications for the Screening for SDOH measure and asked for further clarification on the target population (or denominator), frequency of screening, and screening across multiple outpatient care settings.

A commenter was further concerned that some domains will have small denominators that could produce inaccurate or biased results. Another commenter noted that the measure specifications were vague and needed additional clarification. A commenter requested clarification on how entities will verify and confirm that screenings were previously conducted within the reporting period. The commenter recommended allowing screening results to remain valid for 12 months to reduce risk of over-screening.

A few commenters requested clarification on the measure specifications under the Hospital OQR Program. A commenter requested additional clarification on the denominator of the measure as the word ''admitted'' is vague. Another commenter requested clarification on the frequency of screening required under the Hospital OQR Program. A commenter expressed concern that the broad screening policy fails to consider the nuances of screening pediatric patients for the Hospital OQR program. The commenter asked for clarification on the screening and reporting requirements for screening pediatric patients along with members of the household.

Response: We acknowledge commenters' concerns regarding the measure specifications. The target population, or denominator, for the Screening for SDOH measure includes patients who are 18 years or older on the date of service and who are admitted to an HOPD, REH, or ASC. Patients can be excluded from the denominator if they opt-out of screening or are unable to complete the screening and have no legal guardian or caregiver to do so on their behalf during the visit. Additionally, as previously noted, patients receiving services that are limited to specific medical tests are not included in the denominator of this measure. These services include imaging, laboratory, and pharmacy services, which are typically specific types of auxiliary services to a patient's more comprehensive care, where such screenings and referrals should be provided.

In addition, we acknowledge that certain patients will have frequent outpatient visits, such as patients receiving outpatient hospital-based chemotherapy or patients regularly receiving outpatient hospital-based infusions or injections. These patients and other patients frequently admitted to the hospital do not need to be re-screened at every outpatient admission. Rather, after receiving an initial screening, during subsequent visits within the calendar year the patient's provider could confirm the accuracy of their previously reported screening result and provide an opportunity for the patient to update that information as needed. In addition, if a patient has documented SDOH screening results available for review within the patient's medical record or EHR at the time of the outpatient admission, even if the screening occurred outside of the HOPD, REH, or ASC, and these SDOH screening results fall within the same measure performance period year, then these previously captured SDOH Screening results could be included in the outpatient settings' reporting of numerator and denominator data, during the measure's reporting period. In addition, if a patient has multiple admissions during the same performance period, and receives multiple SDOH screenings and has results of each SDOH screening documented, then the most recent result should be submitted.[372] [373] For example, if the patient was screened in May 2025 and then screened again in December 2025, the results of the December 2025 admission would be used for the CY 2025 reporting period.[374] We intend to monitor and evaluate the measure screening requirements, including frequency, in these outpatient settings to ensure balance between quality of care for patients and facility burden.

We thank the commenter for their concern regarding screening pediatric patients in the Hospital OQR Program and note that as outlined in the measure specifications, screening is only required for patients who are admitted to an outpatient facility and who are 18 years or older on the date of admission. If the patient admitted to the HOPD is over 18 years of age and other members of the household are present, only the admitted patient is required to be screened.[375] We note that the measure specifications do not prevent hospitals from screening additional patients at their discretion.

With respect to the commenter's question regarding the use of the word ''admitted'' in the HOPD setting, the term admitted patients refers to a person who receives ambulatory care in these designated settings. We agree that screening for SDOH is most appropriate when administered so that the patient's information can be used by the patient's care team. As we stated in the proposed rule, screening for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety can help identify and provide appropriate referrals for patients who may benefit from greater support in one or more of those areas. As such, we are clarifying that while outpatient care can refer to numerous types of health services, such as emergency department (ED) services, observation services, outpatient surgical services, lab tests, and X-rays, for purposes of this measure in the Hospital OQR Program, REHQR, and ASCQR programs, patients receiving services that are limited to specific medical tests are not included in the denominator cohort. These services include imaging, laboratory, and pharmacy services, which are typically specific types of auxiliary services to a patient's more comprehensive care, where such screenings and referrals should be provided.

For additional information on how to apply and report these screenings, we refer readers to the Hospital IQR Program's FAQ document regarding this measure in the Hospital IQR Program, available at: *https://www.qualityreportingcenter.com/globalassets/2024/04/iqr/17.-sdoh-measure--faqs_april-2024_vfinal508.pdf*. We will develop a similar Frequently Asked Questions document for the Hospital OQR, REHQR and ASCQR Programs as part of providing educational and training materials; this document will be conveyed through routine communication channels.

Comment: A few commenters asked for clarification as to why the five HRSN domains were chosen for screening.

Response: We have prioritized selection of the proposed five HRSN domains based on existing evidence

[372] Centers for Medicare & Medicaid Services. (April 2024). Hospital Quality Reporting Program Frequently Asked Question: Social Drivers of Health (SDOH) Measures. Available at: *https://www.qualityreportingcenter.com/globalassets/2024/04/iqr/17.-sdoh-measure--faqs_april-2024_vfinal508.pdf*.

[373] Measure specifications are posted at *https://qualitynet.cms.gov/outpatient/oqr/proposedmeasures2#tab2* for the Hospital OQR and REHQR Programs, and *https://qualitynet.cms.gov/asc/ascqr/proposedmeasures2#tab2* for the ASCQR Program and may be moved to other pages on QualityNet upon publication of the final rule.

[374] Ibid.

[375] Measure specifications are posted at *https://qualitynet.cms.gov/outpatient/oqr/proposedmeasures2#tab2* for the Hospital OQR and REHQR Programs, and *https://qualitynet.cms.gov/asc/ascqr/proposedmeasures2#tab2* for the ASCQR Program and may be moved to other pages on QualityNet upon publication of the final rule.

from the AHC Model that informed the initial selection, and emerging evidence of correlations between given SDOH and worse health outcomes and SDOH for which interventions have shown marked improvements in health outcomes and healthcare utilization (89 FR 59444).

Comment: A few commenters raised concerns about penalization among healthcare facilities for not complying with the measure requirements. A commenter recommended sensitivity and a formulaic coefficient when evaluating under-resourced ASCs to ensure congruency on quality performance relative to facilities with more resources and adjusting programmatic requirements to ensure that reporting on quality measures is feasible for all facilities and that under-resourced facilities do not face undue difficulty or burdensome penalties that could affect access to care for vulnerable populations.

A commenter expressed concern that mandatory reporting of SDOH data would place undue burden on REHs that could penalize or reduce reimbursement. This commenter recommended to continue with voluntary reporting and avoid linking mandatory reporting to financial penalties or reimbursement reductions.

Response: We thank the commenters for their feedback and acknowledge their concerns. We note that the Hospital OQR and ASCQR Programs are pay-for-reporting programs, and participants are not scored, and do not have their payments affected, based on their performance on measures. The REHQR Program does not include a financial incentive or penalty for REHs. Additionally, we note that as discussed in the CY 2025 OPPS/ASC proposed rule (89 FR 59516 and 59517, 89 FR 59522 and 59523, and 89 FR 59526, respectively) and in sections XXVI.A.c, XXVI.B.c, and XXVI.C.c of this final rule with comment period, we estimate minimal burden of 2 minutes per patient screening and 10 minutes per hospital/facility to report the measure annually.

Comment: A few commenters recommended we ensure alignment with Project Gravity standards and promote interoperability standards for data collection. A commenter recommended we harmonize drivers of health assessment approaches with the National Committee for Quality Assurance (NCQA) to ensure these initiatives that address SDOH in patient assessments are not active performance measures, cause confusion, or waste resources. This commenter also recommended we ensure screening tools are approved by the Social Innovation and Research Evaluation Network (SIREN) and with the Core Quality Measures Collaborative (CQMC) to promote alignment across public and private payers.

Response: We thank the commenters for this feedback. This data collection will inform meaningful and sustainable solutions for other provider types through similar collections in other quality reporting programs. We will continue identifying opportunities for collaboration with other stakeholders to align drivers of health assessment across CMS programs. We commend additional stakeholder efforts currently underway to expand capabilities to capture additional drivers of health data elements, including the Gravity Project.[376] We support harmonization of social risk factor data for interoperable electronic health information exchange that will meet information exchange standards.

We note that this rule finalizes a requirement at § 419.46(j)(1) that hospitals participating in the Hospital OQR Program ''utilize certified technology updated to be consistent with the Office of the National Coordinator for Health Information Technology's health IT certification criteria, as adopted and updated in 45 CFR 170.315,'' which is consistent with ONC's current ''edition-less'' approach to the ONC health IT certification criteria (89 FR 1207). We also note that, for clarity, this finalized requirement differs from our proposal by the removal of an acronym and its replacement by the full agency name. Additionally, many REHs reported under the Medicare Promoting Interoperability and Hospital IQR Programs prior to conversion, and thus are likely to also have EHR systems already embedded in their workflows.

Extraction of structured data from a certified EHR can make the data more accessible for utilization and submission for quality measurement reporting.[377] As previously stated, this rule finalizes a requirement at § 419.46(j)(1) that hospitals participating in the Hospital OQR Program ''utilize certified technology updated to be consistent with the Office of the National Coordinator for Health Information Technology's health IT certification criteria, as adopted and updated in 45 CFR 170.315.'' We encourage use of tools that will meet information exchange standards and facility interoperability. We also encourage providers to identify and utilize tools that rely on standards-based approaches to data collection and utilization to support interoperability of these data.

We agree with the commenter that SIREN is a good resource when selecting a screening tool as it contains descriptions of the content and characteristics of various tools, including information about intended populations, completion time, and number of questions. Another example is the AHC HRSN Screening Tool. The AHC HRSN Screening Tool is a 10-item screening tool, with 16 supplemental questions, to identify patient needs that can be addressed through community services in four domains (economic stability, social and community context, neighborhood and physical environment, and food). Outpatient settings are encouraged to prioritize screening tools that have undergone adequate testing to ensure they are accurate and reliable.

Comment: A few commenters recommended ensuring that screenings are performed in a person-centered way due to the sensitive nature of the screening domains and encouraged educating and building trust with patients as to why this SDOH data is being used and collected. A few commenters encouraged working with stakeholders to ensure different approaches to social needs screening are considered. These commenters recommended developing a database that provides information on the methods and processes that are most effective for HRSN screening.

Response: We thank commenters for their recommendations on screening methods and agree with the importance of conducting person-centered screenings to maintain trust between patients and their providers. We reiterate that healthcare facilities would have the flexibility to customize screening and data collection to their patient populations and individual needs. We encourage HOPDs, REHs, and ASCs to train staff on culturally sensitive engagement and trauma-centered care. We also encourage HOPDs, REHs, and ASCs to ensure that patients feel safe when answering questions and remind patients that they may opt out of the screening for any reason. We note that the measure specifications exclude patients: (1) who opt-out of screening; and (2) are

[376] The Gravity Project. Introducing the Gravity Project. Available at: *https://thegravityproject.net/.*

[377] ONC certification criteria for health IT can be found at 45 CFR 170.315. Please refer to the following for more details on CEHRT requirements: *https://www.cms.gov/medicare/regulations-guidance/promoting-interoperability-programs/certified-ehr-technology.* Please refer to the Measure Calculation section for more details on CEHRT and the HCHE Measure.

themselves unable to complete the screening and have no legal guardian or caregiver able to do so on the patient's behalf (89 FR 59447). Providers are also encouraged to use tools and screening protocols that consider the sensitive nature of the screening domains. We will continue identifying opportunities for collaboration with interested parties to align screening for social drivers of health assessment across CMS programs.

Comment: Many commenters expressed concerns about the risk of over-screening, as patients may receive care in multiple settings and that interoperability challenges prevent access to data collected by other healthcare facilities. These commenters noted that repeated screenings could be burdensome for both staff and patients and distressing for patients who would expect the healthcare facility to address their needs after the screening.

A commenter expressed concern that ASCs are already engaging in facility-appropriate screening efforts to support patients with the social determinants of health and additional screening would be duplicative.

Response: We acknowledge commenter's concerns regarding the risk of over screening and reiterate that HOPD, ASCs, and REHs could confirm the current status of any previously reported HRSNs in another care setting and inquire about others not previously reported in lieu of re-screening a patient for all HRSN domains within the reporting period. This will reduce the burden and time necessary for re-screening a patient for all five HRSN domains. If this information has been captured in the EHR in another outpatient setting or the inpatient setting during the same reporting period, the HOPD, REH, and ASC could include that information in the reporting of numerator and denominator data during the measure's reporting period. Patients should be screened during every admission, but only unique patients should be included in each reporting period (year).[378]

We thank commenters for their questions regarding the technical specifications of the measure. In addition, as we stated in the proposed rule, screening for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety can help identify and provide appropriate referrals for patients who may benefit from greater support in one or more of those areas. As such, we are clarifying that while outpatient care can refer to numerous types of health services, such as emergency department (ED) services, observation services, outpatient surgical services, lab tests, and X-rays, for purposes of this measure in the Hospital OQR Program, REHQR, and ASCQR programs, patients receiving services that are limited to specific medical tests are not included in the denominator cohort. These services include imaging, laboratory, and pharmacy services, which are typically specific types of auxiliary services to a patient's more comprehensive care, where such screenings and referrals should be provided.

We commend ASC efforts currently underway to capture additional drivers of health data elements. As previously stated in the proposed rule, we are allowing healthcare facilities to select their screening tool to reduce burden and in recognition of the fact that some healthcare facilities may already be screening their patients for HRSNs as we recognize the benefits of providing healthcare facilities with flexibility to customize screening and data collection to their patient populations and individual needs (89 FR 59447). We note that while the Screening for SDOH measure requires screening for the five identified HRSNs, ASCs may screen for additional HRSNs that they determine are relevant for their patient population and the community in which they serve. For example, the AHC HRSN Screening Tool includes questions for eight supplemental domains, including financial strain. Furthermore, we note that this measure is a first step towards development of a long-term strategy to integrate social drivers of health and HRSN data into quality performance measurement and is part of our broader commitment to health equity.

Comment: A few commenters that did not support the Screening for SDOH measure expressed concerns regarding patient safety and privacy when conducting screening in small or rural communities. A commenter expressed concern about the increased reliance on quality measures for measuring safety. The commenter noted their belief that safety measures are surrogate measures of harm, subject to variation based on patient populations.

Response: We acknowledge the commenters' concerns and recognize that facilitating quality improvement for rural healthcare facilities can present unique challenges and is a high priority under the Meaningful Measures Framework. One of the potential benefits of screening data will be identification of opportunities to enable meaningful action, including prioritizing and investing in community-based resources that address patients' health-related social needs. We believe that each hospital best understands the patient population they serve and hope that hospitals can discern whether they have existing resources to meet their populations' unmet needs or dedicate further resources for which they know a need exists and now have evidence of the extent that resource allocation is necessary. It is important to use quality measures as a benchmark for identifying best practices in care and to accurately track quality improvement progress.[379] We emphasize that quality measures help to improve the quality of healthcare through an approach that is consistent and holds healthcare facilities accountable.[380]

We also understand the sensitive nature of screening, and that patient safety must remain the HOPD's, REH's, and ASC's principal concern. We encourage all outpatient settings to train staff on culturally sensitive engagement and trauma-centered care and note that there are a variety of methods to screen for HRSNs that increase privacy, including written or digital methods, such electronically through a patient portal or on tablets. We advise HOPDs, REHs, and ASCs to ensure that patients feel safe answering questions and to further remind patients that they may opt out of the screening for any reason. We note that the measure specifications exclude patients: (1) who opt-out of screening; and (2) are themselves unable to complete the screening and have no legal guardian or caregiver able to do so on the patient's behalf (89 FR 59447). We also note that, because these healthcare facilities are covered entities under the HIPAA Privacy and Security Rule (codified at 45 CFR parts 160 and 164),[381] information provided by patients in response to screening for this

[378] Centers for Medicare & Medicaid Services. (April 2024). Hospital Quality Reporting Program Frequently Asked Question: Social Drivers of Health (SDOH) Measures. Available at: *https://www.qualityreportingcenter.com/globalassets/2024/04/iqr/17.-sdoh-measure--faqs_april-2024_vfinal508.pdf.*

[379] Centers for Medicare & Medicaid Services. (2024). Quality Measurement and Quality Improvement. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Quality-Measure-and-Quality-Improvement-#:~:text=Patient%20and%20families%20use%20quality,likelihood%20of%20desired%20health%20outcomes.*

[380] Centers for Medicare & Medicaid Services. (September 2021). Quality Measures: How They Are Developed, Used, & Maintained. Available at: *https://www.cms.gov/sites/default/files/2021-09/Quality-Measures-How-They-Are-Developed-Used-Maintained.pdf.*

[381] For more information on the three HIPAA rules, we refer readers to the HIPAA for Professionals site at: *https://www.hhs.gov/hipaa/for-professionals/index.html.*

measure likely would be PHI.[382] Therefore, these healthcare facilities are responsible for complying with applicable privacy and security requirements under HIPAA and other laws to ensure that patients' PHI is protected and not impermissibly disclosed.

In response to the commenter's concern about the increased reliance on quality measures for measuring safety, it is important to use quality measures as a benchmark for identifying best practices in care and to accurately track quality improvement progress.[383] We emphasize that quality measures help to improve the quality of healthcare through an approach that is consistent and holds healthcare facilities accountable.[384]

Comment: A few commenters that did not support the Screening for SDOH measure expressed concern that the measure does not account for geographic variation in screening. A commenter noted that there exists significant variation in community needs across geographic areas and not accounting for geographic variation of social drivers could be misleading. The commenter recommended using the Vizient Vulnerability Index for benchmarking to address these concerns.

Response: Due to variability across healthcare facilities and the populations they serve, and in alignment with the Hospital IQR Program, we would allow healthcare facilities flexibility with the selection of tools to screen for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety. As we noted in the CY 2025 OPPS/ASC proposed rule (89 FR 59447), one example of a screening tool that healthcare facilities could consider using is the AHC HRSN Screening Tool, which providers used in the AHC Model to screen for HRSNs in their Medicare, Medicaid, and dually eligible beneficiary populations. The AHC HRSN Screening Tool has been tested across many care delivery sites in diverse geographic locations across the United States and demonstrates evidence of both reliability and validity across geographic regions. Moreover, the AHC HRSN Screening Tool can be implemented in a variety of healthcare settings, including HOPDs, REHs, and ASCs. We thank the commenter for their recommendation to utilize the Vizient Vulnerability Index and will take this into consideration as appropriate as we monitor implementation of the Screening for SDOH measure in our quality reporting programs.

Comment: A few commenters recommended combining inpatient and outpatient reporting and noted that this would reduce duplicative efforts.

Response: We thank commenters for their recommendation. As previously stated in the CY 2025 OPPS/ASC proposed rule, the populations represented by the Hospital IQR and Hospital OQR programs are distinct, resulting in a different denominator calculation of the measure for each program (89 FR 59446). Therefore, inpatient and outpatient settings will be unable to accurately report this measure if data are combined for the Hospital IQR and Hospital OQR Programs. We will continue to require a separate data submission for each program in the HQR system.

Comment: A few commenters did not support the Screening for SDOH measure in the ASCQR Program due to the sensitive nature of screening for risk of interpersonal violence. These commenters recommended changes that included removing this domain from the measure specifications and updating the measure to ensure patient privacy when responding to this screening question, either by excluding patients who could not respond to the question confidentially, or by ensuring responses remain hidden in all records and handouts accessible to patients. Additionally, a commenter expressed concerns regarding the cited literature, stating their belief that the discussed pilot study was not representative of the ASC setting. A commenter also stated that CMS's assertion that ASCs already collect data regarding HRSNs is inaccurate.

Response: We have prioritized selection of the proposed five HRSN domains based on existing evidence from the AHC Model that informed the initial selection, and emerging evidence of correlations between given social drivers of health and worse health outcomes and social drivers of health for which interventions have shown marked improvements in health outcomes and healthcare utilization. However, we understand commenters' concerns regarding the sensitive nature of screening for risk of interpersonal violence within the ASC environment and agree that patient safety must remain the ASC's principal concern.

Regarding the interpersonal safety domain and appropriateness of screening in the ASC environment, we note that with a year of voluntary reporting, there is time for ASCs to train staff in the collection of data for HRSNs. Additionally, there are a variety of methods, other than audible methods, to screen for HRSNs that increase privacy, including written or digital methods, including electronically through a patient portal or on tablets. We advise ASCs to ensure that patients feel safe answering questions and to further remind patients that they may opt out of the screening for any reason. We note that the measure specifications as proposed excludes patients: (1) who opt-out of screening; and (2) are themselves unable to complete the screening and have no legal guardian or caregiver able to do so on the patient's behalf (89 FR 59447).

Comment: A commenter expressed concern that the lack of standardization for this measure is not in alignment with the Medicaid and Children's Health Insurance Program (CHIP) data collection standards which require that data collection on race, ethnicity, sex, primary language, and disability status must be standardized. This commenter requested clarification on which aspects of SDOH would be exempt from necessary aggregation due to intrinsic intersection with race, ethnicity, sex, primary language, and disability status. The commenter further noted that if the data collected by a tool developed for this new proposed measure are not applicable or in line with Medicaid and CHIP data standards, it does not align with the first priority of CMS's Health Equity Framework of the ''collection . . . of standardized data . . . across CMS programs''.

Response: We acknowledge the commenter's concern. We will explore opportunities to align with Medicaid and CHIP data collection standards; however, we currently collect race and ethnicity data for chart-abstracted measures, CAHPS surveys, and eCQMs.

After consideration of the public comments we received, we are finalizing the adoption of the Screening for SDOH measure as proposed in the Hospital OQR, REHQR, and ASCQR Programs beginning with voluntary reporting for the CY 2025 reporting period/CY 2027 payment or program determination followed by mandatory reporting beginning with the CY 2026

[382] U.S. Department of Health and Human Services. What is PHI? Available at: *https://www.hhs.gov/answers/hipaa/what-is-phi/index.html.*

[383] Centers for Medicare & Medicaid Services. (2024). Quality Measurement and Quality Improvement. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Quality-Measure-and-Quality-Improvement-#:~:text=Patient%20and%20families%20use%20quality,likelihood%20of%20desired%20health%20outcomes.*

[384] Centers for Medicare & Medicaid Services. (September 2021). Quality Measures: How They Are Developed, Used, & Maintained. Available at: *https://www.cms.gov/sites/default/files/2021-09/Quality-Measures-How-They-Are-Developed-Used-Maintained.pdf.*

reporting period/CY 2028 payment or program determination.

3. Adoption of the Screen Positive Rate for Social Drivers of Health (SDOH) Measure for the Hospital Outpatient Quality Reporting (OQR), Rural Emergency Hospital Quality Reporting (REHQR), and Ambulatory Surgical Center Quality Reporting (ASCQR) Programs Beginning With Voluntary Reporting for the CY 2025 Reporting Period Followed by Mandatory Reporting Beginning With the CY 2026 Reporting Period/CY 2028 Payment or Program Determination

a. Background

In the outpatient setting, we encourage systematic screening of patients' HRSNs to identify patient needs and support improvements in health outcomes. While the Screening for SDOH measure (discussed previously in section XIV.B.2 of this final rule with comment period) identifies individuals with HRSNs, the Screen Positive Rate for SDOH measure estimates the magnitude of these needs for a healthcare facility's patient population served. We believe the adoption of the Screen Positive Rate for SDOH measure would encourage healthcare facilities to track the prevalence of specific HRSNs among patients over time and use the data to stratify risk as part of quality performance improvement efforts.

We proposed that healthcare facilities would be required to report the Screen Positive Rate for SDOH measure as the rate of patients who screened positive for each of the five core HRSNs domains discussed in Table 161: food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.[385]

b. Measure Overview

While the Screening for SDOH measure (discussed in section XIV.B.2 of this final rule with comment period) enables identification of individuals with HRSNs, the Screen Positive Rate for SDOH measure would allow healthcare facilities to capture the magnitude of these needs by requiring healthcare facilities to report the rates of patients who screened positive for each of the five core HRSNs. The Screen Positive Rate for SDOH is a process measure that provides information on the percent of patients receiving care at an HOPD, REH, or ASC, who were 18 years or older on the date of service, who were screened for all five HRSNs described in Table 161, and who screened positive for one or more of those HRSNs. Healthcare facilities would report this measure as five separate rates, one for each of the HRSNs: food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety. This measure is not intended for comparison of screen positive rates of HRSNs between healthcare facilities but is rather to provide transparency in the delivery of care and actionable information to healthcare facilities on the unmet needs among their patients.

c. Pre-Rulemaking Measure Review

As part of the PRMR process, the Hospital Recommendation Group reviewed and voted on the Screen Positive Rate for SDOH measure[386] during their meeting on January 18 and 19, 2024.[387] [388] The committee did not reach the 75 percent vote required to reach a consensus as to its recommendation for the Screen Positive Rate for SDOH measure for the Hospital OQR, REHQR, or ASCQR Programs. The committee expressed a concern about ambiguity in the interpretation of data from the Screen Positive Rate for SDOH measure as well as expectations regarding healthcare facilities. We acknowledge that a high score could be interpreted in different ways but that the objective of this measure is to incentivize collection of these data to help identify patient needs and where resources constraints exist. The committee also discussed a condition specific to the Hospital OQR Program, which was to allow hospitals to report this measure one time each year for both the Hospital IQR Program and Hospital OQR Program.[389] We note that we considered allowing hospitals to report this measure jointly for the Hospital IQR and Hospital OQR Programs (if applicable); however, as the patient populations represented by the programs are different, as is the measure calculation due to this difference in the denominator, we proposed to require a separate data submission for each program.

Further, we have identified the implementation of this measure in the Hospital OQR, REHQR, and ASCQR Programs as an important way to address the health equity measurement gap. We also believe that the information collected from this measure can help HOPDs, REHs, and ASCs understand SDOH needs in their patient population and to devise appropriate interventions. On this basis, we proposed this measure for adoption for all three of our programs.

d. CBE Endorsement

As discussed in section XIV.B.2.d of this final rule with comment period, we find no other feasible and practicable measures set forth by a national consensus building entity on the topic of screening for SDOH. While we recognize the value of measures undergoing CBE endorsement review and prefer to use endorsed measures, there are currently no CBE-endorsed measures that address screening for SDOH in the outpatient setting. Given the urgency of achieving health equity, it is important to implement this measure as soon as possible. We note that the five domains for which patients would be screened were chosen based upon literature review and expert consensus, and that these five domains informed development of the Screen Positive Rate for SDOH measure. We will consider submitting the Screen Positive Rate for SDOH measure to the CBE for endorsement in the future.

e. Data Sources

The data sources for this measure are as described for the Screening for SDOH measure found in section XIV.B.2.e of this final rule with comment period.

f. Measure Calculation

The Screen Positive Rate for SDOH measure is calculated with a numerator and denominator. The numerator is defined as the number of patients receiving care at an HOPD, REH, or ASC who are 18 years or older on the date of admission, who were screened for all five HRSNs described in Table 161, and who screen positive for having a need in one or more of those HRSNs (calculated separately). The denominator is defined as the number of patients receiving care at the HOPD, REH, or ASC who are 18 years or older on the date of admission and are screened for all five HRSNs during their care.

[385] Billioux A, Verlander, K, Anthony S, Alley D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. *NAM Perspectives,* 7(5). *https://doi.org/10.31478/201705b.*

[386] The Screen Positive Rate for SDOH measure is identified on the MUC List as MUC2023–171.

[387] Centers for Medicare & Medicaid Services. List of Measures Under Consideration for December 1, 2023. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[388] Centers for Medicare & Medicaid Services. (December 2023). Overview of the List of Measures Under Consideration. Available at: *https://mmshub.cms.gov/sites/default/files/2023-MUC-List-Overview.pdf.*

[389] Partnership for Quality Measurement. (2023). 2023 Pre-Rulemaking Measure Review (PRMR) Meeting Summary: Hospital Committee. Available at: *https://p4qm.org/sites/default/files/2024-02/PRMR-Hospital-Recommendation-Group-Meeting-Summary-Final.pdf.*

The results of this measure are calculated and reported as five separate rates—one for each HRSN, each calculated with the same denominator. The measure excludes patients who: (1) opt-out of screening; or (2) are themselves unable to complete the screening and have no legal guardian or caregiver able to do so on the patient's behalf.

g. Data Submission and Reporting

While this measure would require healthcare facilities to collect patient-level data on their patients' SDOH screening results, consistent with the Screening for SDOH measure, we proposed to adopt this measure as an aggregate measure in the CY 2025 OPPS/ASC proposed rule. Specifically, we proposed that healthcare facilities would be required to submit aggregated data representing the total numerator results for each of the five screening areas and the total number of patients screened for all five of the HRSNs. We proposed to require aggregate data because we believe it is unnecessary for healthcare facilities to submit data collected at the patient level as this would cause undue burden due to the transfer of large quantities of data. However, in the future, we may consider the reporting of patient-level information. This measure aims to encourage healthcare facilities to screen for and identify HRSNs as it is most important for healthcare facilities to collect this HRSN data to address social needs among their patient populations.

Healthcare facilities would be required to submit information via a CMS-designated information system (currently the HQR system) consistent with the prior adoption of this measure in the Hospital IQR, IPFQR and PCHQR Programs. We refer readers to sections XV.E.2.a, XVI.E.3.b, and XVII.E.2.a of this final rule with comment period for additional details regarding data submission using the CMS-designated information system in the Hospital OQR, REHQR, and ASC Programs, respectively.

As we noted in section XIV.B.3.c of this final rule with comment period, we considered allowing hospitals to report this measure jointly for the Hospital IQR and Hospital OQR Programs; that is, allowing hospitals to submit once under both programs rather than submitting data twice in the HQR system. However, as the populations represented by the programs are different, resulting in different calculations of the measure denominator under each program, we proposed to require a separate data submission for each program.

We proposed to adopt this Screen Positive Rate for SDOH measure beginning with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment or program determination to be consistent with the Screening for SDOH measure. Similar to the Screening for SDOH measure, a voluntary period would allow time for healthcare facilities to select and integrate screening tools into their clinical workflow processes and gain experience with both measures before measure results are publicly displayed on the Compare tool.

We invited public comment on our proposal to adopt the Screen Positive Rate for SDOH measure for the Hospital OQR, REHQR, and ASCQR Programs beginning with voluntary reporting on this measure for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment or program determination, as described above.

Comment: Many commenters supported adoption of the Screen Positive Rate for SDOH measure and CMS's continuing efforts towards measure alignment across the CMS quality reporting programs. Commenters expressed support for hospitals not only tracking who gets screened but also who screens positive as a step toward hospitals developing action plans to address the risk factors identified. Commenters additionally supported the five domains identified as they support a stronger safety net and focus on unmet needs, noting that all five domains affect health and quality of patient lives. Some commenters noted that adoption of the measure will ensure that the practitioners' time conducting the screening is properly reimbursed.

Response: We thank commenters for their support of the Screen Positive Rate for SDOH measure. We agree that HRSNs are critical factors that impact patient outcomes and health equity. By systematically screening for these factors and enabling early interventions, healthcare providers can address the root causes of disparities and encourage a shift toward a healthcare culture that prioritizes proactive intervention and data-driven policy changes to close the gap in health outcomes between different populations.

Comment: A few commenters did not support the Screen Positive Rate for SDOH measure because it was not endorsed by the CBE or because the PQM did not reach consensus for recommending the measure. A few commenters recommended additional testing in the outpatient setting. A few commenters recommended that CMS continue to test these measures through voluntary reporting in the programs where they have already been adopted prior to expanding them into additional quality reporting programs. For ASCs, a commenter noted that the measure cannot be said to meet the requirement for consensus through broad acceptance of the measure by ASCs or through use of the measure by ASCs as ASCs were not involved in the development of the measure.

Response: While we recognize the value of measures undergoing review for potential CBE endorsement, measures of health equity are a priority for CMS, and it is important to implement this measure as soon as possible. For the Hospital OQR and ASCQR Programs, we note that section 1833(t)(17) of the Act does not require that each measure we adopt be CBE-endorsed (76 FR 74494), but states that the Hospital OQR and ASCQR Programs, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities. We reviewed measures endorsed by consensus organizations and were unable to identify any other measures on this topic endorsed by a consensus organization, so the inclusion of such a measure is not feasible or practicable. Section 1833(t)(17)(C)(i) also requires measures included in the Hospital OQR and ASCQR Programs to reflect consensus among affected parties. As we have stated in previous rulemaking (75 FR 72064 and 76 FR 74494), consensus among affected parties can be reflected in ways other than CBE endorsement, including through the measure development process, through broad acceptance and use of the measure(s), and through public comment. The Screen Positive Rate for SDOH measure achieved the aim of consensus among affected parties through its broad use in a number of quality reporting programs, including the Hospital IQR Program (87 FR 49215 through 49220), IPFQR Program (88 FR 51117 through 51121), PCHQR Program (88 FR 59219 through 59222), and ESRD QIP (88 FR 76476 through 76480).

For the REHQR Program, we note that under section 1861(kkk)(7)(C)(ii) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed measures endorsed by consensus organizations and were unable to identify any other measures on this topic endorsed by a consensus organization, and therefore, the

exception in section 1861(kkk)(7)(C)(ii) of the Act applies.

As noted above, the Screen Positive Rate for SDOH measure has been adopted in four other CMS quality reporting programs (Hospital IQR Program, IPFQR Program, PCHQR Program, and ESRD QIP), and this measure establishes an important foundation to prioritize the achievement of health equity among outpatient settings. Additionally, we intend to conduct outreach and education to share information about the Screen Positive Rate for SDOH measure rates in conjunction with public reporting to prevent potential misinterpretation of the measure.

Comment: Several commenters that did not support adoption of the Screen Positive Rate for SDOH measure raised concern with the burden associated with data collection and operational challenges associated with addressing needs identified through screening. A few commenters urged CMS to consider the staff burden and challenges experienced by different provider and facility types. A few commenters expressed concern about the administrative burden this may place on outpatient settings, particularly those that are under resourced, without accompanying reimbursement. A commenter expressed concern about the lag time between reporting or performance periods and reimbursement adjustments. A commenter suggested that CMS adjust programmatic requirements for under-resourced providers to ensure that health equity gaps could feasibly be addressed.

For the ASCQR Program, a few commenters did not support the Screen Positive Rate for SDOH measure and raised concerns about interoperability challenges, noting that a large percentage of ASCs do not have an EHR. Therefore, they noted that those healthcare facilities would have to acquire EHR technology to improve patient care coordination and then turn their attention to SDOH data collection.

Response: We thank commenters for their feedback. We acknowledge commenters' concerns regarding burden; however, achieving health equity is an issue that deserves serious focus and rapid action development. Additionally, as outlined in the CY 2025 OPPS/ASC proposed rule (89 FR 59517, 89 FR 59523, and 89 FR 59527), the estimated burden for HOPDs, REHs, and ASCs to report this measure is estimated to be about 10 minutes annually. Considering this burden estimate is a reasonable expectation for quality data submission, we do not agree it is necessary to provide reimbursements for the time taken to report this measure. We view this measure as a first step towards development of a long-term strategy to integrate social drivers of health data into healthcare facility quality performance measurement as part of our broader commitment to health equity. We will continue to take comments, concerns, and suggestions into consideration as appropriate in any future rulemaking.

Regarding the ASCQR Program, we acknowledge that some ASCs may face challenges adopting EHR technology. We note that the ASCQR Program is a pay-for-reporting program, not a pay-for-performance program, and ASCs that do not have EHR technology can still satisfy reporting of both SDOH measures as the measures does not require an EHR for screening. As noted in the CY 2025 OPPS/ASC proposed rule (89 FR 59447), in alignment with the Hospital IQR Program, we proposed that HOPDs, REHs, and ASCs could confirm the current status of any previously reported HRSNs in another care setting and inquire about others not previously reported, in lieu of re-screening a patient within the reporting period.

We note that this measure was designed to be implemented with or without an EHR. However, we also encourage ASCs to allocate resources towards EHR adoption if they are able. Adoption of EHR technology within ASCs will lead to more positive outcomes, as EHR usage has been shown to have positive impacts on care quality, coordination, efficiency, patient care safety, documentation accuracy, and cost reduction.[390] Although initial EHR adoption has associated costs, it is expected that, over time, ASCs will experience a decrease in financial and operational burden. By purchasing an EHR, an ASC will save costs previously spent on maintaining and managing patient charts.[391] EHRs additionally decrease duplicative testing and interventions. Furthermore, EHRs ensure all required patient information is included in the operative note, leading to accurate reimbursements.[392] We continue to encourage ASCs to consider EHR adoption to streamline documentation of patient health information, including demographic characteristics and social determinants of health, which will support ASCs in collecting and utilizing data to identify critical equity gaps, implementing plans to address these gaps, and ensuring that resources are dedicated toward addressing health equity initiatives.

Comment: A few commenters that did not support adoption of the Screen Positive Rate for SDOH measure expressed the concern that implementation of the measure raised expectations for providers to not only collect SDOH data but also be equipped to aid individuals in finding available community services. Some commenters expressed concern that this measure was not actionable and does not adequately match patients with resources. A few commenters argued the measure was inappropriate for the outpatient setting due to the lack of follow-up with patients. Several commenters expressed concern that small or rural outpatient settings may not have the community resources to assist patients.

For the ASCQR Program, some commenters expressed concern that screenings could erode the provider-patient relationship if SDOHs are assessed, but the provider does not have a robust system in place to address the patient's needs once identified. A commenter expressed concerns with the requirement to screen for interpersonal safety in the context of outpatient surgical care, noting that this could jeopardize patient privacy and carry risk of patient harm.

Response: We thank the commenters for their input. We appreciate the concerns noted and we have given them significant consideration in development of the proposal to adopt the Screen Positive Rate for SDOH measure. Regarding commenters' concerns with regard to potential erosion of the provider-patient relationship in the ASCQR Program, we first note that patients may decline participation, and second, reiterate that the intent of the measure is to promote adoption of HRSN screening by providers as part of a larger long-term strategy to improve patient outcomes and eliminate health equity gaps. As we noted in the CY 2025 OPPS/ASC proposed rule (89 FR 59448), the measure is intended to provide information to providers on the level of unmet social needs among patients served. Initiating data collection remains imperative and such data collection has already allowed some entities to reallocate resources to address HRSNs in disproportionately affected populations. We note this data collection is valuable in the continuing development of the CMS health equity quality measurement efforts and our aims to acknowledge the impact of HRSNs on healthcare access, utilization,

[390] Geier, A., & Smith, D. (2019). The role of electronic documentation in Ambulatory Surgery Centers. AORN Journal, 109(4), 444–450. *https://doi.org/10.1002/aorn.12636.*

[391] Ibid.

[392] Ibid.

outcomes, and costs. The ability of medical providers to contextualize the interaction between HRSNs and poor health outcomes could strengthen referrals to and partnerships with community-based service providers for patients with the most complex needs.

Regarding the interpersonal safety domain and appropriateness of screening in the ASC environment, we note that with a year of voluntary reporting, there is time for ASCs to train staff in the collection of data for HRSNs. Additionally, there are a variety of methods, other than audible methods, to screen for HRSNs that increase privacy, including written or digital methods, and electronically through a patient portal or on tablets. We advise ASCs to ensure that patients feel safe answering questions and to further remind patients that they may opt out of the screening for any reason. We note that the measure specifications as proposed excludes patients: (1) who opt-out of screening; and (2) are themselves unable to complete the screening and have no legal guardian or caregiver able to do so on the patient's behalf (89 FR 59447).

Comment: A few commenters that did not support adoption of the Screen Positive Rate for SDOH measure expressed concern regarding interpretation and potential penalization of measure reporting, especially for REHs. A few commenters expressed concern that the measure is not standardized or validated, potentially leading to inappropriate comparisons among outpatient settings. A few commenters noted that the measure specifications were vague and needed additional clarification. A commenter was also concerned that facilities with higher screen positive rates would be penalized.

For the ASCQR Program, a commenter requested that CMS maintain the measure as voluntary for the ASCQR Program as CMS continues to work through technical reporting challenges, such as publishing guidance on what constitutes a ''positive'' screen, with providers already reporting the measure in other quality reporting programs.

Response: We appreciate the commenters' concerns. The measure is intended to provide information to providers on the level of unmet need among their patients and potentially in the community. To prevent potential misinterpretation of the measure rates, explanatory information will be included for the Screen Positive Rate for SDOH measure rates in conjunction with public reporting. We reiterate that the objective of this measure is to incentivize collection of these data to help identify patient needs and where resources constraints exist and is not intended for comparison between providers. Public reporting of healthcare quality data promotes transparency in the delivery of care by increasing the involvement of leadership in healthcare quality improvement, creating a sense of accountability, helping to focus organizational priorities, and providing a means of delivering important healthcare information to consumers and patient advocates. When the measure rates are publicly reported, the data will be accompanied by detailed explanations to understand what the measure means and how to interpret the rates in the appropriate context.

Reporting a separate screen positive rate for each of the five HRSNs will provide important information to healthcare facilities, the communities that they serve, and policy makers. Because different community-based resources are appropriate to address each of the five HRSNs, reporting each of these rates separately will provide reliable and valid information to identify which communities are most in need of which resources to better enable support in addressing the most prevalent HRSNs. Additionally, as we stated in the CY 2025 OPPS/ASC proposed rule (89 FR 59448), this measure is not for comparison between healthcare facilities. Rather, the objective of this measure is to incentivize collection of these data to help identify patient needs and where resources constraints exist. Moreover, when the measure rates are publicly reported, the data will be accompanied by detailed explanations to understand what the measure means and how to interpret the rates in the appropriate context.

Regarding commenters' concerns that these measures would penalize providers, we remind readers that the Hospital OQR and ASCQR Programs are pay-for-reporting programs. Participants are not scored, and their payments are not affected, based on their performance on measures; participants are only penalized for failure to submit required data on quality measures as specified. Additionally, the REHQR Program does not include a financial incentive or penalty for REHs.

As we noted in the CY 2025 OPPS/ASC proposed rule (89 FR 59447), one example of a screening tool that healthcare facilities could consider using is the AHC HRSN Screening Tool, which providers used in the AHC Model to screen for HRSNs in their Medicare, Medicaid, and dually eligible beneficiary populations. We have tested the AHC HRSN Screening Tool across many care delivery sites in diverse geographic locations and determined that it demonstrates evidence of both reliability and validity. The AHC HRSN Screening Tool can be implemented in a variety of healthcare settings, including HOPDs, REHs, and ASCs. While the AHC Model focused on HRSNs among community-dwelling Medicare and Medicaid beneficiaries, the AHC HRSN Screening Tool can be used to screen patients with any insurance status or type, including commercially insured and uninsured individuals.

We acknowledge that this measure was initially developed for the general acute care setting. While we recognize the value of measures undergoing testing and evaluation of validity and feasibility in the setting for which they are being adopted, given the urgency of achieving health equity, it is important to implement this measure as soon as feasible. We note that health equity is a critical topic for patients and that there are high levels of health disparities experienced by the ASC patient population, for example. Measure specifications are posted at: *https://qualitynet.cms.gov/outpatient/oqr/proposedmeasures2#tab2* and *https://qualitynet.cms.gov/asc/ascqr/proposedmeasures2#tab2* and may be moved to other pages on QualityNet upon publication of the final rule. We will monitor measure implementation and data reporting as part of standard program and measure review and will consider updates to the measure if improvements are identified through this process.

Regarding comments about the ASCQR Program, for additional information on what constitutes a ''positive'' screen, we refer readers to discussion of this measure in section XIV.B.3 of this final rule with comment period and the CY 2025 OPPS/ASC proposed rule (89 FR 59448 through 59449). We also refer readers to a Frequently Asked Questions document for the SDOH measures developed for the Hospital IQR Program, which can be found at: *https://www.qualityreportingcenter.com/globalassets/2024/04/iqr/17.-sdoh-measure--faqs_april-2024_vfinal508.pdf.* We intend to conduct outreach and education to share information about the Screen Positive Rate for SDOH measure rates in conjunction with public reporting. We reiterate that with a year of voluntary reporting, there is time for ASCs to train staff in the collection of data for HRSNs and that there are a variety of methods to screen for HRSNs including electronically through a patient portal or via tablets.

Comment: Several commenters expressed that publicly reporting these data may lead to inaccurate perceptions of the quality of care in outpatient settings, particularly in the absence of any context. A commenter added that interpretation of this measure is difficult. Therefore, these commenters recommend that the measure not be publicly reported and instead be used for organizational quality improvement.

Response: We appreciate the commenters' concerns. The measure is intended to provide information on the level of unmet need among patients and potentially in the community, and not for comparison between healthcare facilities (89 FR 59448). The objective of this measure is to incentivize collection of these data to help identify patient needs and determine where resource constraints exist. Public reporting of healthcare quality data promotes transparency in the delivery of care by increasing the involvement of leadership in healthcare quality improvement, creating a sense of accountability, helping to focus organizational priorities, and providing a means of delivering important healthcare information to consumers and patient advocates. When the measure rates for the Screen Positive Rate for SDOH measure are publicly reported, the data will be accompanied by detailed explanations to understand what the measure means and how to interpret the rates in the appropriate context. We also intend to conduct outreach and education to share information about the Screen Positive Rate for SDOH measure in conjunction with public reporting.

Comment: Several commenters requested that CMS delay mandatory implementation of the measure until the CY 2027 reporting period, with mandatory reporting beginning in CY 2029, which would give providers at least 2 years to build needed infrastructure and community networks, and effectively collect and analyze necessary information without compromising care quality.

For the Hospital OQR Program, a commenter noted that the measure would require significant time for participating hospitals to integrate the data collection and create clinical workflows to capture and improve patient care, particularly if they intend to integrate the measure into the HOPD's EHR system, which is often not the same vendor as what is used in the inpatient setting.

For the ASCQR Program, a commenter noted challenges with the implementation timeline for the Screen Positive Rate for SDOH measure because it does not account for mandatory reporting of the OAS CAHPS Survey measure in the ASCQR Program, which begins in 2025, and would thus not allow sufficient time for work that would need to be done for the Screening for SDOH measure, if it were to include screening for interpersonal safety.

Response: We thank the commenters for their recommendation. Collecting these data will help healthcare facilities improve care coordination and use of community resources to better deliver patient-centered care. The proposed voluntary reporting period provides a sufficient transition period for healthcare facilities to select and integrate screening tools into their clinical workflow processes (89 FR 59448), as we have permitted flexibility in tool selection and have already adopted this measure in other care settings to which these settings may utilize as resources for best practices. Regarding interoperability, we encourage healthcare facilities to configure their health IT in a manner that uses health IT vocabulary standards that enable interoperability of this data across systems. We note that the use of certified health IT that uses standardized exchange protocols and vocabularies can support the capture and exchange of HRSN information in an interoperable fashion, because standards increase the likelihood that facilities use the same encoding and exchange protocols for data transfer. These data can then be shared across the care continuum to support coordinated care.

Regarding the ASCQR Program, we reiterate that with a year of voluntary reporting, there is time for ASCs to train staff in the collection of data for HRSNs and that there are a variety of methods to screen for HRSNs including electronically through a patient portal or via tablets. We will consider feedback about timeline, OAS CAHPS Survey overlap, and reporting as appropriate, in future potential rulemaking, should issues arise as we monitor implementation of this measure in the ASCQR Program.

Comment: A few commenters recommended we facilitate the development of partnerships as well as sharing HRSN information with community health workers and community-based organizations to help patients with basic resource needs. A commenter recommended we ensure alignment with Project Gravity standards and promote interoperability standards for data collection. A commenter recommended harmonization of drivers of health assessment approaches with the National Committee for Quality Assurance (NCQA). The commenter also recommended we ensure screening tools are approved by the Social Innovation and Research Evaluation Network (SIREN) and with the Core Quality Measures Collaborative (CQMC) to promote alignment across public and private payers. A commenter recommended improving the measure's interoperability to avoid administrative burden and duplicative efforts.

Response: We thank the commenters for their recommendations. We are working with our partners to ensure standardization and alignment where possible. The measure aligns with NCQA's Healthcare Effectiveness Data and Information Set (HEDIS®) measure, Social Need Screening and Intervention (SNS–E), by focusing on food insecurity, housing instability, and transportation needs. We also note that the five domains covered by this measure are included within the ''social risk domains'' of the Gravity Project. We also note ongoing reevaluation efforts that aim to improve the Screening for SDOH and Screen Positive Rate for SDOH measures through the development of the Addressing Social Needs (ASN) electronic clinical quality measure (eCQM) for introduction into the Hospital IQR Program and eventually the MIPS and Hospital OQR Programs.[393] As noted in the CY 2025 OPPS/ASC proposed rule (89 FR 59447), we refer readers to evidence based resources like the SIREN website which includes comprehensive information about the most widely used HRSN screening tools. We encourage healthcare facilities to consider digital standardized screening tools. We refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49207 through 49208), where we discuss how the use of certified health information technology (IT), including but not limited to CEHRT, can support capture of HRSN information in a standardized, interoperable fashion. We also encourage healthcare facilities to learn about the United States Core Data for Interoperability (USCDI) standard used in certified health IT and how this standard can support interoperable exchange of health and HRSN assessment data. We wish to reiterate that our approach to developing health equity measures is incremental and will evolve over time to capture health

[393] Centers for Medicare & Medicaid Services. (2023). Addressing Social Needs (ASN) Electronic Clinical Quality Measure (eCQM) Specifications Document for Public Comment. Available at: *https://mmshub.cms.gov/sites/default/files/Yale-CORE-ASN-measure-specs-for-public-comment.pdf.*

equity outcomes and ensure alignment with our partners.

Comment: A few commenters recommended other factors to include in the measure to make it more meaningful, including demographics across communities other than race and ethnicity (such as age, gender, health literacy, etc.), accessibility of services, as well as more granularity in reporting to identify the patients with the greatest need for follow-up referrals or to vary interventions based on patient need. A few commenters urged CMS to evaluate ways to better support providers and community-based organizations in addressing HRSNs, including through Innovation Center model tests and flexibilities in the Medicare statute.

For the ASCQR Program, a few commenters suggested that a measure be developed to assess whether an ASC's quality program addresses equitable care and outcomes for the surgical services provided at the center. A commenter suggested that CMS should develop claims-based measures that evaluate surgical care outcomes stratified by patient characteristics such as race and ethnicity, SES, dual eligibility and other related factors.

Response: We thank the commenters for their recommendations and will take them into consideration as appropriate as we monitor implementation of the Screen Positive Rate for SDOH measure in our quality reporting programs.

After consideration of the public comments we received, we are finalizing the adoption of the Screen Positive Rate for SDOH measure as proposed in the Hospital OQR, REHQR and ASCQR Programs.

C. Modification of the Immediate Measure Removal Policy for the Hospital Outpatient Quality Reporting (OQR) and Ambulatory Surgical Center Quality Reporting (ASCQR) Programs Beginning With CY 2025

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60634 through 60635) and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66967 through 66968), we finalized a process for immediate removal of Hospital OQR and ASCQR Program measures, respectively, based on evidence that the continued use of a measure as specified raises patient safety concerns. We refer readers to our regulations at 42 CFR 419.46(i)(2) for the Hospital OQR Program and 42 CFR 416.320(b) for the ACSQR Program for the codification of these immediate measure removal policies.

When there is evidence that continued use of a measure potentially raises patient safety concerns, we believe that immediate action should be taken to discontinue collection of the measure to not encourage potentially harmful practices. We also believe that seeking public input on the removal of such measures increases the public's voice in decision-making and increases transparency. We noted this in the CY 2024 OPPS/ASC final rule (88 FR 82052), where we finalized an immediate measure suspension policy for the REHQR Program in lieu of an immediate measure removal policy. The REHQR Program's immediate measure suspension policy more appropriately provides that, in cases where we believe that a measure raises patient safety concerns, we will suspend the measure's use in the program, instead of immediately removing the measure, until its potential removal undergoes the standard rulemaking process (88 FR 82052).

We believe that our rationale for finalizing the immediate measure suspension policy in the REHQR Program (88 FR 82052) also applies to the Hospital OQR and ASCQR Programs. On this basis, in the CY 2025 OPPS/ASC proposed rule, we proposed to modify the immediate measure removal policies in the Hospital OQR and ASCQR Programs so that they are more appropriately referred to as immediate measure suspension policies beginning with CY 2025.

Under the proposed immediate measure suspension policy in the Hospital OQR or ASCQR Programs, in cases where we determine there is evidence that the collection and reporting of a measure raises potential patient safety concerns, we would suspend the measure from the program (as applicable) until potential removal can be proposed through the rulemaking process. We will notify the healthcare facility (HOPDs or ASCs, as applicable) and the public of the decision to suspend the measure through standard communication channels, including, but not limited to, program-specific listservs and program guidance currently housed on a CMS-designated website. We would then address the suspension and propose policies regarding any such suspended measure in the next feasible rulemaking cycle.

In the CY 2025 OPPS/ASC proposed rule, we also proposed to revise the Hospital OQR Program regulatory text at § 419.46(i)(2) and the ASCQR Program regulatory text at § 416.320(b) to codify the immediate measure suspension policy. We further proposed to clarify the standard for immediate measure suspension in these regulatory texts by revising references to patient safety concerns raised by ''continued use of a measure as specified'' to patient safety concerns raised by ''collection and reporting activities related to a quality measure''.

We invited public comment on these proposals.

Comment: Several commenters expressed broad support of CMS's proposal to modify the immediate measure removal policy to an immediate measure suspension policy for the Hospital OQR and ASCQR Programs, stating that the revised policy promotes transparency and allows for thorough assessment of a measure prior to its potential removal. A few commenters supported soliciting public input through rulemaking prior to removal, and one commenter specifically noted that this could result in modifications to a measure rather than permanent removal.

Response: We thank commenters for their support of our proposal to immediately suspend a measure, instead of removing it, when potential patient safety concerns arise. As previously noted, we would suspend the use of such a measure until removal, modification, or retention could be proposed and finalized through the rulemaking process. We agree with the commenters that this revised policy would enhance transparency and increase public involvement in decision-making regarding permanent action for suspended measures.

Comment: A commenter supported finalizing the immediate measure suspension policy for the ASCQR Program, stating their belief that the proposed policy will help address potential safety concerns associated with screening for interpersonal safety as part of the Screening for SDOH measure.

Response: We thank the commenter for their support of our proposal, and we acknowledge their concern regarding possible patient safety issues with the Screening for SDOH measure. We will monitor the impacts of this measure on patient safety, as we do with all measures, and in cases where we determine there is evidence that the collection and reporting of a measure raises patient safety concerns, we will suspend the measure from the program (as applicable) until potential removal can be proposed through the rulemaking process.

Comment: A commenter did not support the proposal and urged CMS to utilize the rulemaking process prior to suspending a measure. If the proposal is finalized, the commenter urged CMS to limit suspension to public reporting while continuing data collection and measure calculation to assess whether a

lack of transparency results in diminished performance for the measure. Additionally, the commenter suggested that CMS focus on improving and developing measures rather than removing them.

Response: We thank the commenter for their feedback. However, we note that patient safety is a high priority area, as underscored by our National Quality Strategy goal to achieve zero preventable harm. When a measure raises potential patient safety concerns, immediate action must be taken to halt data collection and reporting activities. Limiting the suspension to public reporting alone would not accomplish our objective of preventing patient harm. Public reporting does not occur until after the performance period, whereas data collection is continuous. Immediate suspension of both data collection and reporting ensures that potentially harmful actions do not continue in between rulemaking periods and that appropriate modification or removal can then be proposed and finalized in a subsequent rulemaking cycle. We acknowledge the commenter's recommendation to assess whether a lack of transparency results in diminished performance. However, when a measure presents a potential safety risk, the priority is eliminating any risks to patient harm.

While we agree that the Hospital OQR and ASCQR Programs should prioritize retaining and adopting meaningful, high-quality measures, patient safety is an urgent issue and measures that result in potential safety risks should be thoroughly evaluated and considered for potential removal or modification from the programs. This approach allows us to safeguard patients while still ensuring transparency and public participation in decision-making.

We also reiterate that this is an amendment to a currently adopted policy in which a measure is immediately removed if there are patient safety concerns. This revised policy would allow for appropriate modification or retention of a measure over removal, thus supporting the preservation of a measure set that ensures safe, quality care.

Comment: A commenter recommended that once a measure is suspended, hospitals should not be penalized for non-compliance with the requirements of the suspended measure in the subsequent payment determination year. Another commenter suggested expanding the immediate measure suspension policy to the REHQR Program.

Response: We appreciate the commenters' feedback, and we wish to clarify that, under the immediate measure suspension policy we proposed, once a measure is suspended, data collection and reporting would cease until permanent action could be determined in a subsequent rulemaking cycle. Entities would not be penalized for non-compliance with the suspended measure as the requirement to collect and report data would not be in effect. This approach ensures that any potentially harmful actions related to the measure are halted until permanent action regarding the suspended measure is determined. We also wish to clarify that this policy was previously finalized for the REHQR Program in the CY 2024 OPPS/ASC final rule (88 FR 82052).

After consideration of the public comments we received, we are finalizing immediate measure suspension policies for the Hospital OQR and ASCQR Programs, as proposed. We are codifying these policies at § 419.46(i)(2) for the Hospital OQR Program and at § 416.320(b) for the ASCQR Program, as proposed.

XV. Hospital Outpatient Quality Reporting (OQR) Program

A. Background and Statutory Authority

The Hospital Outpatient Quality Reporting (OQR) Program is a pay-for-reporting program intended to improve the quality of care provided to Medicare beneficiaries, facilitate public transparency, and ensure accountability of hospital outpatient departments (HOPDs). Section 1833(t)(17)(A) of the Social Security Act (the Act) states that subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act) that do not submit data required for measures selected with respect to such a year, in the form and manner required by the Secretary, will incur a 2.0 percentage point reduction to their annual Outpatient Department (OPD) fee schedule increase factor.

We refer readers to the CY 2011 OPPS/ASC final rule (75 FR 72064 through 72065) for a detailed discussion of the statutory history of the Hospital OQR Program, as well as program requirements codified at 42 CFR 419.46, and to the CY 2024 OPPS/ASC final rule for information regarding the program's regulatory history (88 FR 81961 through 82012).

1. Previously Finalized Program Measure Set Beginning With the CY 2027 Payment Determination

Table 162 summarizes the previously finalized Hospital OQR Program measures beginning with the CY 2027 payment determination:

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TABLE 162: PREVIOUSLY FINALIZED HOSPITAL OQR PROGRAM MEASURE SET BEGINNING WITH THE CY 2027 PAYMENT DETERMINATION

CBE #	Measure Name
None	Abdomen Computed Tomography (CT) – Use of Contrast Material
3490	Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
0658	Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
None	Breast Cancer Screening Recall Rates
None†	Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery
None†	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery*
3636	COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP)
3663e	Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults electronic clinical quality measure (Excessive Radiation eCQM)**
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy
0661	Head CT or Magnetic Resonance Imaging (MRI) Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival
None†	Left Without Being Seen
None†	MRI Lumbar Spine for Low Back Pain
None†	Median Time from ED Arrival to ED Departure for Discharged ED Patients
None	Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS)
2687	Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery
None	Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the HOPD Setting (THA/TKA PRO–PM)***
None	ST-Segment Elevation Myocardial Infarction (STEMI) eCQM

†Measure is no longer endorsed by the Consensus Based Entity (CBE) but was endorsed previously.
*This measure is voluntary.
**This measure begins with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2029 payment determination, as discussed in the CY 2024 OPPS/ASC final rule (88 FR 81988 through 81992).
***This measure begins with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2028 reporting period/CY 2031 payment determination, as discussed in the CY 2024 OPPS/ASC final rule (88 FR 81984 through 81986).

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B. Program Measure Set Policies

1. Measure Retention

We refer readers to § 419.46(i)(1) and the CY 2013 OPPS/ASC final rule (77 FR 68471) for our policies regarding measure retention. We did not propose any changes to these policies in the CY 2025 OPPS/ASC proposed rule.

2. Measure Suspension or Removal

We refer readers to § 419.46(i)(2) and (3) and the CY 2013 OPPS/ASC final rule (77 FR 68472 and 68473) for our program policies regarding: (1) general measure removal, suspension, and replacement; and (2) immediate measure removal.

We refer readers to section XIV.C of this final rule with comment period for the discussion of public comments received and our subsequent decision regarding our cross-program proposal to modify the immediate removal policy for adopted Hospital OQR Program measures.

3. Measure Adoption

We refer readers to the CY 2024 OPPS/ASC final rule with comment period (88 FR 81973) for a discussion of the statutory requirements and our considerations for adopting quality measures under the Hospital OQR Program. We did not propose any changes to these policies in the CY 2025 OPPS/ASC proposed rule.

C. Program Measure Updates

1. Adoption of New Measures for the Hospital OQR Program Measure Set

a. Adoption of the Health Equity Measures in the Hospital OQR Program

We refer readers to sections XIV.B.1, XIV.B.2, and XIV.B.3 of the final rule with comment period, respectively, for our cross-program proposals and discussion of public comments received to adopt the following measures in the Hospital OQR Program: (1) the Hospital Commitment to Health Equity (HCHE) measure, beginning with the CY 2025 reporting period/CY 2027 payment determination; (2) the Screening for Social Drivers of Health (SDOH) measure, beginning with voluntary reporting for the CY 2025 reporting

period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; and (3) the Screen Positive Rate for SDOH measure, beginning with voluntary reporting for the CY 2025 reporting period and mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination.

b. Adoption of the Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery Patient Reported Outcome-Based Performance Measure (Information Transfer PRO–PM) Beginning With Voluntary Reporting for the CY 2026 Reporting Period Followed by Mandatory Reporting Beginning With the CY 2027 Reporting Period/CY 2029 Payment Determination

(1) Background

Recent studies have shown that compared to inpatient settings, outpatient settings are associated with worse patient understanding and lower patient activation (that is, an individual's understanding, competence, and willingness to participate in care decisions during their recovery), indicating an area for quality of care improvement.[394] [395] [396] One study found that providers in the inpatient setting provided more complete discharge instructions and end-of-visit summaries to patients when compared to providers in the ambulatory setting, including continuing medication names and instructions (96 percent vs. 40 percent), new medication names and instructions (99 percent vs. 29 percent), and pending diagnostic test names and instructions (90 percent vs. 61 percent).[397] A lack of understanding of recovery information [398] and other aspects of health literacy have been linked to poor adherence to treatment, decreased patient safety, increased return to the emergency department (ED), lower levels of patient satisfaction, and disproportionate effects on patients with limited English proficiency and patients over age 65, who face additional barriers and recovery issues after their receipt of a hospital outpatient service.[399] [400] Reduced patient engagement and a deficiency in detailed discharge information in the inpatient setting were also associated with a higher risk of readmissions to an inpatient setting.[401] Research indicates that information that is simpler to read and more complete has been associated with fewer follow-up calls to providers as well as less frequent hospital readmissions.[402] [403]

(2) Measure Overview

The Information Transfer PRO–PM aims to assess the level of clear, personalized recovery information provided to patients aged 18-years or older who had surgery or a procedure at an HOPD. The measure reports the average score of a patient's ratings on a three-domain, 9-item survey [404] to evaluate the clarity of the clinical information patients are given before, during, and after an outpatient surgery or procedure. The survey covers three domains for patients or their caregivers to rate the clarity of information received regarding their post-discharge [405] recovery: applicability to patient needs, medication, and daily activities. The applicability to patient needs domain assesses whether the recovery information considered a patient's health needs and personal circumstances. The medications domain examines the clarity of medication information provided, specifically guidance on taking new medications, potential side effects, and discontinuing medication. The daily activities domain assesses the clarity of guidelines around diet, physical activity, returning to work, and driving. Results from the survey provide hospitals with patient reported outcome (PRO) data designed to assess communication efforts and enable hospitals to reduce the risk of patient harm that may occur if the patient does not fully understand the recovery information.

This measure addresses the priority area stated in our Meaningful Measures Framework of adopting high-quality measures that focus on person-centered care.[406] Additionally, the Information Transfer PRO–PM supports the National Quality Strategy goal of equity and engagement by engaging individuals to become partners in their care and ensuring that individuals and caregivers have the information needed to make the best choices for their health.[407]

Pilot testing conducted by the measure developer in 26 HOPDs in five states demonstrated that the measure is reliable and meaningful.[408] [409] The measure developer assessed reliability of the measure using the Cronbach alpha score [410] to determine whether the nine survey questions reliably measured the same underlying characteristic; that is, the clarity and applicability of recovery instructions. The Cronbach alpha score, which compares the amount of shared variance, or covariance, among the instrument items

[394] Kang E, Gillespie BM, Tobiano G, et al. (2018). Discharge education delivered to general surgical patients in their management of recovery post discharge: A systematic mixed studies review. Int J Nurs Stud. 87:1–13. *https://doi.org/10.1016/j.ijnurstu.2018.07.004*.

[395] Hoek AE, Anker SCP, van Beeck EF, et al. (2020). Patient Discharge Instructions in the Emergency Department and Their Effects on Comprehension and Recall of Discharge Instructions: A Systematic Review and Meta-analysis. Ann Emerg Med. 75(3):435–444. *https://doi.org/10.1016/j.annemergmed.2019.06.008*.

[396] Downey E, Olds DM. (2021). Comparison of Documentation on Inpatient Discharge and Ambulatory End-of-Visit Summaries. J Healthc Qual. 43(3):e43–e52. *https://doi.org/10.1097/JHQ.0000000000000269*.

[397] Ibid.

[398] We use the term ''recovery information'' to mean the clinical care instructions provided to patients or their caregivers after the completion of surgery or a non-surgical procedure.

[399] DeSai C, Janowiak K, Secheli B, et al. (2021). Empowering patients: simplifying discharge instructions. BMJ Open Quality;10(3)001419. *http://doi.org/10.1136/bmjoq-2021-001419*.

[400] Malevanchik L., Wheeler M., Gagliardi K., Karliner L., Shah S.J. (2021). Disparities After Discharge: The Association of Limited English Proficiency and Postdischarge Patient-Reported Issues, The Joint Commission Journal on Quality and Patient Safety, 47(12):775–782. *https://doi.org/10.1016/j.jcjq.2021.08.013*.

[401] Erlang AS, Schjødt K, Linde JKS, Jensen AL. (2021). An observational study of older patients' experiences of involvement in discharge planning. Geriatr Nurs 42(4):855–862. *http://doi.org/10.1016/j.gerinurse.2021.04.002*.

[402] Choudhry AJ, Younis M, Ray-Zack MD, et al. (2019). Enhanced readability of discharge summaries decreases provider telephone calls and patient readmissions in the posthospital setting. Surgery. 165(4):789–794. *https://doi.org/10.1016/j.surg.2018.10.014*.

[403] Mitchell JP. (2015). Association of provider communication and discharge instructions on lower readmissions. J Healthc Qual., 37(1):33–40. *https://doi.org/10.1097/01.JHQ.0000460126.88382.13*.

[404] A copy of the survey instrument is available at: *https://www.cms.gov/files/document/patient-understanding-key-information-related-recovery-after-facility-based-outpatient-procedure-or.pdf*.

[405] The term ''discharge'' appears in the measure specifications and is intended to refer to the transition of a patient from the outpatient hospital setting to home or next level of care.

[406] Centers for Medicare & Medicaid Services. (2024). Meaningful Measures 2.0: Moving to Measure Prioritization and Modernization. Available at: *https://www.cms.gov/medicare/quality/cms-national-quality-strategy/meaningful-measures-20-moving-measure-reduction-modernization#:~:text=Meaningful%20Measures%202.0%20promotes%20innovation%20and%20modernization%20of,variety%20of%20settings%2C%20intereste*.

[407] Centers for Medicare & Medicaid Services. (2024). CMS Quality Strategy. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy*.

[408] Partnership for Quality Measurement. (2024). 2023 Pre-Rulemaking Measure Review (PRMR) Meeting Summary: Hospital Committee. Available at: *https://p4qm.org/sites/default/files/2024-02/PRMR-Hospital-Recommendation-Group-Meeting-Summary-Final.pdf*.

[409] Partnership for Quality Measurement. Submission Tool and Repository Measure Database. *https://p4qm.org/measures/4210*.

[410] For more information on what the Cronbach alpha score determines and how it is used, we refer readers to: Tavakol M & Dennick R. (2011). Making sense of Cronbach's alpha. Int J Med Educ. 27;2: 53–55. *www.doi.org/10.5116/ijme.4dfb.8dfd*.

to the total variance, indicated that the survey items are reliable because they reflect a high level of covariance relative to the total variance.[411] Additionally, the measure developer found the performance scores among facilities in the pilot study to be moderately reliable using a signal-to-noise ratio, which estimated variance among facilities and facility specific errors to determine the extent to which variance in facility scores can be attributed to variance in actual performance.[412]

To assess meaningfulness, the measure developer asked members of a Patient and Family Engagement (PFE) Work Group and a Technical Expert Panel (TEP) to vote on the measure's ability to distinguish between good and poor quality of care at measured facilities.[413] [414] All of the patients from the PFE Work Group and 80 percent of the TEP panel members who participated in the vote agreed that the measure could distinguish between good and poor quality of care.[415] We refer readers to *https://p4qm.org/measures/4210* for more information about the feasibility, scientific acceptability, meaningfulness, and validity of the Information Transfer PRO–PM.

As previously stated in the CY 2024 OPPS/ASC final rule (88 FR 81985), while we acknowledge that PRO–PMs require providers to integrate data collection into clinical information systems, this integration provides an important opportunity for patient-reported outcomes to inform clinical decision-making and benefits patients by engaging them in discussions about potential outcomes. The testing of this measure by the measure developer, which included interviews with clinicians, nurses, quality improvement officers, and data administrators in HOPDs, indicated that the increased burden on HOPDs would be minimal because the data would be collected and reported electronically by administrative staff and quality officers engaged in data sharing activities, outside of the clinical workflow, before being integrated into a clinical information system. Additionally, testing indicated that the increased burden on respondents would be minimal and contribute minimally to patient survey fatigue because the survey is easily understood and consists of only nine questions administered electronically,[416] presenting a low burden for completion.

(3) Pre-Rulemaking Measure Review

Under the PRMR process, the Hospital Recommendation Group reviewed and voted on the Information Transfer PRO–PM [417] during their meeting on January 18–19, 2024.[418] The voting results for the Information Transfer PRO–PM measure for the Hospital OQR Program were ''recommend with conditions''. The condition was that the survey be administered at the time of the surgery or procedure so there is no conflict with other measured pain and function outcomes to improve response rates.[419] We have taken into account the condition to administer the survey at the time of the surgery or procedure; however, we have determined that allowing time after the surgery or procedure before administration of the survey is important to limit the possibility that the patient's responses are influenced by time-dependent variables related to proximity to the surgery or procedure, such as medications that could affect comprehension, fatigue, or acute pain. In addition, administering the survey more than 1 day but less than 7 days post-procedure mitigates overlap of the initial administration and survey reminder of the OAS CAHPS, which is administered on the first day post-procedure and then followed up at 14 days.[420]

(4) CBE Endorsement

We submitted the Information Transfer PRO–PM to the CBE for endorsement review in the Fall 2023 cycle (CBE #4210), and the CBE endorsed the measure on March 18, 2024.[421]

(5) Data Collection, Submission, and Reporting

(a) Data Collection

(i) Data Sources

In the CY 2025 OPPS/ASC proposed rule (89 FR 59453 through 59454), we proposed that the Information Transfer PRO–PM would be calculated based on PRO data collected by HOPDs directly or through their authorized third-party vendors through a web-based survey instrument distributed to patients or their caregivers.

[411] Ibid.

[412] Partnership for Quality Measurement. Submission Tool and Repository Measure Database. *https://p4qm.org/measures/4210*.

[413] Partnership for Quality Measurement. 2023 Pre-Rulemaking Measure Review (PRMR) Meeting Summary: Hospital Committee. Available at: *https://p4qm.org/sites/default/files/2024-02/PRMR-Hospital-Recommendation-Group-Meeting-Summary-Final.pdf*.

[414] See also *https://www.cms.gov/medicare/quality/initiatives/hospital-quality-initiative/measure-methodology*.

[415] Ibid.

[416] Examples of survey administration and collection include email, text, and patient information portals. These examples are not exhaustive. By leaving the method of survey administration and collection to the HOPD, we allow facilities the flexibility to choose the most appropriate method for their current infrastructure and patient base.

[417] The Information Transfer PRO–PM is identified on the MUC List as MUC2023–17.

[418] Partnership for Quality Measurement. (2024). 2023 Pre-Rulemaking Measure Review (PRMR) Meeting Summary: Hospital Committee. Available at: *https://p4qm.org/sites/default/files/2024-02/PRMR-Hospital-Recommendation-Group-Meeting-Summary-Final.pdf*.

[419] Ibid.

[420] Centers for Medicare and Medicaid Services. Schedule of OAS CAHPs Contact Attempts by Survey Mode. Available at: *https://oascahps.org/ScheduleOASCAHPSContactAttempts_7-20-21.pdf*.

[421] Partnership for Quality Measurement. Submission Tool and Repository Measure Database. *https://p4qm.org/measures/4210*.

We also proposed that the survey would be administered 2-to-7 days post-procedure or surgery, based on evidence that the most common time period for patients to be delivered a survey is within 0–48 hours post-procedure or surgery at a HOPD (n=6),[422] [423] [424] [425] [426] [427] while other time periods include within 2 weeks post-procedure or surgery (n=4),[428] [429] [430] [431] 1 week post-procedure or surgery, (n=3) [432] [433] [434] or 90 days post-procedure or surgery (n=1).[435] We proposed that the survey would be administered not less than 2 days post-procedure or surgery because we have determined, as discussed above, that allowing time after the surgery or procedure before administration of the survey will limit the possibility that the patient's responses are influenced by time-dependent variables related to proximity to the surgery or procedure, such as medications that could affect comprehension, fatigue, or acute pain. We proposed that the survey would be administered no later than 7 days post-procedure or surgery because this timeframe may be more appropriate for patient reporting of specific events than longer time periods.[436] [437] In pilot testing, patients were sent a reminder to complete the survey 7 days after receipt. The survey remained open until pilot testing was completed, with the mean length of time between the procedure date to the survey response date being 65 days, or approximately 2 months. We therefore proposed a 65-day window for patient response.

The survey has been tested and reliability determined in English and Spanish, and the survey can be completed using a translator, proxy, or caregiver.

(ii) Measure Specifications

The measure numerator is the sum of all individual scores a HOPD receives from eligible respondents, which could be patients or caregivers. Individual scores are calculated using a top-box approach; each individual score is calculated for each respondent by taking the sum of items for which the respondent gave the most positive response (''Yes'' or ''Very Clear'') and dividing by the number of items the respondent deemed applicable to their procedure or surgery. Applicable items are calculated by subtracting the sum of items for which the respondent selected ''Does not apply'' from the total number of survey items (nine).[438]

The measure denominator is the total number of patients 18 years or older who had a procedure or surgery in an HOPD, left the HOPD alive, and responded to the survey.[439] [440] Only fully completed surveys are included in the measure calculation.

The intent of the measure is to encourage HOPDs to provide individualized recovery instructions regardless of the patient's unique characteristics; therefore, there is no need for risk-adjustment. For additional details regarding the measure specifications, we refer readers to our QualityNet website.[441]

(b) Data Submission and Reporting

In the CY 2025 OPPS/ASC proposed rule (89 FR 59492 through 59454), we proposed to adopt the Information Transfer PRO–PM as a voluntary measure for the CY 2026 reporting period followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2029 payment determination. We would utilize the voluntary period to monitor the implementation and operationalization of the measure.

We refer readers to section XV.E.2.c of this final rule with comment period for a discussion of the Information Transfer PRO–PM form, manner, and timing of data submission and reporting requirements.

We invited public comment on the proposal.

Comment: Many commenters supported adopting the Information Transfer PRO–PM into the Hospital OQR Program. Commenters noted that this measure addresses an important measurement area (care coordination) and is an effective means of collecting patient experience data. A few of these commenters noted the importance of patients receiving clear, personalized recovery information and engaging in a shared decision-making process with their healthcare provider. A few commenters further emphasized that this measure may increase patient satisfaction and trust in their healthcare providers, as patients feel more informed and supported during their recovery. Commenters also stated that this measure can provide valuable feedback to clinicians about their communication practices, highlighting areas for improvement. A commenter applauded CMS for including caregivers as eligible respondents for providing survey feedback, stating that caregivers play a vital role in a patient's post-procedure care. Another commenter expressed gratitude for the time CMS has allotted for hospitals to implement this measure.

Response: We thank commenters for their support. We agree that this measure addresses an important measurement area (care coordination) and is an effective means of collecting patient experience data. We agree with

[422] Engel KG, Buckley BA, Forth VE, et al. (2012). Patient understanding of emergency department discharge instructions: where are knowledge deficits greatest? *Acad Emerg Med.* 19(9):E1035–1044.

[423] Engel KG, Heisler M, Smith DM, Robinson CH, Forman JH, Ubel PA. (2009). Patient comprehension of emergency department care and instructions: are patients aware of when they do not understand? *Ann Emerg Med.* 53(4):454–461 e415.

[424] Erlang AS, Schjodt K, Linde JKS, Jensen AL. (2021). An observational study of older patients' experiences of involvement in discharge planning. *Geriatr Nurs.* 42(4):855–862.

[425] Lin MJ, Tirosh AG, Landry A. (2015). Examining patient comprehension of emergency department discharge instructions: Who says they understand when they do not? *Intern Emerg Med.* 10(8):993–1002.

[426] Makaryus AN, Friedman EA. (2005). Patients' understanding of their treatment plans and diagnosis at discharge. *Mayo Clin Proc.* 80(8):991–994.

[427] Hastings S, Stechuchak K, Oddone E, et al. (2012). Older veterans and emergency department discharge information. *BMJ Qual Saf.* 21(10):835–842.

[428] Clarke C, Friedman SM, Shi K, Arenovich T, Monzon J, Culligan C. (2005). Emergency department discharge instructions comprehension and compliance study. *CJEM.* 7(1):5–11.

[429] Henderson A, Zernike W. A study of the impact of discharge information for surgical patients. (2001). *J Adv Nurs.* 35(3):435–441.

[430] Karliner LS, Auerbach A, Napoles A, Schillinger D, Nickleach D, Perez-Stable EJ. (2012). Language barriers and understanding of hospital discharge instructions. *Med Care.* 50(4):283–289.

[431] Makaryus AN, Friedman EA. (2005). Patients' understanding of their treatment plans and diagnosis at discharge. *Mayo Clin PRac.* 80(8):991–994.

[432] Albrecht JS, Gruber-Baldini AL, Hirshon JM, et al. (2014). Hospital discharge instructions: comprehension and compliance among older adults. *J Gen Intern Med.* 29(11):1491–1498.

[433] Coleman EA, Chugh A, Williams MV, et al. (2013). Understanding and execution of discharge instructions. *AM J Med Qual.* 28(5):383–391.

[434] Flacker J, Park W. Sims A. (2007). Hospital discharge information and older patients; do they get what they need? *J Hosp Med.* 2(5):291–296.

[435] Hastings SN, Barrett A, Weinberger M, et al. (2011). Older patients' understanding of emergency department discharge information and its relationship with adverse outcomes. *J Patient Saf.* 7(1):19–25.

[436] Stull, D, Leidy, N, Parasuraman, B, et al. (2009). Optimal recall periods for patient-reported outcomes: Challenges and potential solutions. Current medical research and opinion. 25. 929–42. *www.doi.org/10.1185/03007990902774765.*

[437] Peasgood T, Caruana JM, Mukuria C. (2023). Systematic Review of the Effect of a One-Day Versus Seven-Day Recall Duration on Patient Reported Outcome Measures (PROMs). Patient. 16(3):201–221. *www.doi.org/10.1007/s40271-022-00611-w.*

[438] Partnership for Quality Measurement. Submission Tool and Repository Measure Database. *https://p4qm.org/measures/4210.*

[439] Surveys could be completed by patient or a caregiver.

[440] Partnership for Quality Measurement. Submission Tool and Repository Measure Database. *https://p4qm.org/measures/4210.*

[441] The specifications for the newly finalized OQR Program measures can be found at *https://qualitynet.cms.gov/outpatient.*

commenters that this measure can provide valuable feedback to clinicians about their communication practices and highlight areas of needed improvement.

Comment: A few commenters supported CMS' proposal and noted that the measure is CBE-endorsed and tested, showing moderate reliability and a reliable Cronbach alpha score.

Response: We thank commenters for their support.

Comment: Several commenters supported CMS' proposal to adopt the Information Transfer PRO–PM citing evidence that poor recovery instructions result in poor outcomes, such as mortality and readmissions. A few of these commenters noted that clear communication between healthcare providers and patients regarding post-procedure recovery is crucial to ensure positive health outcomes and fewer readmissions. A commenter noted that many older patients being discharged from surgery experience post-operative cognitive dysfunction (POCD), which, when added to possible limited English proficiency, literacy, or pre-existing vision or cognitive concerns, can significantly impact a patient's ability to understand and follow post-operative recommendations without additional intervention and instruction. Further, this commenter noted that post-surgical instructions received by occupational therapy (OT) clinics are often incomplete, missing, or confusing to the patient and the OT practitioner, forcing the practitioner to seek additional clarification resulting in delay in care initiation and increased risk of re-injury.

Response: We thank commenters for their support. We agree that clear communication between healthcare providers and patients is crucial to ensure positive health outcomes and fewer readmissions. We further thank commenters for their feedback of how poor post-procedure instructions to patients could adversely impact their ability to receive proper and timely post-procedure care such as physical or occupational therapy.

Comment: A commenter supported CMS' use of PRO–PMs in quality reporting programs because PRO–PMs provide valuable insights into patients' perspectives on their health, quality of life, and functional status. This commenter further noted that PRO–PMs are especially important in the outpatient setting where procedures and patients are typically less complex compared to the inpatient setting. The commenter noted that PRO–PMs offer every patient an opportunity to provide direct feedback about their care, which is valuable when this feedback is typically collected only when measuring a rare or adverse event.

Response: We thank the commenter for their support of the use of PRO–PMs.

Comment: Several commenters expressed concerns with CMS' proposal to adopt the Information Transfer PRO–PM due to the burden on HOPDs to implement the PRO–PM. Commenters expressed concern regarding the challenge of integrating surveys into provider workflows. Commenters expressed concern that HOPDs are currently facing staffing challenges and resource constraints. Commenters stated that the burden of implementing this measure is greater than CMS indicated in the proposed rule and does not account for a facility's time spent strategizing, reviewing and updating policies, building the technology, training staff, and implementing change management processes required for new measures. A commenter expressed concern that the cost of programming the measure into health information technology may not be minimal because the survey would have to be set up as a stand-alone survey instead of being grafted onto an already existing survey, such as OAS CAHPS, and the potential cost of the initial programming and implementation is not acknowledged in the proposed rule. Another commenter expressed concern that ensuring consistency in communication, so all patients receive the same quality and clarity of recovery information, can also be challenging, especially in busy hospital outpatient departments.

Response: We acknowledge that collecting PRO–PM data may involve more burden and initial implementation resources compared to some other types of quality measures. However, we believe the benefit of collecting direct functional improvement information from the patients outweighs the burden. Measuring patient-reported outcomes is an important aspect of patient-centered healthcare and we continue to emphasize, as highlighted in our Meaningful Measures 2.0 Framework, that the patient voice should be elevated across the healthcare system. As also discussed in a recent request for information related to guiding principles for patient-reported outcome measures in Federal models and quality reporting and payment programs, patient-reported outcomes, as captured using PRO–PMs, are critical for the support of person-centered care, as they provide information from the patient or caregiver perspective and offer important information to improve patient-provider communications (89 FR 62043 through 62044).

As we stated in the CY 2024 OPPS/ASC proposed rule (89 FR 59518), we estimate that annually each HOPD would spend 10 minutes (0.167 hours) per response to report the Information Transfer PRO–PM data to CMS, and that annually 498,843,518 patients would be screened if the Information Transfer PRO–PM became mandatory. While PRO–PMs may require providers to integrate data collection into clinical workflows, this integration provides an important opportunity for patient-reported outcomes to inform clinical decision-making and benefits patients by engaging them in discussions about potential outcomes. Specifically, regarding the Information Transfer PRO–PM, as stated in the CY 2025 OPPS/ASC proposed rule, data would be collected and reported electronically by administrative staff and quality officers engaged in data sharing activities, outside of the clinical workflow, before being integrated into a clinical information system (89 FR 59453). Additionally, to provide more flexibility, we are not requiring HOPDs to collect data in a standardized way. HOPDs may use a variety of data collection, storage, and submission approaches, and we encourage HOPDs to use processes best suited to them. Further, a study in the Journal of the American Medical Association found that, when reviewing the annual person-hours and personnel costs across different elements of quality reporting (that is, entering information, reviewing reports, tracking specifications, developing processes, and collecting and validating data) for surveys, the majority of annual person-hours and personnel costs were allocated to reviewing reports.[442] Therefore, the burden of developing processes (such as a facilities' time strategizing, reviewing and updating policies, building technology, training staff, and implementing change management processes) for the Information Transfer PRO–PM should be minimal. Finally, we note that additional actions an HOPD may take in the process of implementing this measure will vary among HOPDs due to, for example, an HOPD's size, services, and current processes and policies in place.

As to commenters' concern regarding ensuring consistency in communication so all patients receive the same quality and clarity of recovery information, we note that the goal of this measure is to assess how well facilities provide clear,

[442] Saraswathula A, Merck SJ, Bai G, et al. (2023). The Volume and Cost of Quality Metric Reporting. JAMA. 329(21):1840–1847. *www.doi.org/10.1001/jama.2023.7271.*

personalized recovery information. While we agree that HOPDs are busy, it is important for patients to understand their recovery information and for HOPDs to communicate to each patient in a clear, personalized way.

Comment: Several commenters expressed concerns with CMS' proposal to adopt the Information Transfer PRO–PM due to patient survey burden. Commenters stated that the addition of this patient survey to the Hospital OQR Program would result in patient survey fatigue and decreased patient responses to surveys across the board. A commenter noted that if a patient received a hospital outpatient total knee replacement, the surveys the patient would receive would include: (1) screening for five SDOH domains, (2) pre-operative data collection for the THA/TKA PRO–PM, (3) OAS CAHPS, (4) Information Transfer PRO–PM, and (5) post-operative data collection for the THA/TKA PRO–PM. The commenter further noted that patients would likely also receive additional questionnaires (such as the CAHPS for MIPS survey) from other provider types. A few commenters expressed concern regarding low participation rates due to language barriers, lack of internet access, lack of understanding of or access to technology, and the current timeframe in which the survey is administered.

Response: Our aim is to promote better collection and integration of patients' voices by incorporating Patient Reported Outcome Measures (PROMs) that are embedded into clinical workflow, easy to use, and as minimally burdensome to patients and providers as possible. We are dedicated to improving the quality of care provided to patients, and believe patients are a vital source of information in assessing quality of care provided at a HOPD. Patient feedback from a Technical Expert Panel (TEP), which informed our initial selection and development of this measure, indicated that patients are experiencing survey fatigue in all facets of their lives, and as such preferred shorter surveys in an electronic format.[443] Several TEP members also noted the importance of a quick and easy survey built into the care process as part of a positive patient experience following outpatient surgery.[444]

Regarding screening for five SDOH domains, as finalized in section XIV.B of this final rule with comment period, we recognize that some healthcare facilities may already be screening their patients for HRSNs, and in alignment with the Hospital IQR Program, we proposed that HOPDs could confirm the status of any previously reported HRSNs in another care setting and inquire about others not previously reported, in lieu of re-screening a patient within the reporting period. In addition, if this information has been captured in the EHR in another outpatient setting or the inpatient setting during the same reporting period, we proposed that the HOPD could use that information for purposes of reporting the measure in lieu of screening the patient.

Regarding pre-operative and post-operative data collection for the THA/TKA PRO–PM, the Information Transfer PRO–PM is a nine-item survey offered once to patients who meet the measure denominator specifications and, unlike the THA/TKA PRO–PM, does not require pre-operative and post-operative surveys to evaluate functional improvement following the surgical procedure. Regarding OAS CAHPS, we selected a timeframe for administration of 1 to 7 days post-procedure for the Information Transfer PRO–PM, both to limit the possibility that the patient's responses are influenced by time-dependent variables related to proximity to the surgery or procedure (such as medications that could affect comprehension, fatigue, or acute pain), and to mitigate overlap of the initial administration and survey reminder of the OAS CAHPS, which is administered on the first day post-procedure and then followed up at 14 days.

Regarding concerns about low participation rates due to language barriers, lack of internet access, lack of understanding of or access to technology, and the current timeframe in which the survey is administered, as we note later in this final rule, the Information Transfer PRO–PM is available in English and Spanish. Additionally, in order to ensure that hospitals are administering the survey in the patient's preferred language, hospitals are permitted to use interpretation and translation services. For patients that lack internet access or lack understanding of or access to technology, we note that the Information Transfer PRO–PM can be completed using a translator, proxy, or caregiver.

We anticipate data collection for the Information Transfer PRO–PM to present a low burden to patients thereby fostering receptiveness to survey participation. As we stated in the CY 2024 OPPS/ASC proposed rule (89 FR 59518), we estimate that each patient would require an average of 6 minutes to complete the nine-item survey. We intend to evaluate response rates associated with the Information Transfer PRO–PM and continue to consider ways to reduce patient survey fatigue.

Comment: A few commenters did not support adoption of any additional PROMs, including the Information Transfer PRO–PM, because of the challenges they have recently experienced while implementing the THA/TKA PRO–PM measure, such as the financial burden of implementing that measure and challenges in meeting the current 50 percent reporting threshold for the THA/TKA measure.

Response: We do not believe that the challenges providers may face in implementing the THA/TKA PRO–PM warrant declining to adopt other important PRO–PMs in the Hospital OQR Program. We addressed commenters' concerns regarding implementation of the THA/TKA PRO–PM in the CY 2024 OPPS/ASC final rule (88 FR 81984 through 81986) and maintain that this measure is an important addition to the Hospital OQR Program as the volume of THA and TKA procedures for Medicare beneficiaries aged 65 years and older have been increasing in outpatient settings.

We note that, in comparison to the THA/TKA PRO–PM, the Information Transfer PRO–PM does not have a reporting threshold and thus providers would not be subject to a similar reporting threshold. Additionally, we note that the Information Transfer PRO–PM is a nine-item survey offered to patients who meet the measure denominator specifications as a one-time survey, and that, unlike the THA/TKA PRO–PM, it does not require pre-operative and post-operative surveys to evaluate functional improvement following the surgical procedure. We therefore believe that the financial burden would be reduced in comparison to the THA/TKA PRO–PM which has multiple surveys within the measure.

Comment: A few commenters expressed concerns around the measure testing of the Information Transfer PRO–PM and recommended more testing be done before inclusion into the Hospital OQR Program. A commenter stated that the limited geographic scope of testing might not have captured the diversity of patient experiences across the country. A commenter expressed concern regarding the lack of risk adjustment in the measure because it prevents understanding of which vulnerable

[443] Centers for Medicare & Medicaid Services. (July 2021). Summary of Technical Expert Panel (TEP) Meeting, April 23, 2021: Patient Receipt of Key Information Following Outpatient Procedure Patient-Reported Outcome-Based Performance Measure (PRO–PM). Available at: *https://www.cms.gov/files/document/patient-receipt-key-info-tep-summary-072621.pdf.*

[444] Ibid.

patients/populations could benefit from additional education.

Response: We thank the commenters for their feedback on this measure. Testing of the measure results including for risk adjustment need, response rates, and data missingness was conducted and is described in the methodology report.[445] As the outcome for this measure is the patient's rating of the clarity of information about their recovery process, it is important to test for certain patient characteristics that may bias results. Analysis of factors that are and are not correlated with the measure is critical in assessing whether the measure should be risk adjusted. Evaluation of risk adjustment in pilot testing survey results found no statistically significant differences between adjusted and unadjusted result scores. Additionally, non-response bias, which is the likelihood of a patient responding to a survey based on patient characteristics, was also analyzed during pilot testing. Non-responders were significantly younger and more likely to be male, but these factors were not significant toward measure results. We reiterate that this measure was submitted to the CBE by the measure developer for endorsement review (CBE #4210), which includes a review of testing data, measure importance, feasibility, and usability. When submitted for endorsement, a measure is reviewed on its reliability and validity within the context of its intended application, justifying a measure's use in the HOPD setting.[446] This measure was endorsed on March 18, 2024. Furthermore, during measure testing, the measure developer engaged in extensive discussions with clinicians and patient stakeholders regarding the need to risk-adjust. After discussion and analysis of pilot data, risk-adjustment was not added to the measure because it could unintentionally encourage disparate outcomes between different patient populations. The performance differences between the adjusted and unadjusted measures in testing were also minimal.[447]

Comment: Several commenters expressed concern regarding the measure's feasibility as CMS requires a minimum random sample size of 300 completed surveys, which is inconsistent with the minimum responses outlined in the measure specifications. A commenter requested clarification on how to count partially completed surveys, and whether 100 percent of questions need to be completed to meet the 300-survey minimum.

Response: We acknowledge the commenters' concerns regarding the inconsistency of the minimum sample size as stated in the proposed rule (89 FR 59459) and the measure specifications. We intend to update the measure specification manual to reflect the minimum random sample size of 300 completed surveys. A minimum random sample size of 300 completed surveys is recommended for a population of 1,500 to provide a 95 percent confidence interval and a 90 percent confidence interval for a population of over 10,000 by reducing the standard error.[448] [449] We also believe it is important for the Information Transfer PRO–PM to be administered to every patient following an outpatient surgery or procedure, as recent studies show outpatient settings are associated with worse patient understanding, [450] [451] [452] and that a lack of understanding of patient recovery information is associated with worse outcomes, including poor adherence to treatment, decreased patient safety, increased return to the ED, lower levels of patient satisfaction, and disproportionate effects on patients with limited English proficiency and patients over age 65.[453] [454] We note that all questions on the survey need to be completed to meet the 300-survey minimum. Partially completed surveys should not be counted towards the 300-survey minimum.

Comment: A commenter expressed concern that safety net hospitals might face difficulty adopting the Information Transfer PRO–PM due to a large, underserved population with low health literacy, and language and cultural differences contributing to lower response rates. The commenter recommended CMS investigate how disadvantaged populations may impact PRO data collection before adopting PRO–PMs in the Hospital OQR Program.

Response: We believe that the measurement of patient-reported outcomes is vital for advancing patient-centered care and improving overall healthcare quality for all patients. We note that one of our CMS National Quality Strategy goals, ''Advance Equity and Engagement for All Individuals'' seeks to ensure engagement to improve healthcare quality by incorporating individual and community input into strategy and policy. PRO–PMs are unique because they are based on patients' input on their health and the effectiveness of the care they receive, providing a crucial dimension to quality improvement that other measures may not offer. By integrating the Information Transfer PRO–PM into the Hospital OQR Program as a complement to the other outcome measures, CMS can better support patient-centered quality improvement efforts.

While we acknowledge the commenter's concern that safety net hospitals may face lower response rates due to a large, underserved population with low health literacy, in addition to language and cultural differences, the Information Transfer PRO–PM has mitigated these challenges by limiting the survey to nine items and offering the survey in English and Spanish. Additionally, to ensure that hospitals are administering the survey in the patient's preferred language, hospitals

[445] Centers for Medicare & Medicaid Services. (2024). Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance Measure (PRO–PM) Version 1.0 Methodology Report. Available at: *https://www.cms.gov/files/document/patient-understanding-key-information-related-recovery-after-facility-based-outpatient-procedure-or.pdf.*

[446] Partnership for Quality Measurement. (September 2023). Guidebook of Policies and Procedures for Pre-Rulemaking Measure Review and Measure Set Review. Available at: *https://p4qm.org/sites/default/files/2023–09/Guidebook-of-Policies-and-Procedures-for-Pre-Rulemaking-Measure-Review-%28PRMR%29-and-Measure-SetReview-%28MSR%29-Final_0.pdf.*

[447] Partnership for Quality Measurement. Submission Tool and Repository Measure Database. *https://p4qm.org/measures/4210.*

[448] Ahmad, H., & Halim, H. (2017). Determining Sample Size for Research Activities. Selangor Business Review, 2(1), 20–34. Retrieved from *https://sbr.journals.unisel.edu.my/ojs/index.php/sbr/article/view/12.*

[449] Voorhis, C. & Morgan, B. (2007). Understanding Power and Rules of Thumb for Determining Sample Size. Tutorials in Quantitative Methods for Psychology. 3(2), 43–50. *https://doi.org/10.20982/tqmp.03.2.p043.*

[450] Kang E, Gillespie BM, Tobiano G, et al. (2018). Discharge education delivered to general surgical patients in their management of recovery post discharge: A systematic mixed studies review. Int J Nurs Stud. 87:1–13. *https://doi.org/10.1016/j.ijnurstu.2018.07.004.*

[451] Hoek AE, Anker SCP, van Beeck EF, et al. (2020). Patient Discharge Instructions in the Emergency Department and Their Effects on Comprehension and Recall of Discharge Instructions: A Systematic Review and Metaanalysis. Ann Emerg Med. 75(3):435–444. *https://doi.org/10.1016/j.annemergmed.2019.06.008.*

[452] Downey E, Olds DM. (2021). Comparison of Documentation on Inpatient Discharge and Ambulatory End-of-Visit Summaries. J Healthc Qual. 43(3): e43–e52. *https://doi.org/10.1097/JHQ.0000000000000269.*

[453] DeSai C, Janowiak K, Secheli B, et al. (2021). Empowering patients: simplifying discharge instructions. BMJ Open Quality;10(3)001419. *http://doi.org/10.1136/bmjoq-2021-001419.*

[454] Malevanchik L., Wheeler M., Gagliardi K., Karliner L., Shah S.J. (2021). Disparities After Discharge: The Association of Limited English Proficiency and Postdischarge Patient-Reported Issues, The Issues, The Joint Commission Journal on Quality and Patient Safety, 47(12):775–782. *https://doi.org/10.1016/j.jcjq.2021.08.013.*

are permitted to use interpretation and translation services. Minimizing language barriers and survey duration can improve response rates.[455] As previously noted, testing of the measure results including for risk adjustment need, response rates, and data missingness was conducted and is described in the methodology report.[456] As the outcome for this measure is the patient's rating of the clarity of information about their recovery process, it is important to test for certain patient characteristics that may bias results. Analysis of factors that are and are not correlated with the measure is critical in assessing whether the measure should be risk adjusted. Evaluation of risk adjustment in pilot testing survey results found no statistically significant differences between adjusted and unadjusted result scores. Additionally, non-response bias, the likelihood of a patient responding to a survey based on patient characteristics, was also analyzed during pilot testing. Non-responders were significantly younger and more likely to be male, but these factors were not significant toward measure results. We will continue to monitor trends and evaluate feedback on data collection for the Information Transfer PRO–PM.

Comment: A commenter expressed concerns about CMS' ability to correlate patient understanding with overall patient outcomes, stating that recovery can be influenced by numerous external factors beyond comprehension, and that using data from this measure could lead to misguided conclusions about effectiveness of care.

Response: Usability of the measure was tested during measure development. The measure developer interviewed quality officers of the organizations that participated in pilot testing about the meaningfulness of the performance score. The quality officers indicated that the scores aligned with known issues raised by patients in an open-ended survey and accurately quantified known issues with the post-operative process.[457] Further, as previously noted, the measure developer asked members of a PFE Work Group and a TEP panel to vote on the measure's ability to distinguish between good and poor quality of care at measured facilities.[458] [459] All of the patients from the PFE Work Group and 80 percent of the TEP panel members who participated in the vote agreed that the measure could distinguish between good and poor quality of care.[460] Therefore, we do not expect data from this measure to lead to misguided conclusions about effectiveness of care. Additionally, we are not using PRO–PMs such as the Information Transfer PRO–PM to replace outcome measures, but to serve as complementary measures to support patient-centered care.

Comment: Many commenters recommended integrating the Information Transfer PRO–PM into the OAS CAHPS survey, expressing concern regarding the potential for patient confusion, low response rates, and survey fatigue. A commenter stated that OAS CAHPS is experiencing declining response rates over time, citing an 18 percent drop in survey response rates in a seven-year period. A few commenters stated that the Information Transfer PRO–PM survey administration overlaps with the OAS CAHPS survey administration, expressing concern that response rates for both surveys may be affected as patients may experience survey fatigue. A commenter noted that sending multiple surveys would result in survey fatigue and decrease the likelihood of response. A few commenters recommended expanding the survey beyond English and Spanish, stating that it should be made available in the nine languages that are offered for OAS CAHPS.

Response: We considered integrating questions from the Information Transfer PRO–PM survey into the OAS CAHPS survey to reduce the number of surveys a patient could receive regarding their episode of care. However, we decided against doing so as the specifications for administering the OAS CAHPS (such as the survey timing, allowing multiple submission modes, and requiring a CMS-approved vendor) do not align with the Information Transfer PRO–PM. We note that the voting results of the Hospital Recommendation Group under the PRMR process were ''recommend with conditions'' for the Information Transfer PRO–PM measure for the Hospital OQR Program, and that the condition was to administer the survey at the time of the surgery or procedure so there is no conflict with other measured pain and function outcomes to improve response rates.[461] We considered this condition and decided on the current timeframe for survey administration of more than 1 day but less than 7 days post-procedure to strike a balance between patient recovery and comprehension of the Information Transfer PRO–PM and mitigating overlap with the initial administration of the OAS CAHPS on the first day post-procedure and the survey reminder at 14 days.

We are currently working to expand the survey to additional languages beyond English and Spanish. Additionally, in order to ensure that hospitals are administering the survey in the patient's preferred language, hospitals are permitted to use interpretation and translation services.

Comment: A few commenters recommended CMS build on this measure to better align with patient goal identification and attainment across the episode of care. A commenter recommended broadening PRO–PMs to assess the degree to which the entire care journey is understood and accepted. A commenter recommended adding questions to the medication question category of the Information Transfer PRO–PM to ensure proper measurement regarding the completeness of recovery information, and to account for a patient's understanding of the care plan. A commenter recommended extending patient response periods for the Information Transfer PRO–PM beyond 65 days. Another commenter recommended measurement on pre-procedure screening for patients' communication disorders to help ensure post-operative instructions are understood. A commenter recommended that CMS explore ways to leverage technology to reduce the effort required to participate in the survey, such as administering it online rather than on paper. Another commenter recommended that CMS consider how it can support hospitals in efforts to increase responsiveness. Another commenter recommended that CMS consider implementing a bonus to

[455] Reyes, G. (2016). Understanding non response rates: insights from 600,000 opinion surveys. Available at: *https://thedocs.worldbank.org/en/doc/708511466183857404-0050022016/original/paperreyes.pdf.*

[456] Centers for Medicare & Medicaid Services. (2024). Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance Measure (PRO–PM) Version 1.0 Methodology Report. Available at: *https://www.cms.gov/files/document/patient-understanding-key-information-related-recovery-after-facility-based-outpatient-procedure-or.pdf.*

[457] Partnership for Quality Measurement. Submission Tool and Repository Measure Database. *https://p4qm.org/measures/4210.*

[458] Partnership for Quality Measurement. 2023 Pre-Rulemaking Measure Review (PRMR) Meeting Summary: Hospital Committee. Available at: *https://p4qm.org/sites/default/files/2024-02/PRMR-Hospital-Recommendation-Group-Meeting-Summary-Final.pdf.*

[459] See also *https://www.cms.gov/medicare/quality/initiatives/hospital-quality-initiative/measure-methodology.*

[460] Ibid.

[461] Partnership for Quality Measurement. (2024). 2023 Pre-Rulemaking Measure Review (PRMR) Meeting Summary: Hospital Committee. Available at: *https://p4qm.org/sites/default/files/2024-02/PRMR-Hospital-Recommendation-Group-MeetingSummary-Final.pdf.*

encourage investment in reporting PRO–PMs.

Response: We thank commenters for their support and recommendations and will take them into consideration as we begin implementing the Information Transfer PRO–PM in the Hospital OQR Program. As previously noted, the Information Transfer PRO–PM can be distributed electronically via text or email by a vendor or individual facility. Regarding the implementation of a bonus to encourage investment in reporting PRO–PMs, we note that the statutory payment provisions for the Hospital OQR Program do not provide for the payment of any bonus.

Comment: Many commenters expressed concern regarding the implementation timeline of the Information Transfer PRO–PM and recommended that CMS delay voluntary reporting or remove the mandatory reporting requirement. A commenter recommended that CMS provide feedback reports during the voluntary period.

Response: Given the importance of patient understanding of recovery instructions, we believe it is important to adopt this PRO–PM in the Hospital OQR Program and begin reporting as soon as possible while also allowing HOPDs time to implement processes for data collection on this measure, which is why we proposed to begin with a voluntary reporting period. Because the measure only uses a nine-item survey with flexibility to HOPDs on the modes of data collection, as well as sampling when reporting the PRO–PM data to CMS, we consider a one-year voluntary reporting period to be sufficient. We will monitor implementation of the measure and carefully consider feedback received during the voluntary reporting period.

Comment: A few commenters requested additional information regarding measure specifications. A commenter requested that CMS disclose the copyright protections on surveys when adopting new PRO–PMs in the future.

Response: We thank commenters for their questions and point them to the technical specification manuals that can be found on the CMS website at: *https://qualitynet.cms.gov/outpatient/specifications-manuals*. We note that the Information Transfer PRO–PM survey, as well as the THA/TKA PRO–PM survey, is nonproprietary and free to use. We will disclose copyright protections on surveys as necessary.

After consideration of the public comments we received, we are finalizing our proposal to adopt the Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery Patient Reported Outcome-Based Performance Measure beginning with voluntary reporting for the CY 2026 reporting period followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2029 payment determination.

2. Measure Removals From the Hospital OQR Program Measure Set

a. Removal of the MRI Lumbar Spine for Low Back Pain Measure Beginning With the CY 2025 Reporting Period/CY 2027 Payment Determination

In the CY 2009 OPPS/ASC final rule (73 FR 68766), we adopted the MRI Lumbar Spine for Low Back Pain measure beginning with the CY 2010 payment determination. This claims-based measure evaluates the percentage of magnetic resonance imaging (MRI) of the lumbar spine studies for low back pain performed in the outpatient setting where conservative therapy was not attempted prior to the MRI. The MRI Lumbar Spine for Low Back Pain measure was initially endorsed by a consensus-based entity (CBE) in 2008, but endorsement of this measure was removed in 2017 because the measure developer did not submit the measure for review during its designated measure endorsement maintenance cycle.

When we adopted this measure for the Hospital OQR Program, we cited growing concerns about the overuse of imaging services and evidence that a substantial portion of MRIs for low back pain does not lead to any modification of therapy based on MRI results, especially when performed on the first visit prior to any attempt to diagnose or treat the patient through more conservative means (73 FR 68764). Since then, our internal analyses have shown that the measure has maintained stable national performance (excluding the CY 2022 performance period impacted by our COVID–19 exception policies) and low average volumes, indicating limited reliability and capacity to improve the quality of care for patients with reported low back pain. A study in the Journal of the American College of Radiology found that documentation of conditions that fall into the exclusion criteria of the measure increased after implementation, resulting in smaller patient populations and indicating that the measure may not translate to improvement of imaging appropriateness.[462] Other studies have shown that the MRI Lumbar Spine for Low Back Pain measure has not correlated with improved outcomes.[463] [464] [465] The latest findings are consistent with responses to a 2020 request for public comment where commenters expressed concerns regarding measure exclusion conditions, imaging modalities, measure validity, and measure usability. In response to that request for public comments, commenters also stated that an unintended consequence of using this measure may be delayed diagnoses.[466]

Based on these findings, this measure meets the criteria that we have adopted for measure removal Factor 2 (that is, performance or improvement on a measure does not result in better patient outcomes), as codified under § 419.46(i)(3)(i)(B). Therefore, in the CY 2025 OPPS/ASC proposed rule (89 FR 59454 through 59455), we proposed to remove the MRI Lumbar Spine for Low Back Pain measure from the Hospital OQR Program beginning with the CY 2025 reporting period/CY 2027 payment determination.

We invited public comment on the proposal, including feedback on other potential measures that may better address unnecessary imaging, which we will consider for adoption into the Hospital OQR Program in future rulemaking.

Comment: Many commenters supported CMS' proposal to remove the MRI Lumbar Spine for Low Back Pain measure beginning with the CY 2025 reporting period/CY 2026 payment determination. Several of these commenters concurred with the rationale in the CY 2025 OPPS/ASC proposed rule to remove the measure based on measure removal Factor 2, stating that the measure does not provide actionable data toward quality improvement and lacks sufficient

[462] Flug JA and Lind KE. (2017). Public Reporting of MRI of the Lumbar Spine for Low Back Pain and Changes in Clinical Documentation, Journal of the American College of Radiology (14)12: 1545–1551. *https://doi.org/10.1016/j.jacr.2017.07.012*.

[463] Blackmore CC. (2019). The Relationship Between Medicare Outpatient Efficiency Measure OP8 and Lumbar MRI Utilization, Journal of the American College of Radiology 16(3): 276–281. *https://doi.org/10.1016/j.jacr.2018.10.026*.

[464] Lind KE and Flug JA. (2019). Sociodemographic Variation in the Use of Conservative Therapy Before MRI of the Lumbar Spine for Low Back Pain in the Era of Public Reporting, Journal of the American College of Radiology 16(4): 560–569. *https://doi.org/10.1016/j.jacr.2018.12.047*.

[465] Martin BI and Jarvik JG. (2015). The Medicare Outpatient Imaging Efficiency Measure for Low Back Pain (''OP–8''), Radiology 276(1). *https://doi.org/10.1148/radiol.2015150648*.

[466] Centers for Medicare & Medicaid Services, Public Comment Summary Report. Available at: *https://www.cms.gov/files/document/lumbar-spine-imaging-low-back-pain-public-comment-summary-report.pdf*.

evidence that the measure promotes quality of care and improved patient outcomes. A few of these commenters supported CMS' proposal to remove the MRI Lumbar Spine for Low Back Pain measure because the measure is no longer CBE endorsed. Commenters also supported CMS' proposal because it would allow HOPDs to focus improvement initiatives on other areas of quality.

Response: We thank commenters for their support.

Comment: A commenter recommended that CMS continue to prioritize overutilization measures and to work with stakeholders to develop clinically meaningful measures that promote value for all stakeholders and protect patients from harm from unnecessary services.

Response: We thank the commenter for their recommendation to utilize stakeholders in developing clinically meaningful measures. We note that one of our CMS National Quality Strategy goals, ''Advance Equity and Engagement for All Individuals,'' seeks to ensure engagement to improve healthcare quality by incorporating individual and community input into strategy and policy. We will consider the commenter's recommendation to prioritize imaging efficiency and overutilization measures in future potential rulemaking as appropriate.

Comment: A commenter did not support removing the MRI Lumbar Spine for Low Back Pain measure from the measure set, noting that four additional ICD–10–CM codes that describe ''discogenic back pain'' were issued.

Response: We recognize that there are now four additional ICD–10–CM codes that describe ''discogenic back pain.'' These additional ICD–10–CM codes do not reflect a new condition but allow practitioners more specificity in coding conditions already captured by the measure. We therefore do not believe the additional ICD–10 codes would substantively expand the measure cohort or impact our analysis that the measure has maintained stable national performance (excluding the CY 2022 performance period impacted by our COVID–19 exception policies) and low average volumes, indicating limited reliability and capacity to improve the quality of care for patients with reported low back pain.

Comment: A few commenters did not support removing the MRI Lumbar Spine for Low Back Pain measure and expressed criticism of the studies cited by CMS supporting the assertion that the measure does not correlate with improved outcomes. The commenters stated that none of the studies analyzed the relationship between the measure and outcomes, and that one study provides a rationale to retain the measure as it underscores disparities in care. These commenters also expressed concern that the rate of inappropriate use of MRIs is high, based on a recent publication of the CMS Provider Data Catalog showing an average rate of 38 percent. Finally, the commenters recommended that CMS make public the denominator for results across all measures.

Response: We appreciate commenters' feedback regarding the removal of the MRI Lumbar Spine for Low Back Pain measure. The studies cited by CMS in the proposed rule (89 FR 59455) analyzed and found limited correlation between the measure and utilization of lumbar MRIs, utilization of conservative therapy, and usage of MRI lumbar imaging in hospitals, respectively.[467] [468] [469] Further, one study found that less than five percent of all MRIs of the lumbar spine for low back pain were included in the MRI Lumbar Spine for Low Back Pain measure because of documented conditions that fell within the measure exclusion criteria.[470] The study also noted that compliance rates may be related to more complete documentation and coding, rather than actual changes in patient care.[471] These findings indicate that improvement on this measure is a result of the continued exclusion of conditions, and that improvement does not drive better patient outcomes.

Regarding recent measure performance rates, this measure calculates the percentage of MRI of the lumbar spine studies with a diagnosis of low back pain on the imaging claim for which the beneficiary did not have prior claims-based evidence of antecedent conservative therapy with lower scores indicating higher performance. The most recent mean score as published in the July 2024 refresh of the CMS Provider Data Catalog for national data was 36.2 percent for data collected from July 2022 to June 2023.[472] As we discussed in the CY 2025 OPPS/ASC proposed rule, the measure has maintained stable national performance and low average volumes, indicating limited reliability and capacity that the measure improves the quality of care for patients with reported low back pain. We will take into consideration commenters' recommendation that CMS make public the denominator for results across all measures in the Provider Data Catalog as appropriate in future potential rulemaking.

Comment: A commenter recommended that CMS review alternative measure concepts that could improve care for patients with low back pain.

Response: We thank the commenter for their recommendation. We will continue engaging with interested parties through education and outreach opportunities for any feedback about potential new measures in the future.

After consideration of the public comments received, we are finalizing our proposal to remove the MRI Lumbar Spine for Low Back Pain measure beginning with the CY 2025 reporting period/CY 2027 payment determination.

b. Removal of the Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery Measure Beginning with the CY 2025 Reporting Period/CY 2027 Payment Determination

In the CY 2011 OPPS/ASC final rule (75 FR 72079 and 72080), we adopted the claims-based Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery measure beginning with the CY 2012 payment determination. This measure calculates the percentage of stress echocardiography, single photon emission computed tomography myocardial perfusion imaging (SPECT MPI), stress magnetic resonance imaging (MRI), or computed coronary tomography angiography (CCTA) performed at each facility in the 30 days prior to an ambulatory non-cardiac, low-risk surgery performed at any location, and was endorsed by a CBE in 2011. Endorsement was removed in 2021 after the measure developer did not submit the measure for review during its designated measure endorsement maintenance cycle.

We adopted the measure for the Hospital OQR measure set, in part, to

[467] Blackmore CC. (2019). The Relationship Between Medicare Outpatient Efficiency Measure OP8 and Lumbar MRI Utilization, Journal of the American College of Radiology 16(3): 276–281. *https://doi.org/10.1016/*j.jacr.2018.10.026.

[468] Lind KE and Flug JA. (2019). Sociodemographic Variation in the Use of Conservative Therapy Before MRI of the Lumbar Spine for Low Back Pain in the Era of Public Reporting, Journal of the American College of Radiology 16(4): 560–569. *https://doi.org/10.1016/j.jacr.2018.12.047.*

[469] Martin BI and Jarvik JG. (2015). The Medicare Outpatient Imaging Efficiency Measure for Low Back Pain (''OP–8''), Radiology 276(1). *https://doi.org/10.1148/radiol.2015150648.*

[470] Flug JA and Lind KE. (2017). Public Reporting of MRI of the Lumbar Spine for Low Back Pain and Changes in Clinical Documentation, Journal of the American College of Radiology (14)12: 1545–1551. *https://doi.org/10.1016/j.jacr.2017.07.012.*

[471] Ibid.

[472] Centers for Medicare and Medicaid Services. Provider Data Catalog. Available at: *https://data.cms.gov/provider-data/dataset/di9i-zzrc.*

address an area of patient safety related to one of the most common imaging services in the Medicare population at the time, as we believed inappropriate use could increase the patient's risk of cancer, contribute no benefit to the quality of care, and result in the unnecessary waste of services (75 FR 72076). In response to commenter concerns regarding the infrequent occurrence of low-risk non-cardiac surgeries, and whether this measure may assess significant differences in the provision of imaging tests and their impact on the quality of care provided, we stated at the time that the measure could identify outlier practice patterns and encourage HOPDs to improve their quality of care.

Our routine monitoring and evaluation shows that the range of cases per HOPD varies greatly (that is, from one to over 1,300 cases), posing limitations when assessing and interpreting comparative performance trends over time. In addition, while there was a slight average performance score improvement from payment determination years CY 2020 to 2024 (despite the COVID–19 pandemic and the larger pool of reporters) of about one percent (4.7 percent and 3.6, respectively), the variation between the 10th and 25th percentiles of performance is not statistically distinguishable, indicating the measure may not provide meaningful data for informing consumers about quality of care for this service in HOPDs. Furthermore, at a 3.5 percent average overall rate for this measure for the CY 2024 payment determination year, there is little room for national performance on this measure to show significant improvement as lower rates are better for this measure.

Based on these findings, this measure meets the criteria for measure removal Factor 2 (that is, performance or improvement on a measure does not result in better patient outcomes), as codified under § 419.46(i)(3)(i)(B). Therefore, in the CY 2025 OPPS/ASC proposed rule (89 FR 59455), we proposed to remove the Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery measure beginning with the CY 2025 reporting period/CY 2027 payment determination.

We invited public comment on the proposal, including feedback on other potential measures that may better address unnecessary imaging, which we will consider for adoption into the Hospital OQR Program in future rulemaking.

Comment: Many commenters supported CMS' proposal to remove the Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery measure beginning with the CY 2025 reporting period/CY 2027 payment determination. Several of these commenters concurred with the rationale in the CY 2025 OPPS/ASC proposed rule to remove the Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery measure based on measure removal Factor 2, stating the measure does not provide actionable data toward quality improvement and lacks sufficient evidence that the measure promotes quality of care and improved patient outcomes. A few of these commenters supported the removal of the measure as it is no longer CBE endorsed. A commenter stated that removing this measure would allow HOPDs to focus improvement initiatives on other areas of quality. Another commenter stated that the removal of this measure can help cardiovascular specialists focus on more meaningful and high-value care practices, aligning with initiatives like Choosing Wisely, a campaign by the American Board of Internal Medicine that advocates for avoiding unnecessary medical tests and procedures. This commenter further noted that studies have shown that such imaging often does not change patient management or outcomes and can lead to unnecessary costs.

Response: We thank commenters for their support.

Comment: A commenter recommended CMS continue to prioritize overutilization measures and to work with stakeholders to develop clinically meaningful measures that promote value for all stakeholders and protect patients from harm from unnecessary services.

Response: We thank the commenter for their recommendation to utilize stakeholders in developing clinically meaningful measures and to prioritize overutilization measures. We note that one of our CMS National Quality Strategy goals, ''Advance Equity and Engagement for All Individuals,'' seeks to ensure engagement to improve healthcare quality by incorporating individual and community input into strategy and policy. We will consider the commenter's recommendation to prioritize imaging efficiency and overutilization measures in future rulemaking.

Comment: A few commenters did not support removal of the Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery measure, stating that measure removal Factor 2 (that is, performance or improvement does not result in better outcomes) is inapplicable because inappropriate testing causes adverse reactions. Commenters expressed concern about categorizing the performance score improvement (4.7 percent to 3.6 percent) from 2020 to 2024 as 'slight,' stating that it was a significant reduction in unnecessary testing.

Response: We disagree with commenters' feedback that removal Factor 2 is inapplicable to this measure. We cannot solely evaluate the 1.1 percentage point improvement from the 4.7 percent 2020 performance score in determining clinical significance for quality measure performance. To adequately determine whether removal Factor 2 applies, we review the performance score data in its entirety, including the number of HOPDs meeting case minimums and the variation between the 10th and 25th percentiles of performance. As previously discussed, this variation is not statistically distinguishable, indicating that the measure may not provide meaningful data for informing consumers about quality of care for this service in HOPDs. Additionally, while inappropriate testing causes adverse reactions, our routine monitoring and evaluation shows that the range of cases per HOPD varies from one to over 1,300 cases, posing limitations when assessing and interpreting comparative performance trends over time. We therefore cannot extrapolate patient outcomes from the measure results.

After consideration of the public comments received, we are finalizing our proposal to remove the Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery measure beginning with the CY 2025 reporting period/CY 2027 payment determination.

3. Summary of Finalized Program Measure Set Updates

a. Newly Finalized Program Measure Set Beginning With the CY 2027 Payment Determination

Table 163 summarizes the newly finalized Hospital OQR Program measure set beginning with the CY 2027 payment determination, which removes the two imaging efficiency measures discussed in sections XV.C.2.a and XV.C.2.b of this final rule with comment period and adds three cross-program health equity measure discussed in sections XV.C.1.a and XIV.B of this final rule with comment period.

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TABLE 163: NEWLY FINALIZED HOSPITAL OQR PROGRAM MEASURE SET BEGINNING WITH THE CY 2027 PAYMENT DETERMINATION

CBE #	Measure Name
None	Abdomen CT – Use of Contrast Material
3490	Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy
0658	Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
None	Breast Cancer Screening Recall Rates
None†	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery*
3636	COVID–19 Vaccination Coverage Among HCP
3663e	Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults**
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy
0661	Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival
None	Hospital Commitment to Health Equity***
None†	Left Without Being Seen
None†	Median Time from ED Arrival to ED Departure for Discharged ED Patients
None	OAS CAHPS
4210	Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance Measure (Information Transfer PRO-PM)****
2687	Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery
None	Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the HOPD Setting (THA/TKA PRO–PM)*****
None	Screening for Social Drivers of Health******
None	Screen Positive Rate for Social Drivers of Health******
None	ST-Segment Elevation Myocardial Infarction (STEMI) eCQM

†Measure is no longer endorsed by the CBE but was endorsed previously.
*This measure is voluntary.
**This measure begins with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2029 payment determination, as discussed in the CY 2024 OPPS/ASC final rule (81988 FR through 81992).
***In this final rule, we adopt this measure beginning with the CY 2025 reporting period/ CY 2027 payment determination, as discussed in section XIV.B.1 of this final rule with comment period.
****In this final rule, we adopt this measure beginning with voluntary reporting for the CY 2026 reporting period, followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2029 payment determination, as discussed in section XV.B.3.B of this final rule with comment period.
*****This measure begins with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2028 reporting period/CY 2031 payment determination, as discussed in the CY 2024 OPPS/ASC final rule (88 FR 81984 through 81986).
******In this final rule, we adopt this measure beginning with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination, as discussed in sections XIV.B.2 and XIV.B.3 of this final rule with comment period.

b. Newly Finalized Program Measure Set Beginning With the CY 2031 Payment Determination

Table 164 summarizes the newly finalized Hospital OQR Program measure set for the CY 2031 payment determination, which removes the two imaging efficiency measures, discussed in sections XV.C.2.a and XV.C.2.b of this final rule with comment period; adds the Information Transfer PRO–PM, discussed in section XV.C.1.b of this final rule with comment period; and adds three cross-program health equity measures, discussed in section XIV.B of this final rule with comment period.

TABLE 164: NEWLY FINALIZED HOSPITAL OQR PROGRAM MEASURE SET BEGINNING WITH THE CY 2031 PAYMENT DETERMINATION

CBE #	Measure Name
None	Abdomen CT – Use of Contrast Material
3490	Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy
0658	Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
None	Breast Cancer Screening Recall Rates
None†	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery*
3636	COVID–19 Vaccination Coverage Among HCP
3663e	Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy
0661	Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival
None	Hospital Commitment to Health Equity**
None†	Left Without Being Seen
None†	Median Time from ED Arrival to ED Departure for Discharged ED Patients
None	OAS CAHPS
4210	Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance Measure (Information Transfer PRO-PM)***
2687	Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery
None	Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the HOPD Setting (THA/TKA PRO–PM)
None	Screening for Social Drivers of Health****
None	Screen Positive Rate for Social Drivers of Health****
None	ST-Segment Elevation Myocardial Infarction (STEMI) eCQM

†Measure is no longer endorsed by the CBE but was endorsed previously.
*This measure is voluntary.
**In this final rule, we adopt this measure beginning with the CY 2025 reporting period/ CY 2027 payment determination, as discussed in section XIV.B.1 of this final rule with comment period.
***In this final rule, we adopt this measure beginning with voluntary reporting for the CY 2026 reporting period, followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2029 payment determination, as discussed in section XV.B.3.B of this final rule with comment period.
****In this final rule, we adopt this measure beginning with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination, as discussed in sections XIV.B.2 and XIV.B.3 of this final rule with comment period.

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D. Administrative Requirements

We refer readers to § 419.46(b) and (c) and the CYs 2014, 2016, and 2019 OPPS/ASC final rules (78 FR 75108 through 75109, 80 FR 70519, and 83 FR 59103 through 59104, respectively) for our policies regarding program participation requirements and withdrawal from the program. We did not propose any changes to these policies in the CY 2025 OPPS/ASC proposed rule.

E. Form, Manner, and Timing of Data Submission

1. General Data Submission Policy

We refer readers to § 419.46(d) and the CY 2023 OPPS/ASC final rule with comment period (87 FR 72110 through 72112) for our general program policies regarding: (1) submission of data under the Hospital OQR Program generally; (2) review and correction of submitted data; and (3) extraordinary circumstance exception requests (ECE) for data submission.

We also refer readers to the CYs 2019 and 2022 OPPS/ASC final rules (83 FR 59104 through 59105 and 86 FR 63861, respectively) for details regarding our maintenance of technical specifications. We maintain measure technical specification manuals (referred to as Specifications Manuals) that can be found on the CMS website at: *https://qualitynet.cms.gov/outpatient/specifications-manuals*.

We did not propose any changes to these policies in the CY 2025 OPPS/ASC proposed rule.

2. Measure Specific Data Submission and Reporting Requirements

We refer readers to the CYs 2014, 2016, 2022, 2023, and 2024 OPPS/ASC final rules (77 FR 68484; 80 FR 70521, 87 FR 72110 through 72112; 78 FR 75097 through 75100; and 88 FR 82004 through 82006, respectively) for information regarding our claims-based, web-based, eCQM, chart-abstracted, PRO–PM, and survey-based data submission and reporting requirements.

a. Web-Based Measures

(1) CMS-Designated Information System and Data Submission for the Hospital Commitment to Health Equity (HCHE), Screening for Social Drivers of Health (SDOH), and Screen Positive Rate for SDOH Measures

We refer readers to the CY2014 OPPS/ASC final rule (78 FR 75112 through 75115), the CY2016 OPPS/ASC final rule (80 FR 70521), and the CMS website, currently available at *https://qualitynet.cms.gov*, for a discussion of the requirements for measure data submitted via the Hospital Quality Reporting (HQR) System (formerly referred to as the QualityNet Secure Portal). The HQR System safeguards protected health information in compliance with the HIPAA Privacy and Security Rules (45 CFR parts 160 and 164, subparts A, C, and E).

In sections XIV.B.1, XIV.B.2, and XIV.B.3 of this final rule with comment period, we are adopting: (1) the Hospital Commitment to Health Equity measure, beginning with the CY 2025 reporting period/CY 2027 payment determination; (2) the Screening for SDOH measure, beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; and (3) the Screen Positive Rate for SDOH measure, beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination.

Consistent with our established data submission requirements (80 FR 70521 and 70522), we proposed in the CY 2025 OPPS/ASC proposed rule (89 FR 59458) that HOPDs would be required to submit all of the data required to calculate each of these three measures annually using a CMS-approved, web-based, data collection tool available within the HQR System starting January 1 through and including May 15 in the year prior to the applicable payment determination year. For the Hospital OQR Program, the performance period (which we refer to as the CY reporting period) for each of these measures on which data is submitted using a web-based tool would be January 1 through and including December 31 of the year that is 2 years prior to the applicable payment determination year; and the data submission period would be January 1 through and including May 15 in the calendar year immediately following the CY reporting period and immediately prior to the applicable payment determination year. For example, for the CY 2025 reporting period/2027 payment determination, the data submission period would be January 1, 2026, through and including May 15, 2026, covering the performance period of January 1, 2025, through and including December 31, 2025. Pursuant to § 419.46(d)(4), a review and corrections period runs concurrently with the data submission period. During this timeframe, HOPDs would be able to enter, review, and correct data submitted for these measures.

We invited public comment on the proposal.

Comment: Several commenters expressed concerns regarding duplicative reporting of attestations between hospital inpatient departments and hospital outpatient departments for the HCHE measure in the Hospital OQR Program, noting that this measure has already been adopted into the Hospital IQR Program. These commenters requested the ability to submit one single submission jointly for both programs. Another commenter noted that many of the priorities included in this measure are currently addressed by hospitals and health systems and urged CMS to catalogue what hospitals are already doing before establishing new measures or requirements to reduce burden and redundancy. A commenter recommended conducting an environmental scan, listening sessions, focus groups, and a TEP to reduce instances of redundant measures.

Response: We appreciate commenters' input on mechanisms to reduce burden and reporting duplication. We acknowledge that the HCHE measure has been adopted into the Hospital IQR Program, and the importance of prioritizing resources and streamlining hospital-wide system processes to promote administrative efficiency. However, because hospital inpatient departments and hospital outpatient departments treat different patient populations and employ different staff, we are requiring that hospitals participating in both the Hospital IQR and Hospital OQR Programs submit their HCHE measure data separately. We will monitor implementation of the HCHE measure and consider modifications to the manner of data submission for this measure in future rulemaking.

We refer readers to sections XIV.B.1, XIV.B.2, XIV.B.3 of this final rule with comment period for our cross-program proposals and full discussion of public comments received. We are finalizing our proposal that HOPDs would be required to submit all of the data required to calculate the HCHE, Screening for SDOH, and Screen Positive Rate for SDOH measures annually using a CMS-approved, web-based, data collection tool available within the HQR System starting January 1 through and including May 15 in the year prior to the applicable payment determination year.

(2) National Healthcare Safety Network (NHSN)

We refer readers to the CY 2014 OPPS/ASC final rule (78 FR 75097 through 75100) for a discussion of the previously finalized requirements for measure data submitted via the Centers for Disease Control and Prevention NHSN website. We did not propose any changes to these policies in the CY 2025 OPPS/ASC proposed rule.

b. Electronic Clinical Quality Measures (eCQMs) and the Requirement That Electronic Health Record (EHR) Technology Be Certified to All eCQMs Available To Report Beginning With the CY 2025 Reporting Period/CY 2027 Payment Determination

In the CY 2024 Medicare Physician Fee Schedule (PFS) final rule (88 FR 79307 through 79312), we finalized revisions to the definition of certified electronic health record technology (CEHRT) for the Medicare Promoting Interoperability Program at 42 CFR 495.4 and for the Quality Payment Program at 42 CFR 414.1305. Specifically, we added a reference to the ''Base EHR definition,'' which ONC proposed in the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI–1) proposed rule (88 FR 23759, 23905). We finalized these revisions to ensure, if the HTI–1 proposals were finalized, the ''Base EHR definition'' would be applicable for the CEHRT definitions going forward (88 FR 79309 through 79312).[473] ONC subsequently finalized a definition of ''Base EHR'' in the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing final rule (89 FR 1192, 1298).

We also finalized the replacement of references to the ''2015 Edition health IT certification criteria'' with ''ONC health IT certification criteria,'' and the addition of the regulatory citation for ONC health IT certification criteria in 45 CFR 170.315. We finalized the proposal to specify that EHR technology must meet ONC's health IT certification criteria ''as adopted and updated in 45

[473] Revisions to the CEHRT definition are intended to incorporate ONC's approach of discontinuing references to yearly editions. For additional background, we refer readers to HTI–1 proposed rule (88 FR 23759).

CFR 170.315'' to qualify as CEHRT (88 FR 79553). These revisions, finalized in the CY 2024 PFS final rule, are consistent with the policy subsequently finalized in ONC's HTI–1 final rule, which appeared in the **Federal Register** on January 9, 2024 (89 FR 1205 through 1210). For additional background and information on this update, we refer readers to the discussion in the CY 2024 PFS final rule on this topic (88 FR 79307 through 79312).

In the CY 2022 OPPS/ASC final rule (86 FR 63868 and 63869), we adopted a requirement for hospitals to utilize certified technology updated to be consistent with the 2015 Edition Cures Update (now referred to as the ONC health IT certification criteria) for reporting eCQMs under the Hospital OQR Program, beginning with the CY 2023 reporting period/CY 2025 payment determination. However, we did not propose or finalize a requirement that the EHR technology used for eCQM reporting must be certified to all eCQMs (that is, tested and validated on each individual eCQM) in the Hospital OQR Program.

The Hospital IQR Program and the Medicare Promoting Interoperability Program require EHRs to be certified to all available eCQMs in the programs. We finalized this policy for the Hospital IQR Program in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38393) for the FY 2019 and FY 2020 payment determination years, and we finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42505 through 42506) that this policy would continue beginning with the CY 2020 reporting period/FY 2022 payment determination. For the Medicare Promoting Interoperability Program, we finalized this policy in the FY 2018 and FY 2019 IPPS/LTCH PPS final rules for CYs 2018 and 2019, respectively (82 FR 38483 through 38485 and 83 FR 41671 through 41672, respectively). We also finalized the continuation of this requirement in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42600 and 42601) for CY 2020 and subsequent years. When EHRs are certified to all available eCQMs in a program measure set, hospitals are able to accurately capture and report data for these measures. For this reason, and to align the Hospital OQR Program's eCQM certification requirements with the Hospital IQR Program and Medicare Promoting Interoperability Program clinical quality measure electronic submission requirements for eligible hospitals, we proposed in the CY 2025 OPPS/ASC proposed rule (89 FR 59458 through 59459) that beginning with the CY 2025 reporting period/CY 2027 payment determination, a HOPD using EHR technology certified to the ONC health IT certification criteria would be required to have its EHR technology certified to all eCQMs that are available to report under the Hospital OQR Program to meet reporting requirements for the Hospital OQR Program.

We further proposed that for the CY 2025 reporting period/CY 2027 payment determination and subsequent years, HOPDs would additionally be required to use the most recent version of the eCQM electronic measure specifications for the designated reporting period available on the Electronic Clinical Quality Improvement (eCQI) Resource Center website at: *https://ecqi.healthit.gov/*. We noted in the CY 2021 OPPS/ASC final rule (86 FR 63861) that we would generally update the measure specifications on an annual basis to align with current clinical guidelines and code systems.

Our proposal to require that EHRs be certified to all available eCQMs would promote more accurate electronic quality reporting by incentivizing HOPDs to have their EHR and other health information technology (IT) vendors test all available eCQMs and offer reporting modules with certified eCQMs. Through this requirement, we expect greater certainty for hospitals that their EHR systems are capable of accurately calculating the eCQMs reported to CMS under the Hospital OQR Program because the EHR technology would be up to date and tested on each eCQM. Additionally, we anticipate this requirement would help reduce burden for hospitals by potentially reducing the frequency of needing to consult with their EHR and other health IT vendors to troubleshoot implementation or reporting issues.

Finally, in the CY 2025 OPPS/ASC proposed rule (89 FR 59459) we proposed to revise regulatory text at § 419.46 to add a new paragraph (j) to codify submission requirements for eCQMs under the Hospital OQR Program. Under the proposal, we would codify in § 419.46(j)(1) the requirement for hospitals to utilize certified technology updated to be consistent with ONC's health IT certification criteria, as adopted and updated in 45 CFR 170.315, for reporting eCQMs under the Hospital OQR Program. We proposed to codify in § 419.46(j)(2) the requirement that the EHR technology used for eCQM reporting must be certified to all eCQMs (that is, tested and validated on each individual eCQM) available to report under the Hospital OQR Program. We also proposed to codify in § 419.46(j)(3) the requirement that hospitals use the most recent version of the eCQM electronic measure specifications for the applicable reporting period available on the Electronic Clinical Quality Improvement (eCQI) Resource Center website at: *https://ecqi.healthit.gov/* or another website as designated by CMS.

We invited public comment on these proposals.

Comment: Several commenters supported the proposal requiring EHRs to be certified to all available eCQMs in the Hospital OQR Program, citing that this policy is an important step to promoting interoperability and will incentivize EHR vendors to take responsibility for eCQMs. A commenter applauded CMS for promoting alignment with other programs.

Response: We thank commenters for their support.

Comment: A few commenters expressed concern about the potential financial and operational burden for hospitals to meet the requirements, such as the need to invest in new technology, train staff, coordinate with EHR vendors, implement new workflows, and the risk of incurring potential penalties due to loss of quality reporting reimbursement. A commenter noted that hospitals continue to grapple with eCQM calculation, data analysis, and performance improvement. The commenter further stated that requiring EHR certification for all eCQMs without adequate time for system updates and testing could create undue burden and hinder quality improvement efforts. A few commenters requested that CMS delay implementation of the policy to provide additional time to meet requirements and for smoother implementation.

Response: Requiring EHR technology to be certified to all available eCQMs is important in collecting the most relevant electronic data and would help streamline the electronic data extrapolation component of HOPD workflow in the future. We recognize that requiring EHRs to be certified to all available eCQMs initially creates some costs for both HOPDs and health IT vendors. However, once the initial process of certifying the EHR to all available eCQMs has been completed, hospitals would not have to certify measures individually, and the EHR would accurately capture and calculate all eCQMs in the Hospital OQR Program. Given the benefits of certifying EHRs to all eCQMs and the small number of eCQMs in the Hospital OQR Program, we will not be delaying the policy.

Comment: A few commenters expressed concerns over accessing timely and reliable eCQM data through their EHR. A commenter specifically

noted that the ability to leverage CEHRT and the most recent eCQM specifications is dependent on updates incorporated by EHR vendors. Commenters urged CMS to work with the Office of the National Coordinator for Health Information Technology (ONC) and health IT vendors to include commensurate requirements on vendors, including making eCQM performance data available within 1 month of the start of the performance period and encouraging EHR vendors to provide functionality with sufficient lead time.[474]

Response: Utilizing certified technology updated consistent with ONC's health IT certification criteria and certified to all eCQMs would streamline and mitigate challenges related to accessing and exporting eCQM data. As specified in 45 CFR 170.315(c)(1) through (4), health IT systems that present for certification to these criteria under the ONC Health IT Certification Program must support the recording, exporting, importing, calculating, reporting, and filtering of clinical quality measures selected for certification by developers and CMS. Specifically, certified health IT certified to 45 CFR 170.315(c)(1) and (3) must be able to record all data necessary to calculate each clinical quality measure and enable users to export a data file that is formatted in accordance with Quality Reporting Document Architecture (QRDA) Category 1 and do so without subsequent developer assistance. For additional information on the ONC certification criteria for health IT, we refer readers to the web page available at: *https://www.healthit.gov/topic/certification-ehrs/certification-criteria*.

We will continue to seek input from health IT vendors and collaborate with ASTP/ONC to define standards that influence eCQM data collection and reporting for our quality reporting programs.

Comment: A commenter stated their belief that CEHRT would not enable CMS to meet its goal of improving data standardization and standardized data collection for eCQMs and encouraged CMS to take these factors into consideration.

Response: We disagree that CEHRT updated consistent with ONC's health IT certification criteria would not support our goal of standardization. Key elements of a number of ONC certification criteria for health IT, such as adopted versions of the United States Core Data for Interoperability (USCDI), are designed to promote the standardization of data collection and exchange, including standards for structured data capture and the use of relevant health data classes and elements.

After consideration of the public comments we received, we are finalizing our proposal requiring use of EHR technology certified to all eCQMs that are available to report under the Hospital OQR Program and codifying this policy in § 419.46(j)(2). We are also codifying in § 419.46(j)(1) the requirement for hospitals to utilize certified technology updated consistent with ONC's health IT certification criteria and codifying in § 419.46(j)(3) the requirement that hospitals use the most recent version of the eCQM electronic measure specifications.

c. Patient-Reported Outcome-Based Performance Measures (PRO–PMs)

(1) Data Submission of PRO–PM Data

In the CY 2024 OPPS/ASC final rule (88 FR 82006) we finalized that for the Total Hip Arthroplasty and/or Total Knee Arthroplasty (THA/TKA) PRO–PM, hospitals must use the HQR system for data submission for a PRO–PM. In the CY 2025 OPPS/ASC proposed rule (89 FR 59459), we proposed to apply this submission method to PRO–PMs generally, including the Information Transfer PRO–PM. We proposed that hospitals must use the HQR system for data submission for any PRO–PM that we adopt for the Hospital OQR Program measure set. HOPDs may choose to: (1) directly submit their PRO–PM data to CMS using the HQR system; or (2) utilize a third-party entity, such as a vendor or registry, to submit their data using the HQR system. The HQR system allows for data submission using multiple file formats (such as CSV, XML) and a manual data entry option, allowing HOPDs additional flexibility in data submission.

We invited public comment on the proposal.

We did not receive any public comments on our proposal and therefore, we are finalizing our proposal that hospitals must use the HQR system for data submission for any PRO–PM that we adopt for the Hospital OQR Program measure set.

(2) Data Submission and Reporting Requirements for the Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance Measure (Information Transfer PRO–PM)

As discussed in section XV.C.1.b of this final rule with comment period, we are adopting the Information Transfer PRO–PM beginning with voluntary reporting for the CY 2026 reporting period followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2029 payment determination.

In the CY 2025 OPPS/ASC proposed rule (89 FR 59459), we proposed that the performance period on which data is submitted would be January 1 through and including December 31 of the year that is two years prior to the applicable payment determination year. We proposed to require HOPDs to submit their Information Transfer PRO–PM data between the period starting January 1st through and including May 15 of the year prior to the applicable payment determination year. All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a non-workday for Federal employees by statute or Executive order would be extended to the first day thereafter.

We proposed to require HOPDs to offer all patients meeting the measure's denominator specifications the opportunity to complete the survey. Additionally, we proposed a minimum random sample size of 300 completed surveys to ensure the reliability of the measure, as this is a recommended minimum sample size for a population of 1,500 to provide a 95 percent confidence interval and a 90 percent confidence interval for a population of over 10,000; this is also generally accepted as a minimum sample size for stable population estimates.[475] [476]

[474] On July 29, 2024, notice was posted in the **Federal Register** that ONC would be dually titled to the Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (89 FR 60903).

[475] Ahmad, H., & Halim, H. (2017). Determining Sample Size for Research Activities. Selangor Business Review, 2(1), 20–34. Retrieved from *https://sbr.journals.unisel.edu.my/ojs/index.php/sbr/article/view/12*.

[476] Voorhis, C., & Morgan, B. (2007). Understanding Power and Rules of Thumb for Determining Sample Size. Tutorials in Quantitative Methods for Psychology. 3(2), 43–50. *www.doi.org/10.20982/tqmp.03.2.p043*.

HOPDs that are unable to collect 300 completed surveys will not be able to perform random sampling, and would instead be required to submit data on survey responses from all completed surveys received.

We invited public comment on these proposals.

We did not receive any public comments on our proposal and therefore, we are finalizing our proposal for data submission and reporting requirements for the Information Transfer PRO–PM as proposed.

F. Public Reporting of Measure Data

1. General Policy

We refer readers to the CY 2024 OPPS/ASC final rules (88 FR 81995 and 81996) for our previously finalized policies regarding public display of quality measures.

2. Public Reporting of Median Time From Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients—Psychiatric/Mental Health Patients Strata on Care Compare

We refer readers to the CY 2011 OPPS/ASC final rule (75 FR 72086) where we adopted the Median Time from ED Arrival to ED Departure for Discharged ED Patients (Median Time for Discharged ED Patients) measure beginning with CY 2013 payment determination. The Median Time for Discharged ED Patients measure is a chart-abstracted measure that evaluates the time from ED arrival to departure, also known as ED throughput time. The measure data are stratified into four separate calculations: (a) Median Time for Discharged ED Patients—Overall Rate; (b) Median Time for Discharged ED Patients—Reporting Measure, which excludes psychiatric/mental health and transfer patients; (c) Median Time for Discharged ED Patients—Psychiatric/Mental Health Patients, which includes information only for psychiatric/mental health patients; and (d) Median Time for Discharged ED Patients—Transfer Patients, which includes information only for patients transferred from the ED.

In the CY 2024 OPPS/ASC final rule (88 FR 81995 and 81996), we finalized that data for three measure strata (that is, the Overall Rate, Reporting Measure, and Transfer Patients strata) would be publicly reported both on *data.medicare.gov* in downloadable data files and on Care Compare (or subsequent CMS-designated websites). Data for the Psychiatric/Mental Health Patients stratum are not currently publicly reported on Care Compare, though these data are published on *data.medicare.gov* in downloadable data files (82 FR 59438). In the CY 2018 OPPS/ASC final rule (82 FR 52576 through 52578), we summarized commenters' concerns that delays in ED discharge of mental health patients may be influenced, in part, by the availability of community resources. In response, we stated that we would take additional time for further consideration prior to displaying this subset of data on Care Compare. We have considered commenters' concern that factors outside of an HOPD's control may influence ED throughput for psychiatric/mental health patients; however, it is our understanding that many hospitals face such concerns, and that timely care is a critical aspect of quality of care. We also stated in the CY 2024 OPPS/ASC final rule (88 FR 82061) in the context of adopting this measure for the REHQR Program that the public reporting of these data on Care Compare could help patients and their caregivers identify which facilities are performing better than others despite potential challenges, and drive quality improvement efforts.

Our routine monitoring and evaluation of the CY 2024 performance period for this measure has shown a median ED throughput time of 4.7 hours for psychiatric/mental health patients compared to 2.6 hours for non-psychiatric/mental health patients, suggesting this is an area that may benefit from additional quality improvement efforts. Data from the Median Time for Discharged ED Patients—Psychiatric/Mental Health Patients will be useful for patients choosing a care location, as well as researchers and hospital staff as they attempt to address health disparities and improve the timeliness of care for mental health patients. Since the data required for public reporting are already collected and submitted by participating HOPDs, publicly reporting this stratification would not create additional hospital burden.

For these reasons, in the CY 2025 OPPS/ASC proposed rule (89 FR 59459 through 59460), we proposed to make data for the Psychiatric/Mental Health Patients stratification available on Care Compare, including data that were previously published on *data.medicare.gov* but not displayed on Care Compare, beginning in CY 2025.

We invited public comment on the proposal.

Comment: Several commenters supported CMS' proposal to publicly report data for the Psychiatric/Mental Health patient stratum on Care Compare, noting that reporting these data would help consumers make educated decisions for timely, appropriate care and promote accountability for throughput time. A commenter noted that these data will provide policymakers the necessary information to address challenges with ED boarding for this patient population.

Response: We thank commenters for their support of our proposal.

Comment: A commenter supported making data for the Median Time for Discharged ED Patients—Psychiatric/Mental Health stratum more accessible but did not support imposing additional reporting burdens on hospitals.

Response: We appreciate the commenter's support for increasing data accessibility. We wish to clarify that the proposed policy would not increase reporting burden for HOPDs. Data for the Median Time for Discharged ED Patients measure are already collected and submitted by participating HOPDs and are currently accessible in downloadable files from CMS' Provider Data Catalog available at *data.cms.gov*. The public reporting of the Psychiatric/Mental Health Patients stratum on Care Compare would not require hospitals to collect or submit any additional data beyond what is already required.

Comment: Many commenters opposed the proposal to publicly report the Median Time for Discharged ED Patients—Psychiatric/Mental Health stratum on Care Compare, noting that ED throughput times for this population are influenced by factors outside of a provider's control, including lack of psychiatric resources in a community, barriers to efficient transition, and challenges with screening this population. Several commenters noted their beliefs that the measure does not reflect the efficacy and quality of care provided in an ED. A few commenters stated concerns regarding a lack of evidence demonstrating that ED throughput time influences patient outcomes.

Response: We understand commenters' concerns that there are many factors outside a hospital's control that could affect ED throughput, such as limited psychiatric resources; however, the Compare tool data indicate that hospitals with 50 beds or less performed better on this measure overall and had lower median ED throughput times for discharged psychiatric/mental health patients than larger hospitals (88 FR 82049), despite evidence indicating that smaller hospitals often lag behind in their quality performance and maintain limited scale and resources compared to

large systems.[477] [478] [479] Therefore, while external factors can play a role in Median Time from ED Arrival to ED Departure, resource constraints alone do not fully account for variations in performance, as evidenced by the better performance of smaller hospitals on this measure.

We respectfully disagree that the measure does not represent the efficacy or quality of care provided in an ED. While ED throughput alone may not reflect all aspects of care in an ED, it is an important indicator of operational efficiency [480] and timely care, which have direct influence on the quality of care provided to patients.[481] Prolonged ED throughput times can lead to overcrowding, and overcrowding is associated with avoidable problems in the ED, such as poor outcomes resulting from delays in treatment and ambulance diversion.[482] Additionally, ED throughput has a direct influence on patient experience [483] in the ED setting, and studies demonstrate that higher patient satisfaction is associated with improved patient outcomes, including decreased mortality [484] and lower readmission rates.[485]

We reiterate that timely care is a critical aspect of quality of care and directly impacts patient outcomes, particularly for an ED episode of care. The public reporting of these data can help patients and their caregivers identify which hospitals are performing better than others, despite the challenges many hospitals face, and drive quality improvement efforts. Additionally, aligning the reporting of ED throughput data across the Hospital OQR and REHQR Programs will allow consumers to make informed comparisons across settings.

Comment: A few commenters expressed their belief that there is no added benefit to reporting the Median Time for Discharged ED Patients—Psychiatric/Mental Health data on Care Compare since these data are already available in downloadable files on *cms.data.gov.* Another commenter noted that reporting the data would be duplicative of other strata listed on the Compare tool, and a few commenters expressed concern that publicly reporting the stratum may not help patients when making care decisions.

Response: The inclusion of the Median Time for Discharged ED Patients—Psychiatric/Mental Health stratum on the Compare tool addresses a critical behavioral health gap in the publicly reported Hospital OQR Program measure set and is not duplicative of other data listed on the Compare tool. By publicly reporting these data, we aim to increase transparency around the care provided to this vulnerable patient population and highlight areas where resources and processes may need to be strengthened. We reiterate that publicly reporting these data on the Compare tool will be useful for patients choosing a care location, as well as researchers, policymakers, and hospital staff as they attempt to address health disparities and improve the timeliness of care for mental health patients.

Comment: A few commenters expressed concerns regarding potential unintended consequences of publicly reporting the data. A commenter expressed their belief that publicly displaying the data could discourage facilities from taking the necessary time to ensure patients have adequate resources in place before discharge. Several commenters stated their belief that reporting the data may deter individuals from seeking care during mental health crises.

Response: We appreciate the commenter's input regarding potential unintended consequences of displaying these data on the Compare tool. We remain confident that rather than deterring individuals from seeking care, publicly reporting these data on the Compare tool would help patients and their caregivers identify the hospitals that are performing better on this metric and empower consumers to make informed decisions. We also respectfully disagree that publicly reporting ED throughput data on the Compare tool for the Psychiatric/Mental Health stratum would incentivize HOPDs to inappropriately limit their care to quickly discharge one of their most vulnerable patient populations from the ED. Rather, we remain confident that HOPDs will continue to provide high quality care for psychiatric/mental health patients and submit data as part of their commitment to the patient experience and ongoing quality improvement efforts. We further note that these data have been available since 2018 in the Provider Data Catalog located at *https://data.cms.gov* (82 FR 59437), as part of CMS' assessment of timely and effective care, and that median time for ED discharge continued to increase for psychiatric/mental health patients after 2018, indicating that HOPDs were not incentivized to limit their care after these data became publicly available.

Comment: A commenter raised concerns that limited pediatric inpatient psychiatric beds contribute to very long boarding times in the ED and recommended further stratifying the data by pediatric and adult populations.

Response: We acknowledge the commenter's concerns that limited pediatric psychiatric resources may contribute to longer ED throughput times for the pediatric patient population. However, we believe it is important to not separate the pediatric and adult populations when calculating this measure. The current measure aims to capture performance for all Psychiatric/Mental Health patients. Stratifying by age does not align with our broader goals of improving emergency care across all age groups, as these patient groups should be provided the same level of care in the ED setting. We will continue to monitor feedback on this measure and evaluate potential future refinements based on trends and stakeholder input.

Comment: A commenter stated that the current data, presented without additional context or risk adjustment may lead to misinterpretation by consumers. The commenter recommended risk-adjusting the data and establishing a cap on the maximum time from ED arrival to ED departure,

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[477] Chartis. Healthcare's uneven financial performance: Large hospitals bounce back while rural facilities face ongoing vulnerability concerns. Available at: *https://www.chartis.com/insights/healthcares-uneven-financial-performance-large-hospitals-bounce-back-while-rural.*

[478] Chartis. Unrelenting Pressure Pushes Rural Safety Net Crisis into Uncharted Territory. Available at: *https://www.chartis.com/sites/default/files/documents/chartis_rural_study_pressure_pushes_rural_safety_net_crisis_into_uncharted_territory_feb_15_2024_fnl.pdf.*

[479] Sherry TB, Damberg CL, DeYoreo M, et al. (2022). Is Bigger Better?: A Closer Look at Small Health Systems in the United States. Med Care. 60(7):504–511. *www.doi.org/10.1097/MLR.0000000000001727.*

[480] Gardner, R.M., N.A. Friedman, M. Carlson, T.S. Bradham and T.W. Barrett. Impact of revised triage to improve throughput in an ED with limited traditional fast track population. Am J Emerg Med., 2017,36(1), 124–127.

[481] Kelen GD, Wolfe R, D-Onofrio G, Mills AM, Diercks D, Stern SA, Wadman MC, Sokolove PE. Emergency Department Crowding: The Canary in the Health Care System. NEJM Catalyst. 2021; 5(2).

[482] Ibid.

[483] Nyce, A, Gandhi, S, Freeze, B, Bosire, J, Ricca, T, Kupersmith, E, Mazzarelli, A, Rachoin, J-S. Association of Emergency Department Waiting Times With Patient Experience in Admitted and Discharged Patients. 2021. J Pat Exp 8:1–7. *https://doi.org/10.1177/23743735211011404.*

[484] Glickman SW, Boulding W, Manary M, Staelin R, Roe MT, Wolosin RJ. et al. Patient satisfaction and its relationship with clinical quality and inpatient mortality in acute myocardial infarction. Circ Cardiovasc Qual Outcomes. 2010; 3:188–95. Available at *https://www.ahajournals.org/doi/10.1161/CIRCOUTCOMES.109.900597?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed.*

[485] Boulding W, Glickman SW, Manary MP, Schulman KA, Staelin R. Relationship between patient satisfaction with inpatient care and hospital readmission within 30 days. Am J Manag Care. 2011;17:41–8. Available at *https://www.ajmc.com/view/ajmc_11jan_boulding_41to48.*

noting that a ceiling on this metric would help level the playing field for hospitals in areas with bed shortages.

Response: We thank the commenter for their input. We believe that publicly displaying the full range of time from ED arrival to ED departure is necessary to improve transparency around wait times for all hospitals and allow for more informed decision-making for patients. Establishing a cap or ceiling for this metric could result in extremely long or outlier wait times not being shown on Care Compare, and we believe that information about outlier wait times is important to display on Care Compare for patient awareness. Similarly, we disagree that risk-adjustment is appropriate for this measure because a patient's ED wait time should not be related to any patient-specific factors.

Comment: A few commenters recommended that the publicly displayed data for the Median Time for Discharged ED Patients—Psychiatric/Mental Health population also include data on the mental health resources in a HOPD's community. Commenters also encouraged partnership with stakeholders to provide the needed resources for this patient population.

Response: We appreciate the recommendation to provide context for the data publicly displayed for the Median Time for Discharged ED Patients—Psychiatric/Mental Health population. Dashboards on resource availability do exist, such as the Health Resources and Services Administration's (HRSA) tool for Health Professional Shortage Areas and the Medically Underserved Areas/Populations dashboard. We will consider using HRSA's dashboards, or other tools that provide context on the availability of resources in a community, to potentially supplement data for the Psychiatric/Mental Health Patients population on Care Compare as appropriate in the future.

We thank commenters for their feedback to work with interested parties and will take these recommendations into consideration as appropriate as we continue to evaluate all elements of the Hospital OQR Program to ensure a relevant and meaningful measure set.

Comment: A few commenters recommended removing the Median Time for Discharged ED Patients measure from the Hospital OQR Program measure set. A commenter specifically noted that the measure currently lacks CBE endorsement and raised concerns regarding the strength of evidence supporting the measure's use in quality reporting programs.

Response: One of the Meaningful Measures 2.0 goals is to address measurement gaps, reduce burden, and increase efficiency by using high-value quality measures impacting key quality domains. ED performance and care continues to be a key quality domain of the Hospital OQR Program. Removal of the Median Time for Discharged ED Patients measure would result in an incomplete measure set with no measures that review ED throughput. We continue to believe that the Median Time for Discharged ED Patients measure supports our Meaningful Measures 2.0 goals. Additionally, behavioral health is a high-priority outcome area and one of the CMS National Quality Strategy Goals is to improve quality and health outcomes across the care journey by driving improvements in high-priority areas, such as behavioral health. We acknowledge that the measure is no longer CBE endorsed because the measure was withdrawn by the developer,[486] however, we continue to assert that the Median Time for Discharged ED Patients continues to provide valuable information regarding timely care. Furthermore, quality improvement efforts aimed at reducing ED overcrowding and length of stay have been associated with an increase in ED patient volume, decrease in number of patients who leave without being seen, reduction in costs, and increase in patient satisfaction.[487] [488] [489] [490] Section 1833(t)(17)(C)(i) of the Act provides that the Hospital OQR Program, to the extent feasible and practicable, shall include measures that reflect consensus among affected parties and, to the extent feasible and practicable, measures set forth by one or more national consensus building entities. As we have noted in previous rulemaking, consensus among affected parties can be reflected in ways other than CBE endorsement, including through the measure development process, through broad acceptance and use of the measure(s), and through public comment (75 FR 72064 and 72065). The CBE's continued endorsement until the measure developer withdrew the measure, and the continuous use of the measure in both the Hospital OQR Program and in academic studies, such as those cited in a previous endorsement cycle,[491] [492] [493] [494] [495] demonstrate ongoing acceptance of its value.

After consideration of the public comments we received, we are finalizing our proposal to publicly display the Median Time for Discharged ED Patients—Psychiatric/Mental Health stratum on the Compare tool, beginning with measure data for the CY 2025 reporting period.

G. Payment Reduction for Hospitals That Fail To Meet the Hospital OQR Program Requirements for the CY 2025 Payment Determination

1. Background

Section 1833(t)(17) of the Act, which applies to subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act), states that hospitals that fail to report data required to be submitted on measures selected by the Secretary, in the form and manner, and at a time, specified by the Secretary will incur a 2.0 percentage point reduction to their Outpatient Department (OPD) fee schedule increase factor; that is, the annual payment update factor. Section 1833(t)(17)(A)(ii) of the Act specifies that any reduction applies only to the payment year involved and will not be taken into account in computing the applicable OPD fee schedule increase factor for a subsequent year.

[486] Partnership for Quality Measurement. Submission Tool and Repository Measure Database. *https://p4qm.org/measures/0496*.

[487] Nyce A, Gandhi S, Freeze B, et al. (2021). Association of Emergency Department Waiting Times With Patient Experience in Admitted and Discharged Patients. Journal of Patient Experience. 2021;8. *www.doi.org/10.1177/23743735211011404*.

[488] Bucci S, de Belvis AG, Marventano S, et al. (2016). Emergency department crowding and hospital bed shortage: Is Lean a smart answer? A systematic review. Eur Rev Med Pharmacol Sci, 20(20), 4209–4219. *https://www.europeanreview.org/article/11589*.

[489] Chang AM, Lin A, Fu R, et al. (2017). Associations of Emergency Department Length of Stay With Publicly Reported Quality-of-care Measures. Acad Emerg Med. 24(2):246–250. *www.doi.org/10.1111/acem.13102*.

[490] Melton JD, Blind F, Hall AB, et al. (2016). Impact of a Hospitalwide Quality Improvement Initiative on Emergency Department Throughput and Crowding Measures. The Joint Commission Journal on Quality and Patient Safety. 42(12); 533–542. *www.doi.org/10.1016/S1553-7250(16)30104-0*.

[491] NQF. Measure Worksheet. *https://www.qualityforum.org/Projects/c-d/Cost_and_Efficiency/Measure_Worksheet_0496.aspx*.

[492] Mullins PM, Pines JM. National ED crowding and hospital quality: Results from the 2013 Hospital Compare data. Am J Emerg Med 2014; 32(6): 634–639. doi: 10.1016/j.ajem.2014.02.008.

[493] Zocchi MS, McClelland MS, & Pines JM. Increasing Throughput: Results from a 42-Hospital Collaborative to Improve Emergency Department Flow. Jt Comm J Qual Patient Saf. 2015 Dec;41(12):532–42. doi: 10.1016/s1553–7250(15)41070–0.

[494] Gardner RM, Friedman NA, Carlson M, Bradham TS, Barrett TW. Impact of revised triage to improve throughput in an ED with limited traditional fast track population. Am J Emerg Med. 2018 Jan;36(1):124–127. doi: 10.1016/j.ajem.2017.10.016.

[495] Chang AM, Lin A, Fu R, McConnell KJ, Sun B. Associations of Emergency Department Length of Stay With Publicly Reported Quality-of-care Measures. Acad Emerg Med. 2017 Feb;24(2):246–250. doi: 10.1111/acem.13102.

The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data in order to receive the full payment update factor and that fail to meet the Hospital OQR Program requirements. Hospitals that meet the reporting requirements receive the full OPPS payment update without the reduction. For a more detailed discussion of how this payment reduction was initially implemented, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68769 through 68772).

The national unadjusted payment rates for many services paid under the OPPS equal the product of the OPPS conversion factor and the scaled relative payment weight for the APC to which the service is assigned. The OPPS conversion factor, which is updated annually by the OPD fee schedule increase factor, is used to calculate the OPPS payment rate for services with the following status indicators (listed in Addendum B to the proposed rule, which is available via the internet on the CMS website): ''J1,'' ''J2,'' ''P,'' ''Q1,'' ''Q2,'' ''Q3,'' ''R,'' ''S,'' ''T,'' ''V,'' or ''U.'' Payment for all services assigned to these status indicators will be subject to the reduction of the national unadjusted payment rates for hospitals that fail to meet Hospital OQR Program requirements, with the exception of services assigned to New Technology APCs with assigned status indicator ''S'' or ''T.'' We refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68770 through 68771) for a discussion of this policy. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79796), we clarified that the reporting ratio does not apply to codes with status indicator ''Q4'' because services and procedures coded with status indicator ''Q4'' are either packaged or paid through the Clinical Laboratory Fee Schedule and are never paid separately through the OPPS.

The OPD fee schedule increase factor is an input into the OPPS conversion factor, which is used to calculate OPPS payment rates. To reduce the OPD fee schedule increase factor for hospitals that fail to meet reporting requirements, we calculate two conversion factors—a full market basket conversion factor (that is, the full conversion factor), and a reduced market basket conversion factor (that is, the reduced conversion factor). We then calculate a reduction ratio by dividing the reduced conversion factor by the full conversion factor. We refer to this reduction ratio as the ''reporting ratio'' to indicate that it applies to payment for hospitals that fail to meet their reporting requirements. Applying this reporting ratio to the OPPS payment amounts results in reduced national unadjusted payment rates that are mathematically equivalent to the reduced national unadjusted payment rates that would result if we multiplied the scaled OPPS relative payment weights by the reduced conversion factor. For example, to determine the reduced national unadjusted payment rates that applied to hospitals that failed to meet their quality reporting requirements for the CY 2010 OPPS/ASC final rule with comment period, we multiplied the final full national unadjusted payment rate found in Addendum B of the CY 2010 OPPS/ASC final rule with comment period by the CY 2010 OPPS final rule with comment period reporting ratio of 0.980 (74 FR 60642).

We note that the only difference in the calculation for the full conversion factor and the calculation for the reduced conversion factor is that the full conversion factor uses the full OPD update, and the reduced conversion factor uses the reduced OPD update. The baseline OPPS conversion factor calculation is the same since all other adjustments would be applied to both conversion factor calculations. Therefore, our standard approach of calculating the reporting ratio as described earlier in this section is equivalent to dividing the reduced OPD update factor by that of the full OPD update factor. In other words:

Full Conversion Factor = Baseline OPPS conversion factor * (1 + OPD update factor)

Reduced Conversion Factor = Baseline OPPS conversion factor * (1 + OPD update factor -0.02)

Reporting Ratio = Reduced Conversion Factor/Full Conversion Factor

Which is equivalent to:

Reporting Ratio = (1 + OPD Update factor -0.02)/(1 + OPD update factor)

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68771 through 68772), we established a policy that the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies would each equal the product of the reporting ratio and the national unadjusted copayment or the minimum unadjusted copayment, as applicable, for the service. Under this policy, we apply the reporting ratio to both the minimum unadjusted copayment and national unadjusted copayment for services provided by hospitals that receive the payment reduction for failure to meet the Hospital OQR Program reporting requirements. This application of the reporting ratio to the national unadjusted and minimum unadjusted copayments is calculated according to § 419.41 of our regulations, prior to any adjustment for a hospital's failure to meet the quality reporting standards according to § 419.43(h). Beneficiaries and secondary payers thereby share in the reduction of payments to these hospitals.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68772), we established the policy that all other applicable adjustments to the OPPS national unadjusted payment rates apply when the OPD fee schedule increase factor is reduced for hospitals that fail to meet the requirements of the Hospital OQR Program. For example, the following standard adjustments apply to the reduced national unadjusted payment rates: the wage index adjustment, the multiple procedure adjustment, the interrupted procedure adjustment, the rural sole community hospital adjustment, and the adjustment for devices furnished with full or partial credit or without cost. Similarly, OPPS outlier payments made for high cost and complex procedures will continue to be made when outlier criteria are met. For hospitals that fail to meet the quality data reporting requirements, the hospitals' costs are compared to the reduced payments for purposes of outlier eligibility and payment calculation. We established this policy in the OPPS beginning in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60642). For a complete discussion of the OPPS outlier calculation and eligibility criteria, we refer readers to section II.G of the CY 2023 OPPS/ASC proposed rule (87 FR 44533 through 44534).

2. Reporting Ratio Application and Associated Adjustment Policy for CY 2025

We proposed to continue our established policy of applying the reduction of the OPD fee schedule increase factor through the use of a reporting ratio for those hospitals that fail to meet the Hospital OQR Program requirements for the full CY 2025 annual payment update factor. For the CY 2025 OPPS/ASC proposed rule, the proposed reporting ratio was 0.9805, which, when multiplied by the proposed full conversion factor of $89.379, equaled a proposed conversion factor for hospitals that fail to meet the

requirements of the Hospital OQR Program (that is, the reduced conversion factor) of $87.636. We proposed to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. We proposed to continue to apply the reporting ratio, when applicable, to all HCPCS codes to which we have proposed status indicator assignments of ''J1,'' ''J2,'' ''P,'' ''Q1,'' ''Q2,'' ''Q3,'' ''R,'' ''S,'' ''T,'' ''V,'' and ''U'' (other than New Technology APCs to which we have proposed status indicator assignments of ''S'' and ''T''). We proposed to continue to exclude services paid under New Technology APCs. We proposed to continue to apply the reporting ratio to the national unadjusted payment rates and the minimum unadjusted and national unadjusted copayment rates of all applicable services for those hospitals that fail to meet the Hospital OQR Program reporting requirements. We also proposed to continue to apply all other applicable standard adjustments to the OPPS national unadjusted payment rates for hospitals that fail to meet the requirements of the Hospital OQR Program. Similarly, we proposed to continue to calculate OPPS outlier eligibility and outlier payment based on the reduced payment rates for those hospitals that fail to meet the reporting requirements. In addition to our proposal to implement the policy through the use of a reporting ratio, we also proposed to calculate the reporting ratio to four decimals (rather than the previously used three decimals) to more precisely calculate the reduced adjusted payment and copayment rates.

For CY 2025, the proposed reporting ratio was 0.9805, which, when multiplied by the proposed full conversion factor of $89.379, equaled a proposed conversion factor for hospitals that fail to meet the requirements of the Hospital OQR Program (that is, the reduced conversion factor) of $87.636.

We did not receive any public comments on our proposal. For this final rule with comment period, the final reporting ratio is 0.9806, which, when multiplied by the final full conversion factor of $89.169, equals a final conversion factor for hospitals that fail to meet the requirements of the Hospital OQR Program (that is, the reduced conversion factor) of $87.439. We are finalizing our proposal to continue to calculate OPPS outlier eligibility and outlier payment based on the reduced payment rates for those hospitals that fail to meet the reporting requirements. We are also finalizing our proposals to implement the policy through the use of a reporting ratio, and to calculate the reporting ratio to four decimals (rather than the previously used three decimals) to more precisely calculate the reduced adjusted payment and copayment rates for hospitals that fail to meet the Hospital OQR Program requirements for CY 2025 payment.

XVI. Rural Emergency Hospital Quality Reporting (REHQR) Program

A. Background and Statutory Authority

The Rural Emergency Hospital Quality Reporting (REHQR) Program's overarching goals are to improve the quality of care provided to Medicare beneficiaries, facilitate public transparency, ensure accountability, and safeguard the accessibility of hospitals in rural settings.

Section 1861(kkk)(7)(A) of the Social Security Act (the Act) provides that the Secretary shall establish quality measurement reporting requirements for Rural Emergency Hospitals (REHs), which may include the use of a small number of claims-based outcomes measures or surveys of patients with respect to their experience in the REH. In selecting measures for quality reporting, section 1861(kkk)(7)(C)(iii) provides that the Secretary shall take into consideration ways to account for REHs that lack sufficient case volume to ensure that the performance rates for such measures are reliable. Although section 1861(kkk)(7)(C)(i) of the Act requires that measures specified by the Secretary for use in the REHQR Program be endorsed by the entity with a contract under section 1890(a) of the Act, section 1861(kkk)(7)(C)(ii) of the Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

In addition, section 1861(kkk)(7)(D) of the Act provides that the Secretary shall establish procedures for making data submitted by REHs for the REHQR Program available to the public, following the opportunity for the REH to review and submit corrections on such data, with such data to be posted on a CMS website as determined appropriate by the Secretary. Beginning with 2023 (or each year beginning on or after the date that is 1 year after one or more measures are first specified), section 1861(kkk)(7)(B)(ii) of the Act requires REHs to submit quality measure data to the Secretary ''in a form and manner, and at a time, specified by the Secretary.''

We refer readers to section XVI of the CY 2024 OPPS/ASC final rule (88 FR 82046 through 82076) for an overview of the REHQR Program, which includes a more detailed discussion of the statutory history and program requirements codified at 42 CFR 419.95.

1. Previously Finalized Program Measure Sets

We refer readers to the CY 2024 OPPS/ASC final rule (88 FR 82066 through 82067) for more information regarding the previously finalized REHQR Program measure set beginning with the CY 2024 reporting period.

Table 165 below summarizes the previously finalized REHQR Program measure set and initial reporting periods with program determinations beginning with the CY 2026 program determination.[496]

[496] We use the phrase ''Program Determination'' for the REHQR Program to represent our assessment of compliance with program requirements for an applicable year because the REHQR Program does not include an associated payment adjustment.

TABLE 165: PREVIOUSLY FINALIZED REHQR PROGRAM MEASURE SET AND INITIAL REPORTING PERIODS BEGINNING WITH THE CY 2026 PROGRAM DETERMINATION

CBE #	Measure Name	Initial Reporting Periods	Initial Program Determination Affected
None	Abdomen Computed Tomography (CT) – Use of Contrast Material	January 1, 2024 – December 31, 2024	CY 2026
None	Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients		
2687	Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery		
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy	January 1, 2024 – December 31, 2026	CY 2028

B. Program Measure Set Policies

We refer readers to § 419.95(e) and the CY 2024 OPPS/ASC final rule (88 FR 82051 through 82053) for our program policies regarding measure retention, and immediate and general measure suspension and removal, and to § 419.95(d) and the CY 2024 OPPS/ASC final rule (88 FR 82054) for our program policies regarding modifications to previously adopted measures.

We further refer readers to the CY 2024 OPPS/ASC final rule (88 FR 82047 through 82051) for a discussion of our considerations for adopting quality measures under the REHQR Program, and to section XIV.B.1.c of this final rule with comment period for information regarding the pre-rulemaking process.

We did not propose any changes to these policies in the CY 2025 OPPS/ASC proposed rule.

C. Program Measure Updates

1. Adoption of Health Equity Quality Measures in the REHQR Program

We refer readers to sections XIV.B.1, XIV.B.2, and XIV.B.3 of this final rule with comment period for a discussion of our cross-program proposals to adopt the following measures in the REHQR Program: (1) the Hospital Commitment to Health Equity (HCHE) measure, beginning with the CY 2025 reporting period/CY 2027 program determination; (2) the Screening for Social Drivers of Health (SDOH) measure, beginning with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 program determination; and (3) the Screen Positive Rate for SDOH measure, beginning with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 program determination. In these sections, we also discuss the public comments received, our responses thereto, and our final decisions regarding these proposals for the REHQR Program.

As noted in the CY 2025 OPPS/ASC proposed rule (89 FR 59462 through 59463), in selecting measures for the REHQR Program, CMS takes into consideration ways to account for REHs that lack sufficient case volume to ensure that performance rates for such measures are reliable.[497] Once mandatory reporting begins, the measure specifications require all patients to be screened so we do not believe the Screening for SDOH measure or the Screen Positive Rate for SDOH measure would suffer from low case volumes. In addition, we noted that, as stated in the CY 2024 OPPS/ASC final rule (88 FR 82066), CMS does not report measures publicly unless it achieves sufficient case volumes for reliability purposes to allow for public reporting of the collected data.

2. Modification to the Reporting Period for the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery Measure Beginning With the CY 2027 Program Determination

In the CY 2024 OPPS/ASC final rule, we adopted the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery measure in the REHQR Program with a 1-year reporting period beginning with the CY 2024 reporting period (88 FR 82064 through 82066).

This measure is calculated from Part A and Part B Medicare administrative claims data for Medicare Fee-for-Service (FFS) beneficiaries with an outpatient same-day surgical procedure excluding eye surgeries and colonoscopies (except colonoscopy with biopsy). Colonoscopies are excluded from this measure as these procedures are examined separately on their own. Eye surgeries are excluded because they are performed in high volume and are generally perceived as being ''low risk.'' As stated in the CY 2024 OPPS/ASC final rule (88 FR 82064), this measure makes unplanned patient hospital visits (ED visits, observation stays, or unplanned inpatient admissions) after surgery more visible to providers and patients through publicly reporting scores.

As noted in the CY 2024 OPPS/ASC final rule (88 FR 82064), we believe this measure could also encourage providers to engage in quality improvement activities to reduce these visits by providing feedback to hospitals and providers. This measure meets the National Quality Strategy goals of embedding quality into the care journey and promoting safety,[498] and we expect that the measure would promote improvement in patient care over time (88 FR 82064 through 82065).

We have monitored and evaluated the reporting patterns of hospitals that have converted to REH status and have found that under the Hospital Outpatient Quality Reporting (OQR) Program, a

[497] *See* section 1861(kkk)(7)(C)(iii) of the Act.

[498] CMS, What is the CMS National Quality Strategy?. Available at: *https://www.cms.gov/medicare/quality/meaningful-measures-initiative/cms-quality-strategy.*

limited number of current REHs were able to publicly report on this measure as specified based on case threshold minimums. Therefore, in consideration of our statutory obligation to consider ways to account for low case volumes and to publicly report on quality-of-care metrics for REHs, in the CY 2025 OPPS/ASC proposed rule (89 FR 59463 through 59464), we proposed to increase the reporting period from 1 year to 2 years beginning with the CY 2027 program determination.

In the CY 2025 OPPS/ASC proposed rule (89 FR 59463), we explained that under the proposal, the previously finalized 1-year data collection period for the CY 2026 program determination would remain (that is, encounters from January 1, 2024, through December 31, 2024), and then beginning with the CY 2027 program determination, the reporting period would be supplemented with data from the prior calendar year. For example, for the CY 2027 program determination, the reporting period would comprise data from CYs 2024 and 2025 (that is, encounters from January 1, 2024, through December 31, 2025). We noted that, as stated in the CY 2024 OPPS/ASC final rule (88 FR 82066), CMS does not report measures publicly unless it achieves sufficient case volumes to allow for public reporting based on reliability or privacy concerns of the collected data.

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TABLE 166: COMPARISON OF 1-YEAR AND 2-YEAR REPORTING PERIODS FOR THE RISK-STANDARDIZED HOSPITAL VISITS WITHIN 7 DAYS AFTER OUTPATIENT SURGERY MEASURE FOR REHS

Data Time Period	REHs with at least 1 Denominator Case	REHs Meeting the Threshold for Public Reporting*	Total Eligible Surgical Cases	Total Number Patients with Visits
Risk-Standardized Hospital Visits Within 7 Days After Outpatient Surgery Measure				
One-Year Reporting Period				
Jan 1, 2020 - Dec 31, 2020	6	1	120	7
Jan 1, 2021 - Dec 31, 2021	7	1	207	14
Jan 1, 2022 - Dec 31, 2022	8	1	225	19
Two-Year Reporting Period				
Jan 1, 2020 - Dec 31, 2021	7	4	327	21
Jan 1, 2021 - Dec 31, 2022	8	3	432	33
Jan 1, 2022 - Dec 31, 2023	8	4	552	40

*30 or more eligible surgical cases are required to meet the Risk-Standardized Hospital Visits Within 7 Days After Outpatient Surgery measure's threshold to establish reliability for public reporting.

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In the CY 2025 OPPS/ASC proposed rule (89 FR 59463), we explained that as seen in Table 166, the longer reporting period of 2 years would facilitate greater case volumes for this measure and, subsequently, a larger portion of REHs would have data that could be reported publicly as more REHs attain the Risk-Standardized Hospital Visits Within 7 Days After Outpatient Surgery measure's minimum case threshold for reliability of 30 surgical cases. In addition, REHs reporting on the measure with 2 years of data would have more eligible patients to assess; this increase in eligible cases would also reduce the error estimate, making the confidence interval narrower, that is, increasing the reliability of the calculated measure. We refer readers to the CY 2019 OPPS/ASC final rule (83 FR 59106 through 59107) where we finalized a similar policy to extend the reporting period of the Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy measure in the Hospital OQR Program from 2 to 3 years.

In the CY 2025 OPPS/ASC proposed rule (89 FR 59464), we explained that under the proposal, there would be no gap in public reporting nor delay in providing REHs with data for quality improvement efforts. As this measure is calculated solely from administrative Medicare information, REHs would not have any additional reporting burden associated with a longer reporting period.

We invited public comment on the proposal.

Comment: Several commenters supported the proposal to extend the reporting period for the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery measure, stating that finalizing the policy would allow a broader range of hospitals to reliably and validly report the measure, provide consumers with ratings for a greater number of facilities, enhance the reliability of the measure results due to the larger sample size, provide hospitals with a more accurate and comprehensive understanding of performance trends over time, allow for improved data analysis and better-informed decisions regarding patient care, and reduce the pressure on hospitals to gather and report data within a shorter window thereby supporting more sustainable and effective reporting practices.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing the extension of the reporting period for the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery measure

from 1 year to 2 years, beginning with the CY 2027 program determination, as proposed.

3. Summary of Finalized Program Measure Set Updates

a. Finalized Program Measure Set Beginning With the CY 2027 Program Determination

Table 167 summarizes the finalized REHQR Program measure set and reporting periods beginning with the CY 2027 program determination.

Table 167 includes the previously finalized measure set with updates to reflect the finalized extension of the reporting period for the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery measure beginning with the CY 2027 program determination, and the three new cross-program health equity measures as detailed in sections XIV.B.1, XIV.B.2, and XIV.B.3, respectively, of this final rule with comment period:

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TABLE 167: FINALIZED REHQR PROGRAM MEASURE SET AND REPORTING PERIODS BEGINNING WITH THE CY 2027 PROGRAM DETERMINATION

CBE #	Measure Name	Reporting Period	Program Determination
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy	January 1, 2024 – December 31, 2026	CY 2028
2687	Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery*	January 1, 2024 – December 31, 2025	CY 2027
None	Abdomen Computed Tomography (CT) – Use of Contrast Material	January 1, 2025 – December 31, 2025	
None	Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients		
None	Hospital Commitment to Health Equity (HCHE)**		
None	Screening for Social Drivers of Health (SDOH)***		
None	Screen Positive Rate for SDOH***		

*We finalized that this measure will have an extended reporting period beginning with the CY 2027 program determination, as discussed in section XVI.C.2 of this final rule with comment period.

**We finalized that this measure will be mandatory beginning with the CY 2025 reporting period/CY 2027 program determination, as discussed in section XIV.B.1 of this final rule with comment period.

***We finalized that this measure will begin with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 program determination, as discussed in sections XIV.B.2 and XIV.B.3 of this final rule with comment period.

b. Finalized Program Measure Set Beginning With the CY 2028 Program Determination

Table 168 summarizes the finalized REHQR Program measure set and reporting periods beginning with the CY 2028 program determination.

Table 168 includes the previously finalized measure set with updates to reflect the finalized extension of the reporting period for the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery measure beginning with the CY 2028 program determination, and the three new cross-program health equity measures as detailed in sections XIV.B.1, XIV.B.2, and XIV.B.3, respectively, of this final rule with comment period.

TABLE 168: FINALIZED REHQR PROGRAM MEASURE SET AND REPORTING PERIODS BEGINNING WITH THE CY 2028 PROGRAM DETERMINATION

CBE #	Measure Name	Reporting Period	Program Determination
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy	January 1, 2024 – December 31, 2026	CY 2028
2687	Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery*	January 1, 2025 – December 31, 2026	
None	Abdomen Computed Tomography (CT) – Use of Contrast Material	January 1, 2026 – December 31, 2026	
None	Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients		
None	Hospital Commitment to Health Equity (HCHE)**		
None	Screening for Social Drivers of Health (SDOH)***		
None	Screen Positive Rate for SDOH***		

*We finalized that this measure will have an extended reporting period beginning with the CY 2027 program determination, as discussed in section XVI.C.2 of this final rule with comment period.
**We finalized that this measure will be mandatory beginning with the CY 2025 reporting period/CY 2027 program determination, as discussed in section XIV.B.1 of this final rule with comment period.
***We finalized that this measure will begin with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 program determination, as discussed in sections XIV.B.2 and XIV.B.3 of this final rule with comment period.

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D. Administrative Requirements

We refer readers to § 419.95(b) and the CY 2024 OPPS/ASC final rule (88 FR 82074) for our policies regarding administrative requirements previously finalized for the REHQR Program. We did not propose any changes to these policies in the CY 2025 OPPS/ASC proposed rule.

E. Form, Manner, and Timing of Data Submission

1. General Policy

We refer readers to § 419.95(c) and (g) and the CY 2024 OPPS/ASC final rule (88 FR 82074 through 82076) for our general policies regarding: (1) submission of data under the REHQR Program generally; (2) review and correction of submitted data; and (3) extraordinary circumstance exception (ECE) requests for data submission. We did not propose any changes to these policies in the CY 2025 OPPS/ASC proposed rule.

2. Data Submission Policy Following Conversion to REH Status

In the CY 2025 OPPS/ASC proposed rule (89 FR 59465), we noted that with implementation of these general data reporting policies and hospitals continuing to convert to REH status throughout the year, we believed that it was necessary to specify when a hospital that converts to REH status is required to begin reporting data to the REHQR Program. Thus, we proposed that an REH must begin submitting data to the REHQR Program on the first day of the quarter following the date that a hospital has been designated as converted to an REH in accordance with the process outlined in section 1861(kkk) of the Act.

We invited public comment on the proposal.

Comment: Several commenters supported the proposal to require REHs to begin submitting data to the REHQR Program on the first day of the quarter following the date that a hospital has been designated as converted to an REH, stating that this aligns with regulatory requirements and ensures a structured transition for newly designated REHs.

Response: We thank the commenters for their support.

Comment: A commenter recommended that CMS provide additional technical assistance to hospitals during the conversion period to help them prepare for reporting and suggested that CMS develop strategies to mitigate the financial impacts associated with reporting requirements in the first fiscal year following the REH conversion, to support a smoother transition and reduce the burden on these facilities.

Response: Technical assistance for reporting information is available on the QualityNet website (*https://qualitynet.cms.gov/reh*) and questions can be submitted via the Quality Question and Answer Tool (*https://cmsqualitysupport.servicenowservices.com/qnet_qa*). We have limited the burden associated with reporting by limiting the number and types of measures in the REHQR Program (for example, by primarily implementing measures calculated using Medicare administrative data and measures submitted using aggregate counts).

After consideration of the public comments we received, we are finalizing the data submission policy following conversion to REH status as proposed.

3. Measure-Specific Data Submission and Reporting Requirements

a. Data Submission Requirements for Chart-Abstracted Measures

We refer readers to the CY 2024 OPPS/ASC final rule (88 FR 82074 through 82075) for information regarding chart-abstracted data submission and reporting requirements. We did not propose any changes to these policies in the CY 2025 OPPS/ASC proposed rule.

b. HCHE, Screening for SDOH, and Screen Positive Rate for SDOH Measures' Data Submission Requirements and Reporting Requirements

In the CY 2025 OPPS/ASC proposed rule (89 FR 59465 through 59466), to align with the Hospital OQR (80 FR 70521 through 70522) and ASCQR (81 FR 79821 through 79822) Programs, we proposed a web-based submission policy where REHs would submit data for applicable measures once annually using a CMS-approved, web-based, data collection tool available within the Hospital Quality Reporting system.[499] We proposed that, in alignment with the Hospital OQR and ASCQR Programs, REHs would submit data during the period of January 1 to May 15 in the year prior to the affected program determination year. For example, for the CY 2025 reporting period/CY 2027 program determination, the data submission period would be January 1, 2026, to May 15, 2026, covering the performance period of January 1, 2025, to December 31, 2025. Under the review and corrections period provided at § 419.95(c)(3), REHs would be able to enter, review, and correct data submitted during the data submission period.

In the CY 2025 OPPS/ASC proposed rule (89 FR 59465), we proposed that these policies would apply to web-based measures adopted by the REHQR Program, including the following three measures:

- The HCHE measure, beginning with the CY 2025 reporting period/CY 2027 program determination;
- The Screening for SDOH measure, beginning with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 program determination; and
- The Screen Positive Rate for SDOH measure, beginning with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 program determination.

As discussed in sections XIV.B.1, XIV.B.2, and XIV.B.3 of this final rule with comment period, we are finalizing adoption of the HCHE, Screening for SDOH, and Screen Positive Rate for SDOH measures into the REHQR Program.

We invited public comment on the proposal.

Comment: A commenter supported the proposed policy to align the web-based measure submission policy for the REHQR Program with the Hospital OQR and ASCQR Programs.

Response: We thank the commenter for its support.

After consideration of the public comments we received, we are finalizing the data submission requirements related to the HCHE, Screening for SDOH, and Screen Positive Rate for SDOH measures as proposed.

c. Data Submission Requirements for Claims-Based Measure Data

In addition, we refer readers to section XVI.C.2 of this final rule with comment period where we discuss finalizing a modification to the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery Measure beginning with the CY 2027 program determination. This claims-based measure would continue to be reported in accordance with other claims-based measures, as previously finalized in the CY 2024 OPPS/ASC final rule (88 FR 85075). We did not propose any changes to these policies in the CY 2025 OPPS/ASC proposed rule.

F. Public Reporting of Measure Data

We refer readers to § 419.95(f) and the CY 2024 OPPS/ASC final rule with comment period (88 FR 82071 through 82074) for our program policy regarding the public reporting of quality data. We did not propose any changes to these policies in the CY 2025 OPPS/ASC proposed rule.

XVII. Ambulatory Surgical Center Quality Reporting (ASCQR) Program

A. Background and Statutory Authority

The Ambulatory Surgical Center Quality Reporting (ASCQR) Program is a pay-for-reporting program intended to improve the quality of care provided to Medicare beneficiaries, facilitate public transparency, and ensure accountability of ambulatory surgical centers (ASCs). Section 1833(i)(7)(A) of the Act authorizes the Secretary to reduce any annual increase under the revised ambulatory surgical center (ASC) payment system by 2.0 percentage points for such year that an ASC that fails to submit required data on quality measures specified by the Secretary in accordance with section 1833(i)(7)(B) of the Act. Section 1833(i)(7)(B) of the Act states that, except as the Secretary may otherwise provide, several of the statutory provisions governing the Hospital Outpatient Quality Reporting (OQR) Program, specifically sections 1833(t)(17)(B) through (E) of the Act, also apply to the services of ASCs under the ASCQR Program in a similar manner to the manner in which they apply to the services of hospital outpatient departments under the Hospital OQR Program. Sections 1833(t)(17)(B) through (E) of the Act generally govern the adoption and replacement of quality measures, the form and manner of submission of data to CMS, and procedures for making the data submitted to CMS available to the public.

We refer readers to the CY 2012 OPPS/ASC final rule (76 FR 74492 through 74494) for a detailed discussion of the program's statutory authority, as well as program requirements codified at 42 CFR part 416, subpart H (§§ 416.300 through 416.330), and the CY 2024 OPPS/ASC final rule (88 FR 82012) for information regarding the program's regulatory history.

1. Previously Finalized Program Measure Sets

We refer readers to the CY 2024 OPPS/ASC final rule (88 FR 82038) for additional information regarding the previously finalized ASCQR Program measure set beginning with the CY 2027 payment determination.

a. Previously Finalized Measure Set Beginning With the CY 2027 Payment Determination

Table 169 summarizes the previously finalized ASCQR Program measures beginning with the CY 2027 payment determination.

[499] The Hospital Quality Reporting (HQR) system (formerly referred to as the QualityNet Secure Portal) is the only CMS-approved website for secure communications and health care quality data exchange to and within various CMS quality reporting programs. For more information regarding the HQR system, we refer readers to the CMS eCQI Resource Center (*https://ecqi.healthit.gov/tool/hospital-quality-reporting-hqr-system*). In addition, we refer readers to the CY 2024 OPPS/ASC final rule (88 FR 82074 through 82075) for a discussion of data submission requirements for chart-abstracted measures under the REHQR Program, which includes submission of measure data via the HQR system.

TABLE 169: PREVIOUSLY FINALIZED ASCQR PROGRAM MEASURE SET BEGINNING WITH THE CY 2027 PAYMENT DETERMINATION

CBE #	Measure Name
None†	All-Cause Hospital Transfer/Admission
None†	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery*
3636	COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP)
0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
3357	Facility-Level 7-Day Hospital Visits After General Surgery Procedures Performed at ASCs
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy
3470	Hospital Visits After Orthopedic Ambulatory Surgical Center (ASC) Procedures
3366	Hospital Visits After Urology ASC Procedures
None	Normothermia Outcome
None	Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) • About Facilities and Staff • Communication About Procedure • Overall Rating of Facility • Preparation for Discharge and Recovery • Recommendation of Facility
None†	Patient Burn
None†	Patient Fall
None	Risk-Standardized Patient-Reported Outcome-Based Performance Measure Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty (THA/TKA PRO-PM) in the ASC Setting**
None	Unplanned Anterior Vitrectomy
None†	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant

†Measure is no longer endorsed by the Consensus Based Entity (CBE) but was endorsed previously.
*This measure is voluntary.
**This measure begins with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2028 reporting period/CY 2031 payment determination, as discussed in the CY 2024 OPPS/ASC final rule (88 FR 82033 through 82036).

b. Previously Finalized Measure Set Beginning With the CY 2031 Payment Determination

Table 170 summarizes the previously finalized ASCQR Program measures beginning with the CY 2031 payment determination.

TABLE 170: PREVIOUSLY FINALIZED ASCQR PROGRAM MEASURE SET BEGINNING WITH THE CY 2031 PAYMENT DETERMINATION

CBE #	Measure Name
None†	All-Cause Hospital Transfer/Admission
None†	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery*
3636	COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP)
0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
3357	Facility-Level 7-Day Hospital Visits After General Surgery Procedures Performed at ASCs
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy
3470	Hospital Visits After Orthopedic ASC Procedures
3366	Hospital Visits After Urology ASC Procedures
None	Normothermia Outcome
None	Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) • About Facilities and Staff • Communication About Procedure • Overall Rating of Facility • Preparation for Discharge and Recovery • Recommendation of Facility
None†	Patient Burn
None†	Patient Fall
None	Risk-Standardized Patient-Reported Outcome-Based Performance Measure Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty (THA/TKA PRO-PM) in the ASC Setting
None	Unplanned Anterior Vitrectomy
None†	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant

†Measure is no longer endorsed by the CBE but was endorsed previously.
*This measure is voluntary.

B. Program Measure Set Policies

1. Measure Retention

We refer readers to § 416.320 and the CY 2012 OPPS/ASC final rule (76 FR 74504) for our policies regarding measure retention. We did not propose any changes to these policies in the CY 2025 OPPS/ASC proposed rule.

2. Measure Suspension or Removal

We refer readers to § 416.320 and the CY 2019 OPPS/ASC final rule (83 FR 59111 through 59115) for our program policies regarding: (1) general measure removal, suspension, or replacement; and (2) immediate measure removal.

We refer readers to section XIV.C of this final rule with comment period for the discussion of public comments received and our subsequent decision regarding our cross-program proposal to modify the immediate measure removal policy for quality measures adopted for the ASCQR Program.

3. Measure Modification

We refer readers to § 416.325 and the CY 2016 OPPS/ASC final rule (80 FR 70531) for our program policies regarding modifications to previously adopted measures. We did not propose any changes to these policies in the CY 2025 OPPS/ASC proposed rule.

4. Measure Adoption

We refer readers to the CY 2013 OPPS/ASC final rule (77 FR 68493 and 68494) for details regarding program priorities we consider for quality measure selection. We did not propose any changes to these policies in the CY 2025 OPPS/ASC proposed rule.

C. Program Measure Updates

1. Adoption of the Health Equity Quality Measures in the ASCQR Program

We refer readers to sections XIV.B.1, XIV.B.2, and XIV.B.3 of this final rule with comment period for our discussion of our cross-program proposals to adopt the following measures in the ASCQR Program: (1) the Facility Commitment to Health Equity (FCHE) measure, beginning with the CY 2025 reporting period/CY 2027 payment determination; (2) the Screening for Social Drivers of Health (SDOH) measure, beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; and (3) the Screen Positive Rate for SDOH measure, beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. In these sections, we also discuss the public comments received, our responses thereto, and our final decisions regarding these proposals for the ASCQR Program. As discussed in sections XIV.B.1, XIV.B.2, and XIV.B.3 of this final rule with comment period,

we are finalizing these three measures for the ASCQR Program, as proposed.

2. Summary of Finalized Program Measure Set Updates

a. Newly Finalized ASCQR Program Measure Set Beginning With the CY 2027 Payment Determination

Table 171 summarizes the newly finalized ASCQR Program measure set beginning with the CY 2027 payment determination.

TABLE 171: FINALIZED ASCQR PROGRAM MEASURE SET BEGINNING WITH THE CY 2027 PAYMENT DETERMINATION

CBE #	Measure Name
None†	All-Cause Hospital Transfer/Admission
None†	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery*
3636	COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP)
0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
None	Facility Commitment to Health Equity (FCHE)***
3357	Facility-Level 7-Day Hospital Visits After General Surgery Procedures Performed at ASCs
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy
3470	Hospital Visits After Orthopedic Ambulatory Surgical Center (ASC) Procedures
3366	Hospital Visits After Urology ASC Procedures
None	Normothermia Outcome
None	Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) • About Facilities and Staff • Communication About Procedure • Overall Rating of Facility • Preparation for Discharge and Recovery • Recommendation of Facility
None†	Patient Burn
None†	Patient Fall
None	Risk-Standardized Patient-Reported Outcome-Based Performance Measure Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty (THA/TKA PRO-PM) in the ASC Setting**
None	Screening for Social Drivers of Health (SDOH)****
None	Screen Positive for Social Drivers of Health (SDOH)****
None	Unplanned Anterior Vitrectomy
None†	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant

†Measure is no longer endorsed by the CBE but was endorsed previously.
*This measure is voluntary.
**This measure begins with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2028 reporting period/CY 2031 payment determination, as discussed in the CY 2024 OPPS/ASC final rule (88 FR 82033 through 82036).
***This measure is finalized for adoption beginning with the CY 2025 reporting period/CY 2027 payment determination, as discussed in section XIV.B.1 of this final rule with comment period.
****This measure is finalized for adoption beginning with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination, as discussed in sections XIV.B.2 and XIV.B.3 of this final rule with comment period.

b. Newly Finalized ASCQR Program Measure Set Beginning With the CY 2031 Payment Determination

Table 172 summarizes the newly finalized ASCQR Program measure set beginning with the CY 2031 payment determination.

TABLE 172: FINALIZED ASCQR PROGRAM MEASURE SET BEGINNING WITH THE CY 2031 PAYMENT DETERMINATION

CBE #	Measure Name
None†	All-Cause Hospital Transfer/Admission
None†	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery*
3636	COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP)
0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
None	Facility Commitment to Health Equity (FCHE)**
3357	Facility-Level 7-Day Hospital Visits After General Surgery Procedures Performed at Ambulatory Surgical Centers (ASCs)
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy
3470	Hospital Visits After Orthopedic ASC Procedures
3366	Hospital Visits After Urology ASC Procedures
None	Normothermia Outcome
None	Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) • About Facilities and Staff • Communication About Procedure • Overall Rating of Facility • Preparation for Discharge and Recovery • Recommendation of Facility
None†	Patient Burn
None†	Patient Fall
None	Screening for Social Drivers of Health (SDOH)***
None	Screen Positive for Social Drivers of Health (SDOH)***
None	Risk-Standardized Patient-Reported Outcome-Based Performance Measure Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty (THA/TKA PRO-PM) in the ASC Setting
None	Unplanned Anterior Vitrectomy
None†	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant

†Measure is no longer endorsed by the CBE but was endorsed previously.
*This measure is voluntary.
**This measure is finalized for adoption beginning with the CY 2025 reporting period/CY 2027 payment determination, as discussed in section XIV.B.1 of this final rule with comment period .
***This measure is finalized for adoption beginning with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination, as discussed in sections XIV.B.2 and XIV.B.3 of this final rule with comment period.

3. Comments Regarding the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure

We received many comments requesting that we remove the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) from the ASCQR Program. A few commenters recommended, in the absence of removal, that we revise the measure specifications to have data submitted annually. While we appreciate these comments, we note that they fall outside the scope of this rulemaking. We will consider these comments as we continue to evolve the ASCQR Program in the future.

D. Administrative Requirements

We refer readers to § 416.305 and the CY 2016 OPPS/ASC final rule (80 FR 70533 and 70534) for our program policies regarding participation and withdrawal requirements. We did not

propose any changes to these policies in the CY 2025 OPPS/ASC proposed rule.

E. Form, Manner, and Timing of Data Submission

1. General Policy

We refer readers to § 416.310 and the CYs 2017, 2018, and 2021 OPPS/ASC final rules (81 FR 79824 and 79825; 82 FR 59472 through 59475; and 85 FR 86191 and 86192, respectively) for our general program policies regarding: (1) submission of data under the ASCQR Program generally; (2) review and correction of submitted data; and (3) extraordinary circumstance exception (ECE) requests for data submission. We did not propose any changes to these policies in the CY 2025 OPPS/ASC proposed rule.

We also refer readers to the CY 2016 OPPS/ASC final rule (80 FR 70531) for details regarding submission requirements for previously adopted ASCQR Program measures in the ASCQR Program Specifications Manual.

2. Measure-Specific Data Submission and Reporting Requirements

We refer readers to § 416.310 and the CYs 2016, 2022, and 2024 OPPS/ASC final rules (80 FR 70534 through 70536; 86 FR 63905 through 63909; and 88 FR 82041 through 82045, respectively) for information regarding our claims-based, survey-based, and PRO–PM data submission and reporting requirements.

a. Web-Based Measures

(1) CMS-Designated Information System and Proposal for Data Submission for the Facility Commitment to Health Equity (FCHE), Screening for Social Drivers of Health (SDOH), and Screen Positive Rate for SDOH Measures

We refer readers to § 416.310(c)(1), the CY 2017 OPPS/ASC final rule (81 FR 79821 and 79822), the CY 2018 OPPS/ASC final rule (82 FR 59473), and the CY 2024 final rule (88 FR 82039 and 82040) for details regarding submission of web-based data via a CMS-designated information system (currently the Hospital Quality Reporting (HQR) system).

In sections XIV.B.1, XIV.B.2, and XIV.B.3 of this final rule with comment period, we discuss the proposals and public comments received regarding the adoption of: (1) the FCHE measure, beginning with the CY 2025 reporting period/CY 2027 payment determination; (2) the Screening for SDOH measure, beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; and (3) the Screen Positive Rate for SDOH measure, beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination.

Consistent with our established data submission requirements (81 FR 79821 and 79822; 82 FR 59473; 88 FR 82039 and 82040), we proposed in the CY 2025 OPPS/ASC proposed rule (89 FR 59471) that ASCs would be required to submit all of the data required to calculate each of these three measures annually using a CMS-approved, web-based, data collection tool available within the HQR System starting January 1 through and including May 15 in the year prior to the applicable payment determination year. As discussed in sections XIV.B.1, XIV.B.2, and XIV.B.3 of this final rule with comment period, we are finalizing the FCHE measure, the Screening for SDOH measure, and the Screen Positive Rate for SDOH measure as proposed.

For the ASCQR Program, the performance period (which we refer to as the CY reporting period) for each measure on which data is submitted using a web-based tool would be January 1 through and including December 31 of the year that is 2 years prior to the applicable payment determination year; and the data submission period would be January 1 through and including May 15 in the calendar year immediately following the CY reporting period and immediately prior to applicable payment determination year. For example, for the CY 2025 reporting period/CY 2027 payment determination, the data submission period would be January 1, 2026, through and including May 15, 2026, covering the performance period of January 1, 2025, through and including December 31, 2025. Pursuant to § 416.310(c)(1)(iii), a review and corrections period runs concurrently with the data submission period. During this timeframe, ASCs would be able to enter, review, and correct data submitted during the data submission period.

We invited public comment on the proposal.

Comment: Several commenters that did not support adoption of the FCHE measure expressed concern over reporting burden, as this timeline coincides with OAS CAHPS and THA/TKA PRO–PM measure compliance. A few commenters expressed that there would not be sufficient time to implement processes, technology, and training needed to successfully report this measure. A few commenters suggested delaying the implementation of this measure or allowing for voluntary reporting.

Response: We acknowledge commenters' concerns regarding resources, including increased data collection burden; however, achieving health equity is an issue which deserves serious focus and rapid action for improvement. Therefore, we do not find it appropriate to delay the implementation of this measure. We believe the benefits of encouraging ASC commitment to health equity outweigh the burden of attestation under this measure.

We note that hospitals participating in the Hospital IQR Program will have already reported data on the similar Hospital Commitment to Health Equity measure for the FY 2025 payment determination (that is, data submitted in FY 2024 representing the FY 2023 performance period) (87 FR 49191 through 49201) before required reporting of the Facility Commitment to Health Equity measure begins within the ASCQR Program, as reporting for this measure would begin with the CY 2027 payment determination. Given the timing of this similar measure's implementation in the Hospital IQR Program, ASCs will have had the opportunity to learn from the experiences of acute care hospitals, including best practices for minimally burdensome assessment of performance on the required domains. We will also monitor measure implementation and data reporting as part of standard program and measure review and will consider updates to the measure if we identify implementation strategies to reduce burden.

Comment: A commenter requested that CMS maintain the Screening for SDOH and the Screen Positive Rate for SDOH measures as voluntary for the ASCQR Program as CMS continues to work through technical reporting challenges, such as publishing guidance on what constitutes a ''positive'' screen, with providers already reporting the measure in other quality reporting programs. Another commenter noted challenges with the implementation timeline in the ASCQR Program because it does not account for mandatory reporting of the OAS CAHPS Survey measure, which begins in 2025, and does not allow sufficient time for the amount of work that would need to be done for the Screening for SDOH measure, if it were to include screening for interpersonal safety.

Response: We thank the commenters for their feedback and recommendations. As previously discussed in sections XIV.B.2 and XIV.B.3 of this final rule with comment

period, the Screening for SDOH and Screen Positive Rate for SDOH measures provide information on the percent of patients receiving care at an ASC who were 18 years or older on the date of service, who were screened for all five HRSNs described in Table 171, and who screened positive for one or more of those HRSNs. For additional information on what constitutes a ''positive'' screen we refer readers to: *https://www.qualityreportingcenter.com/globalassets/2024/04/iqr/17.-sdoh-measure--faqs_april-2024_vfinal508.pdf.* We will develop a similar Frequently Asked Questions document for the ASCQR Program as part of providing educational and training materials. This document will be conveyed through routine communication channels, including, but not limited to, issuing memos, emails, and notices on a CMS website.

We will consider feedback about timeline, OAS CAHPS Survey overlap, and reporting in future rulemaking and measure development. We may address related proposals, including the form, manner, and timing of data reporting, in future rulemaking. We reiterate that, with a year of voluntary reporting for these measures, there is time for ASCs to train staff in the collection of data for HRSNs. Additionally, there are a variety of methods, other than audible methods, to screen for HRSNs that increase privacy, such as written or digital methods, including electronically through a patient portal or on tablets. We advise ASCs to ensure that patients feel safe answering questions and to further remind patients that they may opt out of the screening for any reason.

After consideration of the public comments we received, we are finalizing the data submission requirements related to the adoption of the FCHE, Screening for SDOH, and the Screen Positive Rate for SDOH measures in the ASCQR Program as proposed.

We refer readers to sections XIV.B.1, XIV.B.2, and XIV.B.3 of this final rule with comment period for our cross-program proposals and discussion of all public comments received regarding the FCHE, Screening for SDOH, and Screen Positive Rate for SDOH measures.

(2) National Healthcare Safety Network (NHSN)

We refer readers to § 416.310(c)(2) and the CY 2014 OPPS/ASC final rule (78 FR 75139 and 75140) for our policies regarding submission of web-based data via the Centers for Disease Control and Prevention's NHSN. We did not propose any changes to these policies in the CY 2025 OPPS/ASC proposed rule.

F. Public Reporting of Measure Data

We refer readers to § 416.315 and the CY 2018 OPPS/ASC final rule (82 FR 59472) for our program policies regarding public reporting of quality data. We did not propose any changes to these policies in the CY 2025 OPPS/ASC proposed rule.

G. Request for Information (RFI)—Development of Frameworks for Specialty Focused Reporting and Minimum Case Number for Required Reporting

The ASCQR Program promotes informed patient decision-making regarding clinical care across ASC procedures through a robust set of quality measures, data on which the ASCQR Program publicly reports as discussed in section XVII.F of this final rule with comment period. The ASCQR Program's current measure set captures clinical quality across all ASCs, including specialty clinical procedures performed only by a subset of ASCs. Thus, a portion of the ASCQR Program measure set only applies to an ASC if it performs those specialty procedures. Currently, ASCs are required to attest if they do not have cases for a given measure, increasing reporting burden.

We seek to ensure the most meaningful measures apply to each facility, as requiring an ASC to report on measures minimally relevant to their patient population increases burden with minimal benefit. Therefore, we sought comment on two potential future frameworks which would achieve the following outcomes: (1) the addition of case minimums for specialty measure reporting; (2) the removal of the zero case attestation requirement for specialty measures to decrease reporting burden; and (3) the verification of individual measure case counts using claims data to determine which specialty measures would potentially be required for reporting for individual ASCs. Verifying case counts using claims data would allow us to confirm that individual ASCs are reporting on measures meeting or surpassing case minimums.

Under these potential frameworks, we are considering revising the data reporting requirements for the ASCQR Program to only require that ASCs report data to CMS on quality measures that are related to their medical interventions, policies, processes, and procedures, or can be abstracted from claims. These potential frameworks would require ASCs to report measures generally applicable to all ASCQR Program participants and relevant specialty-specific measures, defined as those which evaluate performance on certain specialty clinical procedures performed only by a subset of ASCs.

The current ASCQR Program measure set has seven generally applicable measures for which reporting would be required in both frameworks for all ASCs: four patient safety measures (Patient Burn; Patient Fall; Wrong Site, Wrong Patient, Wrong Procedure, Wrong Implant; All-Cause Hospital Transfer Admission), one general surgery measure (Facility-Level 7-Day Hospital Visits After General Surgery Procedures Performed at Ambulatory Surgical Centers), one vaccination measure (COVID–19 Vaccination Coverage Among Healthcare Personnel), and one patient experience of care survey measure (OAS CAHPS). In addition, in the CY 2025 OPPS/ASC proposed rule (89 FR 59439 through 59449), we proposed the adoption of three new generally applicable measures (FCHE, Screening for SDOH, and Screen Positive Rate for SDOH), which ASCs would also be required to report. As discussed in section XVII.C.1 of this final rule with comment period, we are finalizing these three measures for the ASCQR Program, as proposed.

The specialties addressed by the current ASCQR Program measure set, and the related specialty-specific measures, are described in Table 173. Under our first potential framework, the ''Specialty-Select'' framework, all ASCs would be required to report all specialty-specific, claims-based measures (currently, three) [500] because these measures are not administratively burdensome to ASCs. Additionally, ASCs would also be required to select a specified number of the remaining non-claims-based specialty-specific measures (currently, five) [501] to report if those measures are applicable to that ASC. We would define the number of

[500] In the CY 2025 OPPS/ASC proposed rule (89 FR 59471), we inadvertently noted that there were currently four specialty-specific, claims-based measures. As noted in Table 173 below, we inadvertently categorized the Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure as a claims-based measure and, on this basis, incorrectly attributed the number of claims-based, specialty-specific measures and non-claims-based, specialty-specific measures. We have corrected this error here in this final rule.

[501] In the CY 2025 OPPS/ASC proposed rule (89 FR 59471), we inadvertently noted that there were currently four non-claims-based specialty-specific measures. As noted in Table 173 below, we inadvertently categorized the Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure as a claims-based measure and, on this basis, incorrectly attributed the number of claims-based, specialty-specific measures and non-claims-based, specialty-specific measures. We have corrected this error here in this final rule.

non-claims-based specialty-specific measures that ASCs would be required to report in future rulemaking.

To determine if a non-claims-based specialty-specific measure is applicable to an ASC, we are considering the implementation of a case threshold minimum, which we would specify in future rulemaking, for each measure. We would determine if case threshold minimums, defined as the number of cases for a specific measure that must be met or exceeded to potentially require reporting, have been met using claims data. Once an ASC met the measure's case threshold minimum, that measure would become available for that ASC to select to meet reporting requirements. We note that reporting claims-based specialty-specific measures would be required regardless of whether the case threshold minimum is met. In the CY 2025 OPPS/ASC proposed rule (89 FR 59472), we sought comment on the number of non-claims-based specialty specific measures that ASCs should be required to report and what the appropriate threshold for the case threshold minimum should be.

We are considering the use of Medicare Fee-for-Service (FFS) and Medicare Advantage claim volume data to determine which non-claims-based specialty-specific measures have met the specified case threshold minimum (that is, claims information would indicate whether an ASC was performing sufficient case volumes in a specialty area). We note that this threshold would be independent from our ''Minimum case volume for program participation'' policy, which exempts ASCs with fewer than 240 total Medicare claims per year from participating in the ASCQR Program, as specified at § 416.305(c). The case threshold minimum discussed in this RFI would be applied to individual non-claims-based specialty-specific measures for ASCs required to participate in the ASCQR Program.

For example, if we decide that each ASC must select three out of the five available non-claims-based specialty-specific measures to report, and an ASC surpasses the specified case threshold minimum for all five non-claims-based specialty-specific measures, the ASC would then choose three out of the five non-claims-based specialty-specific measures to report. If an ASC surpasses the specified case threshold minimum for only one or two non-claims-based specialty-specific measures, the ASC will no longer have a choice, and must report all measures meeting the case threshold minimum. If an ASC does not meet the case threshold minimum for any non-claims-based specialty-specific measures, reporting for any of these measures would be voluntary. Under such a framework, ASCs could not utilize the claims-based measures to meet the Specialty-Select reporting requirements nor could ASCs opt-out of reporting these measures. ASCs which do not have one or more cases for a given measure would no longer be required to provide an attestation of having zero cases.

TABLE 173: CURRENT SPECIALTY-SPECIFIC ASCQR PROGRAM MEASURES

Specialty	Measure	Current Reporting Requirement	Data Source
Ophthalmology	Unplanned Anterior Vitrectomy	Mandatory	Patient Medical Records
Ophthalmology	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	Voluntary	Patient Reported Data and Surveys
Surgical	Normothermia Outcome	Mandatory	Patient Medical Records
Surgical	Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PRO– PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the ASC Setting (THA/TKA PRO–PM)	Voluntary through CY 2027 reporting period; Mandatory beginning with CY 2028 reporting period	Patient Reported Data and Surveys
Gastroenterology	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients	Mandatory	Patient Medical Records*
Surgical	Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures	Mandatory	Medicare Claims
Gastroenterology	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy	Mandatory	Medicare Claims
Urology	Hospital Visits after Urology Ambulatory Surgical Center Procedures	Mandatory	Medicare Claims

*In the CY 2025 OPPS/ASC proposed rule (89 FR 59472), we inadvertently categorized this measure as a claims-based measure.

Five of these measures are not claims-based and, under this potential framework, would not be applicable or required for all ASCs to report, but would rather be available for selection upon meeting a specified case threshold minimum:

- Unplanned Anterior Vitrectomy;
- Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (voluntary);
- Normothermia Outcome;
- Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the ASC Setting (THA/TKA PRO–PM); and
- Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients.

We acknowledge that currently there are few non-claims-based specialty-specific measures from which to choose to report. However, we are interested to learn if such a framework with both mandatory measures applicable to all ASCs and selectable, specialty-specific measures could lay the groundwork for providing higher quality data to patients while ensuring ASCs are not reporting data on measures that are minimally relevant, if not irrelevant, to their patient population.

Regarding this Specialty-Select framework, we requested comment on the following questions:

- Given that ASCs would still be required to report claims-based specialty-specific measures, as these measures are not administratively burdensome to ASCs, and there are currently only five non-claims-based specialty-specific quality measures in the ASCQR Program data set, how many non-claims-based specialty-specific measures should we require ASCs select to report?
- Are there specialty-specific measures that commenters would recommend for development and adoption in the ASCQR Program measure set to create a more robust selection?
- How should we determine what non-claims-based specialty-specific measures would be eligible for a given ASC to select toward meeting reporting requirements? In other words, how can we determine if an ASC meets the minimum case number for a given measure, which would allow the ASC to choose that measure to meet reporting requirements?

As an alternative to the Specialty-Select framework discussed previously, we are considering requiring reporting for all non-claims-based specialty-specific measures for which case counts reach a specified case threshold minimum. This case threshold minimum would not apply to claims-based specialty-specific measures, as their reporting would be mandatory since these measures are not administratively burdensome to ASCs. Under this alternative framework, mandatory data reporting for non-claims-based specialty-specific measures would occur only if an ASC met established case threshold minimums. For example, if an ASC has 30 or more qualifying patients for the measure during the applicable reporting period, which is the current minimum case threshold required for public reporting for some measures, the ASC would be required to submit data for these measures. Likewise, if an ASC has fewer than 30 patients for the measure, data reporting on the measure would be voluntary. This framework could be termed a Specialty Threshold framework and would differ from the previously discussed Specialty-Select framework as an ASC would be required to report on all non-claims-based specialty-specific measures for which the ASC reaches the case threshold minimum.

Regarding both the Specialty Threshold framework and the Specialty-Select framework, we requested comment on the following questions:

- Would use of Medicare Fee-for-Service (FFS) claim volume be sufficient for determining minimum case volumes?
- Should Medicare Advantage claim volume or service data be included when determining case volume thresholds for reporting a measure?
- Do commenters recommend any processes that could be followed or analyses we could conduct to determine case minimums?

We invited public comment on both the Specialty-Select framework and the alternative Specialty Threshold framework for potential inclusion in the ASCQR Program.

Comment: Several commenters supported the implementation of either the Specialty-Select framework or the Specialty-Threshold framework, as they would decrease reporting burden on ASCs to ensure the most meaningful measures apply to each facility. A few commenters specifically supported a Specialty-Threshold framework instead of the Specialty-Select framework to reduce the complexity that may result from measure selection. A commenter specifically supported the use of case minimums for specialty reporting.

Response: We thank commenters for their support of the specialty-focused frameworks. We also believe that these frameworks would reduce burden while ensuring ASCs are reporting on measures most applicable to their performed procedures.

Comment: A few commenters provided feedback on the inclusion of Medicare Advantage data when determining case volume thresholds. A few commenters recommended that CMS only use FFS data and exclude Medicare Advantage service or volume data when determining the applicable case volume thresholds. A commenter further added that ASCs offer a diverse range of services, and the patient population can vary significantly from one center to another. This commenter expressed concern that including Medicare Advantage claim volume in the threshold determination could lead to a misrepresentation of the services most commonly provided by an ASC.

Response: We thank the commenters for their input and appreciate the many thoughtful responses on the use of administrative data that CMS already receives when determining case volume thresholds. We will consider these comments in any future rulemaking on this topic.

Comment: Several commenters offered recommendations for the specialty-focused frameworks. A few commenters recommended measure additions and modifications to the ASCQR Program measure set to support a specialty-focused framework. A few commenters recommended the inclusion of the Toxic Anterior Segment Syndrome (TASS) measure in the ASCQR Program. Another commenter recommended areas for measure development to support a specialty framework, including ASC discharges with subsequent unplanned hospital visits, pain management, and surgical site infections (SSIs). This commenter added that the specialty-specific suitability of targeted services performed in ASCs should be evaluated, as there are currently procedures and treatments that practitioners widely agree are inappropriately used and should be eliminated. A commenter recommended the development of condition or procedure specific PROMs or PRO–PMs for patient goal attainment and patient experience. Another commenter expressed that a number of currently included ASCQR Program measures were not developed for measuring facility-level performance. This commenter recommended that all measures considered for inclusion in the ASCQR Program should first be tested at the facility level for analysis.

Regarding how CMS would determine what non-claims-based, specialty-

specific measures would be eligible for selection, a commenter recommended that there should be a process and analysis managed by CMS to determine an appropriate case threshold for reporting non-claims-based, specialty-specific measures with adequate reliability. This commenter further recommended that reporting of non-claims-based, specialty-specific measures should be mandatory only if a facility meets the minimum threshold requirement during the previous and current performance year. The commenter suggested that if the facility only meets the requirement in the current year, then voluntary reporting should be permitted.

Response: We thank the commenters for their input and appreciate the many recommendations received regarding the specialty-focused frameworks. We will take these comments into consideration as appropriate in any future rulemaking on this topic.

Comment: A few commenters requested clarification regarding the Specialty-Select and Specialty-Threshold frameworks. A commenter requested clarification on when the case count for each specialty measure would be calculated. The commenter further requested clarification on the potential consequences of not meeting the specified case threshold for the specified number of specialty measures ASCs would be required to report. Another commenter raised concern that ASCs may not know definitively which measures they would be required to report on until after the end of the reporting period. This commenter requested clarification on when CMS plans to release this information. Furthermore, a commenter requested clarification on whether measure case counts would include Medicare Advantage data and whether the counts would only include paid claims.

Response: We thank the commenters for highlighting aspects of these frameworks we could clarify in any future rulemaking. We will consider these comments moving forward.

Comment: A few commenters raised concern over the specialty-focused frameworks. A few commenters stated that the ASCQR Program has a small measure set, and raised concerns that these frameworks may inhibit a patient's ability to compare ASCs, or an ASC's ability to compare their performance to other ASCs, as different ASCs may report different measures. These commenters noted that this disparity in quality information may result in the unintended consequence of people electing to receive care in hospital settings for procedures that could be performed at more cost-efficient ASCs. Additionally, a commenter noted that selecting non-claims-based specialty-specific measures may be challenging, as there are few in the measure set. Furthermore, a few commenters raised concerns that these frameworks could increase burden for multi-specialty ASCs, as they would be required to report on more specialty measures than single-specialty ASCs. A few commenters raised concerns that if an ASC has a choice of which measures to report, they will choose the measures which will yield the most favorable results, creating an inaccurate representation of quality.

Furthermore, a few commenters raised concerns about the minimum case threshold, stating that volume and quality are positively correlated. These commenters stated that the exclusion of data from low-volume facilities may result in reduced reporting in clinical areas where performance is worse. A commenter raised concern over the burden of having to collect data regardless of if the case threshold minimum is met, as ASCs would only find out if reporting was mandatory after the relevant reporting period. Another commenter raised concern that the implementation of a specialty framework will be inconsistent with other programs. This commenter further stated that a specialty approach would lead to redundant reporting since Qualified Clinical Data Registries already report specialty data to the Merit-based Incentive Payment System for eligible clinicians.

Response: We thank commenters for raising concerns about the specialty-focused frameworks. We appreciate commenters' identification of areas that may need further consideration and will review these comments during future rulemaking.

Comment: Regarding the current zero-case attestation requirement, a commenter recommended the implementation of automated data validation checks to identify incomplete fields, to alert an ASC of missing information during the completion of the zero-case attestation requirement.

Response: We thank commenters for their feedback and will consider this feedback for any future rulemaking. We would like to note that our HQR system already has mechanisms in place which ensure facilities are aware of missing data entry information. These mechanisms include an online lookup tool where facilities can download data entry reports, as well as phone call and fax reminders.

Comment: A commenter added that public reporting of ASC data should be available at the facility level, rather than the system level.

Response: We thank commenters for their feedback and will consider this feedback for any future rulemaking. We would like to remind commenters that public reporting of ASC data is already captured at the facility level, as opposed to the system level.

Data that an ASC submitted for the ASCQR Program are displayed publicly on a CMS website. Before these data are published, ASCs can review the data. ASC data are publicly displayed by the National Provider Identifier (NPI) when data are submitted by the NPI. When data are submitted by the CCNS, we will publicly display ASC data by the CMS Certification Number (CCN).

H. Payment Reduction for ASCs That Fail To Meet the ASCQR Program Requirements

1. Statutory Background

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74493) for a detailed discussion of the statutory background regarding payment reductions for ASCs that fail to meet the ASCQR Program requirements.

2. Policy Regarding Reduction to the ASC Payment Rates for ASCs That Fail To Meet the ASCQR Program Requirements for a Payment Determination Year

The national unadjusted payment rates for many services paid under the ASC payment system are equal to the product of the ASC conversion factor and the scaled relative payment weight for the APC to which the service is assigned. For CY 2025, the ASC conversion factor is equal to the conversion factor calculated for the previous year updated by the productivity-adjusted hospital market basket update factor. The productivity adjustment is set forth in section 1833(i)(2)(D)(v) of the Act. The productivity-adjusted hospital market basket update is the annual update for the ASC payment system for a 5-year period (CY 2019 through CY 2023), which was extended an additional 2 years (through CY 2025) in the CY 2024 OPPS/ASC final rule with comment period (88 FR 81960). Under the ASCQR Program, in accordance with section 1833(i)(7)(A) of the Act and as discussed in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499), any annual increase in certain payment rates under the ASC payment system shall be reduced by 2.0 percentage points for ASCs that fail to meet the reporting requirements of the ASCQR

Program. This reduction applied beginning with the CY 2014 payment rates (77 FR 68500). For a complete discussion of the calculation of the ASC conversion factor and our finalized proposal to update the ASC payment rates using the inpatient hospital market basket update for CYs 2019 through 2023, we refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59073 through 59080).

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499 through 68500), in order to implement the requirement to reduce the annual update for ASCs that fail to meet the ASCQR Program requirements, we finalized the following policies: (1) to calculate a full update conversion factor and an ASCQR Program reduced update conversion factor; (2) to calculate reduced national unadjusted payment rates using the ASCQR Program reduced update conversion factor that would apply to ASCs that fail to meet their quality reporting requirements for that calendar year payment determination; and (3) that application of the 2.0 percentage point reduction to the annual update may result in the update to the ASC payment system being less than zero prior to the application of the productivity adjustment. The ASC conversion factor is used to calculate the ASC payment rate for services with the following payment indicators (listed in Addenda AA and BB to the proposed rule, which are available via the internet on the CMS website): ''A2,'' ''G2,'' ''P2,'' ''R2'' and ''Z2,'' as well as the service portion of device-intensive procedures identified by ''J8'' (77 FR 68500). We finalized our proposal that payment for all services assigned the payment indicators listed would be subject to the reduction of the national unadjusted payment rates for applicable ASCs using the ASCQR Program reduced update conversion factor (77 FR 68500).

The conversion factor is not used to calculate the ASC payment rates for separately payable services that are assigned status indicators other than payment indicators ''A2,'' ''D2'', ''G2,'' ''J8,'' ''P2,'' ''R2'' and ''Z2.'' These services include separately payable drugs and biologicals, pass-through devices that are contractor-priced, brachytherapy sources that are paid based on the OPPS payment rates, and certain office-based procedures, radiology services and diagnostic tests where payment is based on the PFS nonfacility PE RVU-based amount, and a few other specific services that receive cost-based payment (77 FR 68500). As a result, we also finalized our proposal that the ASC payment rates for these services would not be reduced for failure to meet the ASCQR Program requirements because the payment rates for these services are not calculated using the ASC conversion factor and, therefore, are not affected by reductions to the annual update (77 FR 68500).

Office-based surgical procedures (generally those performed more than 50 percent of the time in physicians' offices) and separately paid radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents) are paid at the lesser of the PFS nonfacility PE RVU-based amounts or the amount calculated under the standard ASC ratesetting methodology. Similarly, in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized our proposal that payment for certain diagnostic test codes within the medical range of CPT codes for which separate payment is allowed under the OPPS will be at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the standard ASC ratesetting methodology when provided integral to covered ASC surgical procedures. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68500), we finalized our proposal that the standard ASC ratesetting methodology for this type of comparison would use the ASC conversion factor that has been calculated using the full ASC update adjusted for productivity. This is necessary so that the resulting ASC payment indicator, based on the comparison, assigned to these procedures or services is consistent for each HCPCS code, regardless of whether payment is based on the full update conversion factor or the reduced update conversion factor.

For ASCs that receive the reduced ASC payment for failure to meet the ASCQR Program requirements, we have noted our belief that it is both equitable and appropriate that a reduction in the payment for a service should result in proportionately reduced coinsurance liability for beneficiaries (77 FR 68500). Therefore, in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68500), we finalized our proposal that the Medicare beneficiary's national unadjusted coinsurance for a service to which a reduced national unadjusted payment rate applies will be based on the reduced national unadjusted payment rate.

In the CY 2013 OPPS/ASC final rule with comment period, we finalized our proposal that all other applicable adjustments to the ASC national unadjusted payment rates would apply in those cases when the annual update is reduced for ASCs that fail to meet the requirements of the ASCQR Program (77 FR 68500). For example, the following standard adjustments would apply to the reduced national unadjusted payment rates: the wage index adjustment; the multiple procedure adjustment; the interrupted procedure adjustment; and the adjustment for devices furnished with full or partial credit or without cost (77 FR 68500). We believe that these adjustments continue to be equally applicable to payment for ASCs that do not meet the ASCQR Program requirements (77 FR 68500).

In the CY 2015 through CY 2024 OPPS/ASC final rules with comment period, we did not make any other changes to these policies. We proposed to continue applying these policies for the CY 2025 reporting period/CY 2027 payment determination and for subsequent years.

We did not receive any public comments on our proposal. We are finalizing as proposed the continuation of these policies for the CY 2025 reporting period/CY 2027 payment determination and for subsequent years.

XVIII. Medicaid Clinic Services Four Walls Exceptions

A. Background

Under section 1902(a)(10) of the Act, States may offer certain Medicaid benefits, at State option, to categorically needy and medically needy Medicaid beneficiaries, as described in that section of the statute. Clinic services are one of these optional benefit categories. Section 1905(a)(9) of the Act, as amended by section 4105 of part 1 of subtitle B of title IV of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87, Pub. L. 100–203), defines clinic services as services furnished by or under the direction of a physician, without regard to whether the clinic itself is administered by a physician, including such services furnished outside the clinic by clinic personnel to an eligible individual who does not reside in a permanent dwelling or does not have a fixed home or mailing address (hereinafter referred to as ''individuals who are unhoused'').[502] [503]

[502] Public Law 100–203, enacted December 22, 1987, 100 Stat. 1330, 1330–147, *https://www.congress.gov/100/statute/STATUTE-101/STATUTE-101-Pg1330.pdf.*

[503] This document contains links to non-United States Government websites. We are providing these links because they contain additional information relevant to the topic(s) discussed in this document or that otherwise may be useful to the reader. We cannot attest to the accuracy of information provided on the cited third-party websites or any other linked third-party site. We are

The regulation implementing section 1905(a)(9) of the Act, 42 CFR 440.90, includes certain conditions and limitations on Medicaid coverage of clinic services. Specifically, § 440.90 defines clinic services as preventive, diagnostic, therapeutic, rehabilitative, or palliative services that are furnished by a facility that is not part of a hospital but is organized and operated to provide medical care to outpatients.[504] Section 440.90 further provides that clinic services include two types of services furnished to outpatients, listed at § 440.90(a) and (b). The first type of services included in the benefit, under § 440.90(a), is services furnished at the clinic (hereinafter referred to as the ''four walls'' requirement) by or under the direction of a physician or dentist. Section 440.90(b) implements the statutory language providing that clinic services also include services furnished outside the clinic, by clinic personnel under the direction of a physician, to an eligible individual who is unhoused. In section 4320 of the State Medicaid Manual, we explained that if a State elects to cover clinic services, the State may choose the type of clinics or clinic services that are covered.[505]

We added § 440.90(b) in 1991, after Congress added the language about services furnished outside the clinic to individuals who are unhoused to section 1905(a)(9) of the Act in OBRA '87.[506] In the preamble to that rule, we explained that clinic services have always been limited to people who go to the clinic (or a satellite location) and get the services onsite, and that the exception added by OBRA '87 represents an exception to the general coverage requirement for services to be furnished on the premises of the clinic. Further, we explained our view that Congress ratified the requirement that other clinic services must be furnished onsite by establishing an explicit exception to the requirement that clinic services be furnished onsite in order to be covered. CMS has long interpreted the exception to the four walls requirement at § 440.90(b) to be mandatory for States that opt to cover the clinic services benefit. We reiterated CMS's longstanding interpretation that section 1905(a)(9) of the Act and § 440.90 establish a four walls requirement in a frequently asked questions document that we published on January 18, 2017 (hereinafter referred to as ''the January 18, 2017 FAQ''), to supplement State Health Official letter number 16–002, Federal Funding for Services ''Received Through'' an IHS/Tribal Facility and Furnished to Medicaid-Eligible American Indians and Alaska Natives.[507] [508]

The Medicaid clinic services benefit is distinct from the Medicaid federally qualified health center (FQHC) services benefit and the Medicaid rural health clinic (RHC) services benefit. The Medicaid FQHC services benefit is defined at section 1905(a)(2)(C) of the Act, and FQHCs and FQHC services are further defined at section 1905(*l*)(2) of the Act. The Medicaid RHC services benefit is defined at section 1905(a)(2)(B) of the Act, and RHCs and RHC services are further defined at section 1905(*l*)(1) of the Act. Unlike the clinic services benefit, which is an optional benefit for States, the FQHC and RHC benefits are mandatory for categorically needy Medicaid beneficiaries under section 1902(a)(10) of the Act. In addition, there is no Federal four walls requirement under the Medicaid FQHC or RHC services benefits, unlike the clinic services benefit. Federal Medicaid law does not prevent States from covering Medicaid FQHC and RHC services provided outside of the four walls of an FQHC or RHC.[509]

On January 28, 2021, President Biden signed Executive Order (E.O.) 14009, ''Strengthening Medicaid and the Affordable Care Act,'' which established the policy objective to protect and strengthen Medicaid and the Affordable Care Act and to make high-quality health care accessible and affordable for every American, and directed executive departments and agencies to review existing regulations, orders, guidance documents, and policies to determine whether such agency actions are inconsistent with this policy.[510] As part of this review of existing policies, E.O. 14009 directed Federal agencies to consider whether to suspend, revise, or rescind agency actions considered inconsistent with this objective. On April 5, 2022, E.O. 14070, ''Continuing to Strengthen Americans' Access to Affordable, Quality Health Coverage,'' directed Federal agencies with responsibilities related to Americans' access to health coverage to review agency actions to identify ways to continue to expand the availability of affordable health coverage, to improve the quality of coverage, to strengthen benefits, and to help more Americans enroll in quality health coverage.[511]

On November 6, 2000, President Clinton signed E.O. 13175, ''Consultation and Coordination With Indian Tribal Governments,'' which recognizes the unique legal relationship between the United States and Indian Tribal governments and, to strengthen this government-to-government relationship and support Tribal sovereignty and self-determination, charges all executive departments and agencies with engaging in meaningful and timely consultation with Tribal officials in the development of Federal policies that have Tribal implications.[512] On January 26, 2021, President Biden issued a ''Memorandum on Tribal Consultation and Strengthening Nation-to-Nation Relationships,'' which reaffirms E.O. 13175's directive to engage in regular, meaningful, and robust consultation with Tribal officials in the development

providing these links for reference only; linking to a non-United States Government website does not constitute an endorsement by CMS, HHS, or any of their employees of the sponsors or the information and/or any products presented on the website. Also, please be aware that the privacy protections generally provided by United States Government websites do not apply to third-party sites.

[504] An outpatient is defined at 42 CFR 440.2 as a patient of an organized medical facility, or distinct part of that facility who is expected by the facility to receive and who does receive professional services for less than a 24-hour period regardless of the hour of admission, whether or not a bed is used, or whether or not the patient remains in the facility past midnight.

[505] U.S. Department of Health and Human Services, Health Care Financing Administration (HCFA), *The State Medicaid Manual,* Manual, (Baltimore, MD, 1985), Section 4320, *https://www.cms.gov/regulations-and-guidance/guidance/manuals/paper-based-manuals-items/cms021927.*

[506] Medicare and Medicaid Programs; OBRA '87 Conforming Amendments, 56 FR 8832, 8835 (March 1, 1991) (hereinafter referred to as the 1991 rule). *https://archives.federalregister.gov/issue_slice/1991/3/1/8829-8854.pdf.*

[507] CMS, *Federal Funding for Services ''Received Through'' an IHS/Tribal Facility and Furnished to Medicaid-Eligible American Indians and Alaska Natives,* State Health Official Letter (SHO) #16–002, (Baltimore, MD, 2016), *https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/sho022616.pdf.*

[508] CMS, *Frequently-Asked Questions (FAQs) Federal Funding for Services ''Received Through'' an IHS/Tribal Facility and Furnished to Medicaid Eligible American Indians and Alaska Natives (SHO #16–002),* FAQ, (Baltimore, MD, 2017), *https://www.medicaid.gov/media/40241.*

[509] We note that the Consolidated Appropriations Act, 2024, Division G, Title I, Section 209 (Pub. L. 118–42) amended section 1905 of the Act to establish a certified community behavioral health clinic (CCBHC) services benefit effective March 9, 2024. The CCBHC services benefit is distinct from the clinic services benefit and there is no four walls requirement for the CCBHC services benefit under Federal Medicaid law.

[510] E.O. 14009, 86 FR 7793 (Jan. 28, 2021). See, *https://www.Federalregister.gov/documents/2021/02/02/2021-02252/strengthening-medicaid-and-the-affordable-care-act.*

[511] E.O. 14070, 87 FR 20689 (Apr. 8, 2021). See, *https://www.Federalregister.gov/documents/2022/04/08/2022-07716/continuing-to-strengthen-americans-access-to-affordable-quality-health-coverage.*

[512] E.O. 13175, 65 FR 67249 (Nov. 6, 2000). See, *https://www.Federalregister.gov/documents/2000/11/09/00-29003/consultation-and-coordination-with-indian-tribal-governments.*

of Federal policies that have Tribal implications.[513]

Consistent with E.O. 13175, CMS issued a Tribal Consultation policy in 2011 and updated it in 2015 for the purpose of building meaningful relationships with Indian Tribes and to establish a clear, concise and mutually acceptable process through which consultation can take place between CMS and Tribes.[514] [515] As one of its core principles, the policy provides that, because Congress amended titles XVIII and XIX of the Act to authorize Indian Health Service (IHS) and Tribal health programs to bill Medicare and Medicaid, ''[t]he involvement of Indian tribes in the development of CMS policy is crucial for mutual understanding and development of culturally appropriate approaches to improve greater access to CMS programs for American Indians and Alaska Natives (AI/ANs), to enhance health care resources to IHS and tribal health programs, and to contribute to overall improved health outcomes for American Indians.'' As part of its government-to-government relationship with the Tribes, CMS has engaged in meaningful consultation with Tribes and Tribal leaders, the CMS Tribal Technical Advisory Group (TTAG), and the HHS Secretary's Tribal Advisory Committee (STAC) regarding concerns about the impact that the four walls requirement could have on IHS/Tribal clinics and AI/AN beneficiaries' access to health care when a grace period currently in place for IHS/Tribal clinics (as discussed later in this section of the preamble) ends. As part of this consultation, Tribes requested a permanent exemption from the four walls requirement for IHS/Tribal clinics.

IHS, a Federal agency within the Department of Health and Human Services, is responsible for furnishing comprehensive, culturally appropriate health services to, as of April 2024, almost $2.8 million AI/ANs who are eligible for services from IHS, per regulations at 42 CFR part 136, as well as other individuals whom IHS or Tribes are authorized to serve under 25 U.S.C. 1680c.[516] IHS's provision of health services to its beneficiaries stems from the special government-to-government relationship between the Federal Government and Indian Tribes. The Federal Government's relationship with Tribes is based on Article I, section 8 of the Constitution, and has been given form and substance by numerous treaties, statutes, Supreme Court decisions, and Executive orders. The IHS delivery system includes hospitals and clinics that are owned and operated by IHS, owned by IHS and tribally-operated as authorized by the Indian Self-Determination and Education Assistance Act (ISDEAA, Pub. L. 93–638 (as amended)), or owned and operated by Tribes and Tribal organizations as authorized by the ISDEAA.[517] We refer to these three kinds of facilities in our discussions of the proposed amendments to § 440.90 as ''IHS/Tribal facilities'' or, when referring to circumstances where these facilities operate as Medicaid clinic services providers, ''IHS/Tribal clinics.'' [518] Section 1911 of the Act and implementing regulations at § 431.110 provide that a facility of IHS, whether operated by IHS or by a Tribe or Tribal organization (CMS has interpreted similar language in section 1905(b) of the Act to refer to all three kinds of IHS/Tribal facilities described previously),[519] may participate in the Medicaid program subject to the conditions and requirements generally applicable under Title XIX of the Act. Many IHS/Tribal facilities are covered and paid as clinic services providers in the Medicaid program. Under section 1903(a)(1) of the Act, the Federal Government is required to match State expenditures for medical assistance at the Federal Medical Assistance Percentage (FMAP), which is defined at section 1905(b) of the Act to be 100 percent for State expenditures for Medicaid-covered services received through an IHS facility whether operated by IHS or by a Tribe or Tribal organization (which, again, CMS has interpreted to refer to all three kinds of IHS/Tribal facilities described previously). Under CMS's longstanding interpretation of section 1905(b) of the Act, this 100 percent FMAP is available only for State expenditures on services received through an IHS/Tribal facility (such as a clinic) by AI/AN Medicaid beneficiaries. State expenditures on services furnished by an IHS/Tribal facility to other individuals are not matched by the Federal Government at 100 percent, but rather at the State's regularly applicable FMAP rate.

As part of our Center for Medicaid & CHIP Services (CMCS) Mental Health and Substance Use Disorder Action Plan published in July 2023, we are pursuing strategies to increase access to prevention and treatment, engagement in care, and improve quality of care for beneficiaries with behavioral health disorders.[520] Behavioral health disorders include both substance use disorders and mental health disorders. Medicaid plays a crucial role in financing health care for individuals with behavioral health disorders and is the largest payer of behavioral health services.[521] There are no Federal requirements for States to cover services furnished by behavioral health clinics or any specific types of behavioral health clinics under the clinic services benefit. However, we are aware that approximately 16 States cover services provided by behavioral health clinics of varying types under the clinic services benefit, such as Community Mental Health Centers certified under the Medicare Conditions of Participation at 42 CFR part 485, subpart J, substance use disorder clinics, or mental health clinics.

We released a framework for advancing health care in rural, Tribal, and geographically isolated communities in November 2022.[522] Our framework focuses on six priorities,

[513] President Joseph R. Biden to Heads of Executive Departments and Agencies, memorandum, ''Tribal Consultation and Strengthening Nation-to-Nation Relationships,'' January 26, 2021, Presidential Actions, *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/26/memorandum-on-tribal-consultation-and-strengthening-nation-to-nation-relationships/.*

[514] CMS, ''Tribal Consultation,'' *CMS.gov*, September 6, 2023, *https://www.cms.gov/training-education/partner-outreach-resources/american-indian-alaska-native/tribal-consultation.*

[515] CMS, Tribal Consultation Policy, Policy (Washington, DC, 2015), *https://www.cms.gov/outreach-and-education/american-indian-alaska-native/aian/downloads/cmstribalconsultationpolicy2015.pdf.*

[516] IHS, *Indian Health Service Health Equity Report,* Fact Sheet, (2024), *https://www.ihs.gov/sites/newsroom/themes/responsive2017/display_objects/documents/factsheets/IHS_Health_Equity_Report_FactSheet_2024.pdf.*

[517] HCFA and IHS, ''Memorandum of Agreement Between the Indian Health Services and the Health Care Financing Administration,'' Memorandum of Agreement, December 19, 1996, *https://www.cms.gov/Outreach-and-Education/American-Indian-Alaska-Native/AIAN/LTSS-TA-Center/pdf/memorandum-of-agreement.pdf.*

[518] Although Urban Indian Organizations that operate under Title V of the Indian Health Care Improvement Act are also part of the IHS delivery system, for purposes of our discussions of the proposed amendments to § 440.90, the terms IHS/Tribal facility and IHS/Tribal clinic do not include a facility operated by an Urban Indian Organization.

[519] HCFA and IHS, Memorandum of Agreement.

[520] CMS, *Mental Health and Substance Use Disorder Action Plan,* (2023), Action Plan, *https://www.medicaid.gov/medicaid/benefits/downloads/cmcs-mntl-helth-substnce-disrdr-actn-plan.pdf.*

[521] Guth, Madeline, Heather Saunders, Lauren Niles, Angela Bergefurd, Kathleen Gifford, and Roxanne Kennedy Published. 2023. ''How Do States Deliver, Administer, and Integrate Behavioral Health Care? Findings from a Survey of State Medicaid Programs.'' KFF. May 25, 2023. *https://www.kff.org/mental-health/issue-brief/how-do-states-deliver-administer-and-integrate-behavioral-health-care-findings-from-a-survey-of-state-medicaid-programs/.*

[522] CMS, *CMS Framework for Advancing Health Care in Rural, Tribal, and Geographically Isolated Communities,* (2022), Framework, *https://www.cms.gov/files/document/cms-geographic-framework.pdf.*

including expanding access to comprehensive health care coverage, benefits, and services and supports to individuals who live in these communities. Medicaid plays an important role in financing health care in rural areas, as nearly a quarter of individuals under age 65 who live in rural areas are covered by Medicaid. Importantly, Medicaid also provides critical access to care for individuals in rural areas who are older or disabled, as more than one in five residents of rural areas (approximately 22 percent) are dually enrolled in Medicaid and Medicare.[523] There are no Federal requirements under the clinic services benefit governing how States should provide coverage of services furnished specifically by clinics located in rural areas under that benefit—the Federal requirements that apply generally to that benefit, including the four walls requirement, also apply to services furnished by clinics in rural areas. A State may cover Medicaid clinic services provided by various types of clinics located in rural areas, such as primary care clinics, behavioral health clinics, surgical clinics, and other types of clinics. As noted earlier in this section, the Medicaid RHC services benefit is different from the Medicaid clinic services benefit and does not include a four walls requirement under Federal Medicaid law; thus, facilities that qualify as RHCs under Federal Medicaid law could provide Medicaid services under the RHC services benefit, including outside of the four walls.

Section 1902(a)(30)(A) of the Act requires that Medicaid payments for services be consistent with efficiency, economy, and quality of care, and be sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area. Under this requirement, States generally have significant latitude in setting payment methodologies and rates for covered services, and there is no specific payment methodology required for clinic services, although regulations at § 447.321 require the application of upper payment limits for clinics that are not IHS/Tribal clinics. States generally pay for clinic services via a facility rate. They typically adopt, as the payment rate for Medicaid clinic services furnished by IHS/Tribal clinics, the Outpatient per Visit Rate (excluding Medicare) that IHS establishes for services provided by IHS facilities to Medicaid beneficiaries and for certain other Federal programs. This rate, and a set of three other rates for Medicare outpatient visits and certain inpatient services, are frequently referred to collectively as the IHS all-inclusive rates (AIRs), and therefore this IHS Outpatient per Visit Rate (excluding Medicare) is hereinafter referred to as the ''AIR.'' [524] In contrast, States generally pay for Medicaid benefits provided by individual practitioners, such as the physician services benefit, at a professional fee schedule rate under the Medicaid State plan.

As we noted in the January 18, 2017 FAQ, CMS recognized in 2017 that IHS/Tribal clinics were providing services outside of the four walls, including to individuals to whom the existing statutory and regulatory exception does not apply, and that States were paying for these services at the clinic services rate (which in all or nearly all cases is the AIR). In the January 18, 2017 FAQ, we announced a 4-year grace period to January 30, 2021, to allow States time to come into compliance with the four walls requirement for IHS/Tribal clinics. On January 15, 2021, due to the COVID–19 Public Health Emergency (PHE), CMS issued a CMCS Informational Bulletin (CIB) announcing an extension of the four walls grace period to October 31, 2021. CMS issued subsequent CIBs on October 4, 2021, and September 8, 2023, announcing further extensions of the grace period to nine months from when the COVID–19 PHE ended, and February 11, 2025, respectively.[525]

Since the release of the January 18, 2017 FAQ and throughout the grace period, we have heard from Tribes, the CMS TTAG, and the HHS STAC, that the four walls requirement will create barriers in access to care for Medicaid beneficiaries who receive care from IHS/Tribal clinics after the grace period expires. Tribes, the TTAG, and the STAC have requested that CMS eliminate the four walls requirement for IHS/Tribal clinics. In addition to these requests, CMS has received a handful of other requests from States to allow exceptions to the four walls requirements for clinics that serve vulnerable populations. For example, we received one section 1115 demonstration request to cover clinic services outside of the four walls for behavioral health clinics, under which the State sought to use the requested section 1115 demonstration authority to improve access to and retention in behavioral health treatment. In addition, we received inquiries from States seeking to cover, under the clinic services benefit, mobile crisis services provided by behavioral health clinics to individuals experiencing a behavioral health crisis, but we advised those States that we could not approve coverage of mobile crisis services under the clinic services benefit due to the four walls requirement.

The proposed rule aimed to address the concerns we have heard from Tribes, the TTAG, the STAC, States, and other interested parties. It aimed to fulfill E.O.s 14009 and 14070 by helping States to strengthen and improve access to clinic services. It also helped to fulfill E.O. 13175 by recognizing the United States' unique legal relationship with Tribes and by responding to advice and input received from Tribes through consultation. In addition, we believe the proposed rule is consistent with our strategies, goals, and objectives to advance health equity and improve health care access for Tribal, behavioral health, and rural populations as described in our CMCS Mental Health and Substance Use Disorder Action Plan and CMS Framework for Advancing Health Care in Rural, Tribal, and Geographically Isolated Communities.

Consistent with our statutory authority at section 1905(a)(9) of the Act, we proposed to add three exceptions to the four walls requirement at § 440.90, for the reasons set forth in section XVIII.B of the proposed rule. First, we proposed to add an exception for clinic services furnished by IHS/Tribal clinics. Second, we proposed to add an exception for clinic services furnished by a clinic that is primarily organized for the care and treatment of outpatients with behavioral health disorders, including mental health and substance use disorders. Third, we

[523] Medicaid and CHIP Payment and Access Commission (MACPAC), *Medicaid and Rural Health,* Issue Brief, (Washington, DC, 2021), 1, *https://www.macpac.gov/wp-content/uploads/2021/04/Medicaid-and-Rural-Health.pdf.*

[524] IHS establishes the AIRs under the authority in sections 321(a) and 322(b) of the Public Health Service Act (42 U.S.C. 248 and 249(b)), Public Law 83–568 (42 U.S.C. 2001(a)), and the Indian Health Care Improvement Act (25 U.S.C. 1601 *et seq.*). IHS calculates AIRs on an annual basis and the rates are then published in the **Federal Register**. The AIRs are based on annual cost report analysis prepared by IHS's contractor. IHS reviews the cost report analysis and upon completion of the review, IHS submits recommended rates to the Office of Management and Budget (OMB) for final approval through HHS and CMS. Upon approval by OMB, the approved rates are published in the **Federal Register**. See *https://www.ihs.gov/BusinessOffice/reimbursement-rates/.* Calendar year 2024 rates and additional information can be found in the **Federal Register** published December 19, 2023 (88 FR 87789): *https://www.Federalregister.gov/documents/2023/12/19/2023-27815/reimbursement-rates-for-calendar-year-2024.*

[525] CMS, *Further Extension of Grace Period Related to the ''Four Walls'' Requirement under 42 CFR 440.90 for Indian Health Service and Tribal Facilities to February 11, 2025,* CMCS Informational Bulletin, (Baltimore, MD, 2023), *https://www.medicaid.gov/sites/default/files/2023-09/cib090823.pdf.*

proposed to add an exception for clinic services furnished by a clinic located in a rural area (and that is not an RHC, which could already provide services covered under a separate Medicaid benefit). We proposed to make the exception for clinic services furnished by IHS/Tribal clinics a mandatory component of the clinic benefit and to make the exceptions for clinic services furnished by behavioral health clinics and clinics located in rural areas optional for States.

B. Summary of the Medicaid Clinic Services Four Walls Exceptions Proposed Provisions, Public Comments and Responses to Comments

On July 22, 2024, the CY 2025 OPPS/ASC proposed rule (89 FR 59186) was published in the **Federal Register**. In response to the proposed exceptions, we received 96 public comments. Commenters included individuals, State Medicaid agencies, health care provider associations, individual health care providers, Tribes, Tribal organizations, urban Indian organizations (UIOs), health plans and associations, advocacy groups, academic and research organizations, and other health organizations. In this section, we provide a summary of the proposals, a summary of the public comments received, our responses to the public comments, and the policies we are finalizing for the Medicaid clinic services benefit.

1. General Comments

Comment: One commenter recommended that the final rule include a severability provision to clarify that the Medicaid clinic services benefit four walls exceptions at § 440.90 are not connected to other provisions contained in the OPPS/ASC final rule, so that if any other provision in the OPPS/ASC final rule is held to be invalid or unenforceable it would not apply to the Medicaid clinic services benefit four walls exceptions.

Response: We thank the commenter for their recommendation that the final rule include a severability provision to clarify that the Medicaid clinic services benefit four walls exceptions at § 440.90 are not connected to other provisions contained in the OPPS/ASC final rule. We agree with the commenter and have included language in the supplementary information section of the final rule explaining our intent that if any provision in the OPPS/ASC final rule is held to be invalid or unenforceable, the remaining provisions that could function independently should take effect and be given the maximum effect permitted by law.

Comment: Many commenters expressed gratitude and support for CMS's proposed efforts to mitigate operational burdens under the proposed rule, such as not proposing to require behavioral health clinics to verify that an individual has a behavioral health diagnosis or that clinics located in rural areas verify that an individual lives in a rural area.

Response: We appreciate the comments in support of our proposed efforts to mitigate operational burdens.

Comment: Many commenters thanked CMS for including a clarifying footnote that the Consolidated Appropriations Act, 2024, Division G, Title I, section 209 (Pub. L. 118–42) amended section 1905(a) of the Act to establish a certified community behavioral health clinic (CCBHC) services benefit effective March 9, 2024; the footnote indicated that the CCBHC services benefit is distinct from the clinic services benefit and that there is no four walls requirement for the CCBHC services benefit under Federal Medicaid law.

Response: We appreciate the comments thanking us for clarifying that the Medicaid CCBHC services benefit is distinct from the Medicaid clinic services benefit and that there is no four walls requirement for the CCBHC services benefit under Federal Medicaid law.

Comment: Three commenters expressed concerns with the physician direction requirement, with two of the comments expressing that the physician direction requirement may limit access to care for individuals who receive services from IHS/Tribal clinics. One commenter recommended that CMS defer to States and providers in determining the meaning of the physician direction requirement for the Medicaid clinic services benefit and indicated that the current definition is overly stringent and reduces access to care.

Another commenter wanted to know if CMS defined ''under the direction of a physician'' in guidance and recommended that CMS reinterpret the physician direction requirement to include non-physician licensed practitioners; the commenter explained that they believed CMS has the statutory authority to allow clinic services to be furnished under the direction of non-physician licensed practitioners because the current regulation at § 440.90 allows clinic services to be under the direction of a dentist despite not being included in section 1905(a)(9) of the Act.

Finally, the third commenter recommended CMS amend the final rule to not apply the physician direction requirement or other clinic services benefit requirements to IHS/Tribal clinics.

Response: We thank the commenters for sharing their concerns about the physician direction requirement. As we noted in section XVIII of the proposed rule (89 FR 59186), section 1905(a)(9) of the Act, as amended by section 4105 of part 1 of subtitle B of title IV of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87, Pub. L. 100–203), defines clinic services as ''services furnished by or under the direction of a physician, without regard to whether the clinic itself is administered by a physician, including such services furnished outside the clinic by clinic personnel to an eligible individual who does not reside in a permanent dwelling or does not have a fixed home or mailing address.'' Because all services covered under the clinic services benefit are required by statute to be furnished by or under the direction of a physician, we proposed to include language in each of the proposed exceptions specifying that services subject to the exception would have to be furnished under the direction of a physician, to make that requirement clear.

Physician direction has been a longstanding component of the clinic benefit. We do not have the statutory authority to eliminate the requirement that clinic services must be furnished by or under the direction of a physician. In addition, we did not propose changes to that requirement, so we are finalizing this rulemaking without any changes to the meaning of ''under the direction of a physician.''

Comment: Two commenters supported CMS's goal of expanding access but expressed concern about the Federal and State budgetary impacts of the proposed policies, given that the policies may increase provider payment rates. The commenters recommended that CMS reinforce that it is important for States to meet the statutory requirement that capitated rates to Medicaid managed care plans be made on an actuarially sound basis during the annual rate setting process or as a mid-year rate update if warranted when payments for clinic services are made through managed care.

Response: We thank the commenters for their comments. We acknowledge that adding additional exceptions to the four walls requirement for IHS/Tribal clinics, and (at State option) behavioral health clinics and clinics located in rural areas is likely to have a Federal and State budgetary impact. As we noted in our economic analysis in section XXVI of the proposed rule, the total estimated impact of the proposed regulation over five years is $1.18

billion, including Federal impact of $1.15 billion and State impact of $30 million. However, as we also described in section XXVI of the proposed rule, the changes to the Medicaid clinic services benefit are expected to benefit Medicaid beneficiaries, Tribes, and States by improving access to care for the populations served by IHS/Tribal clinics, behavioral health clinics, and clinics in rural areas.

When benefits are provided through a managed care delivery system, States must meet statutory and regulatory requirements for setting actuarially sound capitation rates that are projected to provide for all reasonable, appropriate, and attainable costs that are required under the terms of the contract and for the operation of the managed care plan for the time period and the population(s) covered under the terms of the contract. We remind States of the importance of meeting these requirements. States and their actuaries should assess if the programmatic changes under this final rule would materially impact actuarially sound capitation rates, and if so the State and its actuary should account for this programmatic change appropriately in developing capitation rates in accordance with 42 CFR 438.4 and 438.5.

Comment: Two commenters recommended that CMS ensure that all populations that are exempt from the four walls requirement receive the full spectrum of physical and behavioral health care.

Response: We appreciate the commenters' recommendation that we ensure that all populations that are exempt from the four walls requirement receive the full spectrum of physical and behavioral health care. We note that for most Medicaid beneficiaries, the clinic benefit would generally be one component of a broader Medicaid benefit package. Per section 1902(a)(10)(A) and (C) of the Act and implementing regulations at 42 CFR part 440, most beneficiaries in the categorically and medically needy eligibility groups are eligible for a benefit package consisting of an array of mandatory services that address a broad range of healthcare needs, and States can choose to include optional services, such as the clinic services benefit, in that coverage. Other beneficiaries may have different or more limited coverage under the governing statutes and regulations. Nothing about our proposed exceptions to the four walls requirement under the clinic benefit affects States' obligations and options regarding beneficiaries' benefit packages. We are not including any new requirements in response to these comments.

Comment: Several commenters urged CMS to work closely with States and Tribes in implementing the additional exceptions to the four walls requirement if the rule is finalized. One commenter recommended that CMS issue detailed implementation guidance if the proposed rule is finalized.

Response: We appreciate the commenters' suggestions and we intend to work closely with States and Tribes in implementing these exceptions. We have no current plans to issue detailed implementation guidance, but we might revisit those plans based on States' and Tribes' needs for assistance.

Comment: One commenter urged CMS to ensure that FDA-cleared medical devices that help prevent overdose and significantly reduce opioid withdrawal symptoms be adequately covered and reimbursed when furnished outside of the four walls by IHS/Tribal clinics, behavioral health clinics, and clinics located in rural areas if the proposal is finalized.

Response: We appreciate the commenter's recommendation; however, we are not including any new requirements related to this recommendation. We note that nothing about the proposed exceptions to the four walls requirement reduces the scope of items and services that may be paid for under the clinic benefit.

2. Justification and Criteria for Additional Medicaid Clinic Services Four Walls Exceptions

As explained in section XVIII.A of the proposed rule, we previously interpreted section 1905(a)(9) of the Act to limit Medicaid clinic services to services furnished within the four walls of the clinic, except only for services furnished by clinic personnel to individuals who are unhoused. We continue to believe that because Congress added only one specific reference to services furnished outside the clinic to the statute in OBRA '87, it generally ratified our prior interpretation of the four walls requirement. Thus, we continue to believe that the statute authorizes neither broad exceptions to the four walls requirement that have no relationship to the current exception nor a complete elimination of the four walls requirement. However, we now interpret section 1905(a)(9) of the Act as permitting additional exceptions to the four walls requirements for populations served by clinics if those populations have similar health care access issues to individuals who are unhoused. When Congress added the exception to the statute, it introduced the exception with the word ''including'' (OBRA '87). We interpret the word ''including'' in the statute as not precluding additional exceptions to the four walls requirement, so long as any additional exception is similar to the exception for individuals who are unhoused. Had Congress wanted to limit the clinic benefit to only services provided within the four walls and services provided outside the four walls to the unhoused, it could have written a narrower exception instead of using ''including'' as it did when adding the exception to section 1905(a)(9) of the Act. As discussed in the Congressional Record for OBRA '87 in H.R. Rep. 100–391, Congress amended section 1905(a)(9) of the Act to create an exception to the four walls requirement for individuals who are unhoused to address access concerns for a population that has unmet health needs, distrusts mainstream providers, and has difficulty accessing care when providers are unable to meet them where they are located.[526] We believe that adding exceptions to the four walls requirement for populations with similar needs and barriers to access as individuals who are unhoused is consistent with the statutory text and purpose of the initial exception.

In developing the proposed exceptions, we considered the characteristics of the unhoused population that is targeted by the current statutory and regulatory exception. According to data from the Department of Housing and Urban Development (HUD), 21 percent of individuals who are unhoused reported having a serious mental illness while 16 percent reported having a substance use disorder.[527] Individuals who are unhoused often lack transportation to access health care and cite this lack of transportation as a barrier to managing their health.[528] [529] In many cases, individuals who are unhoused distrust providers due to perceptions of

[526] H.R. Rep. No. 100–391, at 523 (1987), reprinted in 1987 U.S.C.C.A.N. 2313–1, 2313–343.

[527] U.S. Department of Housing and Urban Development (HUD), *HUD 2022 Continuum of Care Homeless Assistance Programs Homeless Populations and Subpopulations,* Summary Report, (Washington, DC, 2022), *https://files.hudexchange.info/reports/published/CoC_PopSub_NatlTerrDC_2022.pdf.*

[528] Yale University, ''Barrier to Care,'' Hypertension Awareness & Prevention Program at Yale, accessed March 15, 2024, *https://happy.sites.yale.edu/barriers-care.*

[529] Murphy, Erin Roark. 2019. ''Transportation and Homelessness: A Systematic Review.'' *Journal of Social Distress and the Homeless* 28(2): 1–10. *https://doi.org/10.1080/10530789.2019.1582202.*

disrespect and discrimination.[530] Individuals who are unhoused also experience much poorer health outcomes than those who are housed; for example, nearly two thirds of individuals who are unhoused experience clinically significant dental problems and are four times as likely to visit an emergency department.[531] [532] A recent study found that when controlling for demographic and geographic differences, an individual who is unhoused is three and one half times more likely to experience early mortality than an individual who is housed.[533] As indicated in the proposed rule, we believe that providing additional exceptions to the clinic services four walls requirement for populations with similar needs and barriers to access as individuals who are unhoused is consistent with the statute.

The exceptions outlined in the proposed rule followed four criteria that mirror the needs and barriers to access experienced by individuals who are unhoused:

- The population experiences high rates of behavioral health diagnoses or difficulty accessing behavioral health services;
- The population experiences issues accessing services due to lack of transportation;
- The population experiences a historical mistrust of the health care system; and
- The population experiences high rates of poor health outcomes and mortality.

By authorizing additional clinic services to be furnished outside of the four walls, the proposed exceptions are expected to improve access to care for the populations targeted by the exceptions. The exceptions would authorize States to pay the facility-based clinic services payment rates (such as the AIR for IHS/Tribal clinics) for the excepted services. Currently, due to the four walls requirement, States can cover and pay for services that are provided by clinic personnel outside the four walls—but that do not fit within the exception at § 440.90(b)—only under Medicaid practitioner services benefits, such as physician services, rehabilitative services, or other licensed practitioner services—not under the clinic services benefit.

It is CMS's understanding that State payment rates for these Medicaid practitioner services benefits are generally lower than the facility-based payment rates that States establish or adopt for Medicaid clinic services (such as the facility-based payment rate under the AIR, in the case of IHS/Tribal clinics), because the facility-based payment rates typically account for more overhead costs. While it is CMS's understanding that States generally pay lower rates for Medicaid practitioner services than they do for Medicaid facility-based services, it should be noted that States generally have the flexibility to increase practitioner services payment rates. States must also comply with section 1902(a)(30)(A) of the Act, which requires States to assure that payments are consistent with efficiency, economy, and quality of care, and are sufficient to enlist enough providers so that care and services are available under the Medicaid State plan at least to the extent that such care and services are available to the general population in the geographic area.

Creating the exceptions could thus result in higher payments to providers for the excepted services. Studies of Medicaid payment rates have found that provider willingness to furnish services may be greater in States that pay providers at higher rates.[534] [535] Further, practitioners may be reluctant to provide home-based care when paid under a professional fee schedule rate, since travel expenses and time are often not factored into the payment rate.[536] As this evidence suggests, higher payment rates for services are more likely to incentivize providers to furnish those services. The proposal would authorize payment at the generally higher facility-based clinic services payment rates for the excepted services, therefore we believe that it would incentivize providers to provide these services, and thereby meet these beneficiaries where they are located, which for reasons further discussed later in this section of this preamble, will help to ensure access to necessary care.

We considered whether this change in interpretation could burden States, beneficiaries, providers, or others who have relied on our current interpretation. Based on our current awareness of how States implement the Medicaid clinic services benefit, we do not anticipate that our proposal would create burdens for Medicaid clinic services providers or Medicaid beneficiaries, and we have considered the possible burden for State Medicaid programs in developing the proposal. We invited comments on whether our proposal might create any burdens for States, beneficiaries, providers, or other interested parties.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters agreed with CMS that authorizing payment at the generally higher facility-based clinic services payment rates for services furnished outside of the four walls would help incentivize providers to furnish these services, and thereby meet beneficiaries where they are located and help ensure access to care.

Response: We appreciate the comments that agreed that that authorizing payment at the generally higher facility-based clinic services payment rates for the expected services would help incentivize providers to furnish these services, and thereby meet beneficiaries where they are located and help ensure access to care.

Comment: Many commenters agreed with CMS's interpretation that it is within CMS's authority under section 1905(a)(9) of the Act to include additional exceptions to the four walls requirement for populations with similar needs and barriers to access as individuals who are unhoused.

Response: We appreciate the comments in support of the explanation in the proposed rule for why it is within our authority under section 1905(a)(9) of the Act to include additional exceptions

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[530] Becker, Jenna N., and Karen J. Foli. 2021. ''Health-Seeking Behaviours in the Homeless Population: A Concept Analysis.'' *Health & Social Care in the Community* 30(2). *https://doi.org/10.1111/hsc.13499.*

[531] Baggett, Travis P., James J. O'Connell, Daniel E. Singer, and Nancy A. Rigotti. 2010. ''The Unmet Health Care Needs of Homeless Adults: A National Study.'' *American Journal of Public Health* 100(7): 1326–33. *https://doi.org/10.2105/ajph.2009.180109.*

[532] Lin, Wen-Chieh, Monica Bharel, Jianying Zhang, Elizabeth O'Connell, and Robin E. Clark. 2015. ''Frequent Emergency Department Visits and Hospitalizations among Homeless People with Medicaid: Implications for Medicaid Expansion.'' *American Journal of Public Health* 105(S5): S716–22. *https://doi.org/10.2105/ajph.2015.302693.*

[533] Logani, Ilina, Bruce Meyer, and Angela Wyse. 2023. *The Mortality of the US Homeless Population.* BF Becker Friedman Institute for Economics at UChicago. The University of Chicago. March 27, 2023. *https://bfi.uchicago.edu/insight/research-summary/the-mortality-of-the-us-homeless-population/.*

[534] Candon, Molly, Stephen Zuckerman, Douglas Wissoker, Brendan Saloner, Genevieve M. Kenney, Karin Rhodes, and Daniel Polsky. 2018. ''Declining Medicaid Fees and Primary Care Appointment Availability for New Medicaid Patients.'' *JAMA Internal Medicine* 178 (1): 145. *https://doi.org/10.1001/jamainternmed.2017.6302.*

[535] Holgash, Kayla, and Martha Heberlein. 2019. *Physician Acceptance of New Medicaid Patients: What Matters and What Doesn't.* Health Affairs Blog (blog). April 19, 2019. *https://www.healthaffairs.org/content/forefront/physician-acceptance-new-medicaid-patients-matters-and-doesn-t.*

[536] Klein, Sarah, Martha Hostetter, and Douglas McCarthy. 2017. *An Overview of Home-Based Primary Care: Learning from the Field.* The Commonwealth Fund. The Commonwealth Fund. June 7, 2017. *https://www.commonwealthfund.org/publications/issue-briefs/2017/jun/overview-home-based-primary-care-learning-field.*

to the four walls requirement for populations that meet more of the four criteria we described in the proposed rule.

Comment: Three commenters recommended CMS consider eliminating the four walls requirement completely as they believed the four walls requirement creates barriers to the delivery of Medicaid clinic services via telehealth. One commenter urged CMS to work with Congress to eliminate the four walls requirement through legislation; while another commenter indicated that CMS is misinterpreting section 1905(a)(9) of the Act and that the statute does not require clinic services to be furnished within the four walls of a clinic.

Response: We thank the commenters for their recommendations, but we do not interpret the statute as authorizing us to completely eliminate the four walls requirement in § 440.90 through rulemaking. As we discussed in section XVIII.B of the proposed rule (89 FR 59186), we continue to believe that the statute authorizes neither broad exceptions to the four walls requirement that have no relationship to the current exception nor a complete elimination of the four walls requirement. However, in this rule, we now interpret section 1905(a)(9) of the Act as permitting additional exceptions to the four walls requirements for populations served by clinics if those populations have similar health care access issues to individuals who are unhoused. We will take the commenters' concerns about telehealth into consideration as we contemplate issuing sub-regulatory guidance regarding our interpretation of how the four walls requirement applies when Medicaid clinic services are delivered via telehealth.

3. IHS/Tribal Clinics

In response to advice and input received through Tribal consultation, we proposed to add a new paragraph (c) to § 440.90 to add an exception to the four walls requirement for IHS/Tribal clinics, to authorize payment for clinic services provided outside the four walls by IHS/Tribal clinic personnel. This exception would be mandatory for all States that opt to cover the Medicaid clinic services benefit. We referred in the proposed regulation text to clinics that are facilities of the IHS, whether operated by IHS or by a Tribe or Tribal organization as authorized by the ISDEAA, to make clear that this exception applies only to IHS/Tribal clinics. The proposed regulatory language identifying the facilities that would be subject to the exception is consistent with our longstanding interpretation of the language used in sections 1905(b) and 1911 of the Act, and would mean clinics that are owned and operated by IHS, clinics that are owned by IHS and tribally-operated as authorized by the ISDEAA, or clinics that are owned and operated by Tribes and Tribal organizations as authorized by the ISDEAA.[537]

Under section 1903(a)(1) of the Act, as discussed earlier, the Federal Government is required to match State expenditures for medical assistance at the FMAP, which is defined at section 1905(b) of the Act to be 100 percent for State expenditures for Medicaid-covered services received through an IHS facility whether operated by IHS or by a Tribe or Tribal organization (which, again, CMS has interpreted to refer to all three kinds of IHS/Tribal facilities described previously). Under CMS's longstanding interpretation of section 1905(b) of the Act, this 100 percent FMAP is available only for State expenditures on services received through an IHS/Tribal facility (such as a clinic) by an AI/AN Medicaid beneficiary. State expenditures on services furnished by an IHS/Tribal facility to other Medicaid beneficiaries are not matched by the Federal Government at 100 percent, but rather at the otherwise applicable FMAP, and this would continue to apply for services provided outside the four walls of a clinic.

We did not propose to include facilities operated by UIOs in the proposed exception, because it is our understanding that many of those facilities currently participate in Medicaid as providers of the Medicaid FQHC services benefit, not as providers of the clinic services benefit. Because Medicaid FQHC services are not subject to a four walls requirement under Federal Medicaid law, we believe that UIOs are unlikely to need the proposed exception. UIO facilities that provide Medicaid clinic services might qualify as behavioral health clinics or clinics in rural areas and be exempt from the four walls requirement under one of the two optional exceptions discussed later in this section of the preamble.

This exception would apply to any Medicaid beneficiary who receives services from the IHS/Tribal clinic. Under IHS authorities, these clinics serve Medicaid beneficiaries who are eligible to receive services from the IHS/Tribal clinic under IHS regulations at 42 CFR part 136, and also may serve other Medicaid beneficiaries under 25 U.S.C. 1680c. As mentioned in section XVIII.A of the proposed rule, all services covered under the clinic services benefit must be furnished by or under the direction of a physician, so we proposed to include language in this exception specifying that services subject to the exception would have to be furnished under the direction of a physician to make that requirement clear.

We proposed this exception based on advice and input received through Tribal consultation and because the population served by IHS/Tribal clinics, which is predominately AI/AN, tends to meet the criteria CMS has identified that warrant an exception from the four walls requirement (for example, high rates of behavioral health needs, lack of accessible transportation, mistrust of the health care system, and high rates of morbidity and poor health outcomes).

AI/ANs experience high rates of behavioral health diagnoses. In particular, the opioid crisis plaguing many communities is especially acute in Tribal communities.[538] As reported by the Centers for Disease Control and Prevention (CDC), AI/ANs have the highest rate of drug overdose compared to other U.S. populations, and they experienced a 39 percent increase in overdoses between 2019 and 2020.[539]

Many AI/ANs also experience difficulties accessing services due to lack of transportation. Tribal lands encompass about 56 million acres nationwide, including 145,000 miles of roads.[540] Roads in Tribal communities are typically rudimentary and in poor condition. For example, about 70 percent of Tribal roads across the country are unpaved compared to 45 percent of all rural roads.[541] [542] Because Tribal communities are often located in rural or remote areas covering vast distances, providers can be extremely far away from their patients. For example, it is common for AI/ANs to have to travel between 60 and 90 miles one-way for health care

[537] HCFA and IHS, Memorandum of Agreement.

[538] Tipps, Robin T., Gregory T. Buzzard, and John A. McDougall. 2018. ''The Opioid Epidemic in Indian Country.'' *The Journal of Law, Medicine & Ethics* 46 (2): 422–36. *https://doi.org/10.1177/1073110518782950.*

[539] Centers for Disease Control and Prevention (CDC), ''Drug Overdose Prevention in Tribal Communities,'' CDC, May 2, 2024, *https://www.cdc.gov/overdose-prevention/health-equity/tribal-communities.html?CDC_AAref_Val=https://www.cdc.gov/drugoverdose/health-equity/tribal.html.*

[540] Congressional Research Service (CRS), *Highways and Highway Safety on Indian Lands,* CRS Report, (Washington, DC, 2016), *https://www.everycrsreport.com/files/20160202_R44359_38af583fdef681edc7b5d4daeeeb5bc506a4f919.pdf.*

[541] Id.

[542] CRS, *Rural Highways,* CRS Report, (Washington, DC, 2018), *https://crsreports.congress.gov/product/pdf/R/R45250.*

appointments.[543] Many AI/ANs also do not have reliable personal transportation. The rate of AI/ANs without a personal vehicle is more than double that of individuals in other rural areas.[544] Per a recent CDC report, approximately 17.1 percent of AI/ANs lack reliable transportation, the highest rate compared to other U.S. populations, and this is a barrier to accessing health care.[545] Many AI/ANs have a profound mistrust of the Federal Government and mainstream providers based on trauma from a long history of harmful U.S. Tribal policies, such as removal of AI/ANs from homelands and Tribal community structures, bans on cultural practices and language, forced relocation to reservations, abusive boarding school practices, and other destructive policies. AI/AN health disparities are the visible, lingering result of these harmful policies.[546]

Furthermore, AI/ANs face poorer health outcomes than all other adults on average and have the lowest life expectancy compared to other U.S. populations. For example, AI/ANs have higher rates of obesity, heart disease, and diabetes than other adults in the U.S. population on average.[547] The CDC's Provisional Life Expectancy Estimates for 2021 found a severe drop in life expectancy for AI/ANs—decreasing by 6.6 years from 2019 to 2021.[548] Not only do AI/ANs, on average, die younger than all other Americans, but this disparity is worsening at an alarming rate. AI/AN life expectancy today is the same as it was for the average American in 1944.[549]

This evidence indicates that an exception to the four walls requirement is warranted for IHS/Tribal clinics because the individuals served by these clinics are more likely than those in other groups to meet a higher number of the four criteria we described in the proposed rule. Through Tribal Consultation, Tribal leaders indicated that IHS/Tribal clinics need the flexibility to provide services to AI/ANs where they are located due to their high levels of behavioral health diagnoses, challenges accessing services due to lack of transportation and appropriate infrastructure, historic mistrust of the Federal Government and the health care system, and poor health outcomes.

As explained later in this section of the preamble, we proposed that behavioral health clinics and clinics in rural areas would serve as a proxy for their patient populations, instead of limiting the exception for behavioral health clinics to patients with behavioral health disorders or limiting the exception for clinics in rural areas to patients residing in rural areas. We proposed this approach because we believe that these clinics serve predominantly patients with behavioral health disorders or who live in rural areas (as applicable), and to reduce the operational burden of implementing these exceptions. Similar to the proposed exceptions for behavioral health clinics and clinics in rural areas, we also proposed that the IHS/Tribal clinics would be a proxy for their patient population, but for somewhat different reasons. The operational burden that the proposed proxy approach would address for behavioral health clinics and clinics in rural areas would not be as much of an issue for IHS/Tribal clinics, because the entire patient population of an IHS/Tribal clinic is likely to meet some or all of the four criteria described in the proposed rule. For that same reason, a proxy approach would be appropriate for these clinics. These clinics serve a clearly identifiable group of Medicaid beneficiaries under IHS statutes and regulations: Medicaid beneficiaries whom IHS/Tribal clinics serve under 42 CFR part 136 or other Medicaid beneficiaries whom these clinics may serve under 25 U.S.C. 1680c. As discussed previously, the population served by IHS/Tribal clinics, which is predominately AI/AN, is more likely than other groups to meet a higher number of the criteria identified in the proposed rule as warranting an exception.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Most commenters expressed support for our proposed exception to the Medicaid clinic services benefit four walls requirement for IHS/Tribal clinics at § 440.90(c). Many commenters indicated that Tribal communities face significant barriers in accessing healthcare facilities and could benefit from an exception to the four walls requirement. Several commenters noted that IHS/Tribal clinics are experiencing substantial practitioner shortages that create long wait times for in-person services, and that without a permanent exception to the Medicaid four walls requirement the wait times for in-person services will worsen. One commenter explained that continued access to Medicaid clinic services outside the four walls of IHS/Tribal clinics is vital for isolated Tribal communities that rely upon rely upon traveling practitioners from these clinics, as there are great distances between the communities and the closest IHS/Tribal clinics. Finally, commenters also noted that allowing an exception to the four walls requirement for IHS/Tribal clinics will ensure that services continue to be provided in the location that is best for the Tribal member after the end of the grace period.

Response: We appreciate the comments in support of our proposed exception to the Medicaid clinic services benefit four walls requirement for IHS/Tribal clinics. We agree that the population served by IHS/Tribal clinics faces significant barriers in accessing services and could benefit from an exception to the four walls requirement. We also agree that this exception will allow this population to continue to receive services in the location that best meets the individual's needs after the grace period.

Comment: Many commenters agreed with CMS that the population that receives services from IHS/Tribal clinics meets more of the four criteria we described in the proposed rule than other groups and that an exception to the four walls requirement is justified for IHS/Tribal clinics. Several commenters noted that AI/ANs experience some of the highest rates of chronic illness of any population in the U.S., and a few commenters noted that AI/ANs are more than twice as likely to miss appointment times than other U.S. populations.

[543] Government Accountability Office (GAO), *Indian Health Service: Health Care Services Are Not Always Available to Native Americans,* GAO–05–789, (Washington, DC, 2005), *https://www.gao.gov/assets/gao-05-789.pdf.*

[544] CRS, *Tribal Highway and Public Transportation Programs,* In Focus, (Washington, DC, 2022), *https://crsreports.congress.gov/product/pdf/IF/IF12129.*

[545] CDC, National Center for Health Statistics (NCHS), *Lack of Reliable Transportation for Daily Living Among Adults: United States, 2022,* by Amanda E. Ng, Dzifa Adjaye-Gbewonyo, and James Dahlhamer, NCHS Data Brief No. 490, (Hyattsville, MD, 2024), *https://dx.doi.org/10.15620/cdc:135611.*

[546] U.S. Commission Civil Rights, *Broken Promises: Continuing Federal Funding Shortfall for Native Americans,* Briefing Report, (Washington, DC, 2018), *https://www.usccr.gov/files/pubs/2018/12-20-Broken-Promises.pdf.*

[547] MACPAC, *Medicaid's Role in Health Care for American Indians and Alaska Natives,* Issue Brief, (Washington, DC, 2021), *https://www.macpac.gov/wp-content/uploads/2021/02/Medicaids-Role-in-Health-Care-for-American-Indians-and-Alaska-Natives.pdf.*

[548] CDC, NCHS, *Provisional Life Expectancy Estimates for 2021,* by Elizabeth Arias, Betzaida Tejada-Vera, Kenneth D. Kochanek, and Farida B. Ahmad, Vital Statistics Rapid Release Report No. 23, (Hyattsville, MD, 2022), *https://dx.doi.org/10.15620/cdc:118999.*

[549] IHS, ''Disparities,'' Indian Health Services, October 2019, *https://www.ihs.gov/newsroom/factsheets/disparities/.*

Response: We appreciate the comments in support of the evidence we presented that the population that receives services from IHS/Tribal clinics meets more of the four criteria we described in the proposed rule than other groups and that an exception to the four walls requirement is justified for IHS/Tribal clinics.

Comment: A few commenters inquired whether the proposed IHS/Tribal clinic exception at § 440.90(c) would apply to services furnished to individuals who are not AI/AN.

Response: As we indicated in section XVIII.B of the proposed rule (89 FR 59186), the exception would apply to any Medicaid beneficiary who receives services from the IHS/Tribal clinic, not just individuals who are AI/AN.

Comment: One commenter inquired whether the proposed IHS/Tribal clinic exception at § 440.90(c) would apply to Tribal facilities that participate in Medicaid as FQHCs.

Response: We noted in section XVIII.B of the proposed rule (89 FR 59186) that the Medicaid clinic services benefit is distinct from the Medicaid FQHC services benefit and there is no Federal four walls requirement under the Medicaid FQHC benefit, unlike the Medicaid clinic services benefit.

Comment: One commenter inquired whether the proposed IHS/Tribal clinic exception at § 440.90(c) would apply to traditional healing services.

Response: CMS recently approved several States' section 1115 demonstration proposals to cover traditional health care practices, which cannot currently be covered under Medicaid State plan benefits, such as the clinic services benefit.[550] The traditional health care practices that can be covered under these demonstrations are not clinic services within the meaning of section 1905(a)(9) of the Act, 42 CFR 440.90, or this rulemaking. As such, the clinic services benefit four walls requirement does not apply to that coverage.

Comment: One commenter recommended that CMS expand the IHS/Tribal clinic exception at § 440.90(c) in the final rule to include non-Tribal clinics that operate on Tribal lands.

Response: We appreciate the commenter's recommendation and will take it into consideration for future rulemaking; however, we decline to expand the IHS/Tribal clinic exception at § 440.90(c) in this final rule to include non-Tribal clinics that operate on Tribal lands. We did not propose including non-Tribal clinics that operate on Tribal lands within the exception for IHS/Tribal clinics and believe that such a change would require additional consideration and discussion with the public beyond what could be finalized in this current rule. However, we would also note that we included an exception at § 440.90(e) for clinics located in rural areas and non-Tribal clinics that operate on Tribal lands might fall within that exception in States that choose to adopt such exception.

After consideration of the public comments we received, we are finalizing, without modification, an exception to the Medicaid clinic services four walls requirement at § 440.90(c) for IHS/Tribal clinics.

4. Behavioral Health Clinics

We proposed to add a new paragraph (d) to § 440.90 to authorize an exception to the four walls requirement for clinic services provided outside the four walls by personnel of behavioral health clinics. This exception would not be mandatory in States that opt to cover the clinic services benefit but could be implemented as a State option. Specifically, we proposed an exception for clinics that are primarily organized for the care and treatment of outpatients with behavioral health disorders, including mental health disorders and substance use disorders. We noted that the proposed exception would include any clinic services furnished outside of the four walls by a behavioral health clinic, including non-behavioral clinic services such as physical health services.

The proposed exception would include behavioral clinic types that are recognized nationally, such as Community Mental Health Centers, and other behavioral health clinics organized in a State. We recognize that the types of behavioral health clinics within a State may vary, so we did not propose to limit this exception to specific types of behavioral health clinics. However, to be considered a behavioral health clinic under the proposed exception, the clinic would have to be primarily organized to treat outpatients with behavioral health disorders regardless of the patient mix of the clinic. For example, if a State has established separate licensure or certification requirements for mental health clinics and primary care clinics, under which primary care clinics are licensed to treat outpatients for a range of services beyond the treatment of behavioral health disorders, then we would consider a mental health clinic in that State to be primarily organized to treat outpatients with behavioral health disorders but would not consider a primary care clinic in that State to be primarily organized to treat such outpatients. We recognize that there may be other means by which a State determines that a clinic is primarily organized to treat outpatients with behavioral health disorders (that is, other than through licensure or certification), including behavioral health accreditation by accrediting organizations, such as the Joint Commission, or based on the organizing documents of the clinic, such as a business charter. If the proposal were finalized as described, States that choose to adopt this exception would describe the types of behavioral health clinics such exception applies to in their Medicaid State plan. Just like our proposed exception for IHS/Tribal clinics, we proposed to include language in this exception specifying that services subject to the exception would have to be furnished under the direction of a physician.

Per 2022 data from the Substance Abuse and Mental Health Services Administration (SAMHSA), approximately 94.7 percent of adults nationwide with a substance use disorder did not seek substance use treatment and nearly half of adults nationwide with a mental health disorder did not receive mental health treatment, which suggests that this population may have difficulty accessing behavioral health services.[551] Lack of transportation and geographic distance from behavioral health services are often cited in research as barriers to behavioral health treatment.[552] One study of transportation-disadvantaged adults found that nearly half of adults nationwide who lacked medical transportation were diagnosed with depression or another mental health disorder.[553] Studies have found that

[550] CMS, *Biden-Harris Administration Takes Groundbreaking Action to Expand Health Care Access by Covering Traditional Health Care Practices,* Press Release, (Baltimore, MD, 2024), *https://www.cms.gov/newsroom/press-releases/biden-harris-administration-takes-groundbreaking-action-expand-health-care-access-covering.*

[551] Substance Abuse and Mental Health Services Administration (SAMHSA), *Key substance use and mental health indicators in the United States: Results from the 2022 National Survey on Drug Use and Health,* HHS Publication No. PEP23–07–01–006, NSDUH Series H–58, (Rockville, MD, 2023), *https://www.samhsa.gov/data/report/2022-nsduh-annual-national-report.*

[552] Priester, Mary Ann, Teri Browne, Aidyn Iachini, Stephanie Clone, Dana DeHart, and Kristen D. Seay. 2016. ''Treatment Access Barriers and Disparities among Individuals with Co-Occurring Mental Health and Substance Use Disorders: An Integrative Literature Review.'' *Journal of Substance Abuse Treatment* 61 (61): 47–59. *https://doi.org/10.1016/j.jsat.2015.09.006.*

[553] Wallace, Richard J, Paul Hughes-Cromwick, Hillary J Mull, and Snehamay Khasnabis. 2005.

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individuals with behavioral health disorders often report negative experiences with providers and stigmatizing attitudes from providers are common, which can lead to a mistrust of the health care system and forgone care.[554] Finally, research has found that individuals with a severe mental illness or substance use disorder experience worse health outcomes and increased risk of premature mortality, with one recent study finding individuals with a severe mental illness or substance use disorder experiencing a shorter life span than comparable individuals by an average of 6 years.[555]

State-specific circumstances may affect the degree to which a State's population of individuals with behavioral health disorders meets the four criteria described in the proposed rule. The Health Resources and Services Administration (HRSA), in coordination with State primary care offices, designates as Health Professional Shortage Areas (HPSAs) [556] areas experiencing a shortage in primary care, dental care, or mental health care providers for a whole geographic area, a specific population within a geographic area, and facilities that serve these areas. HRSA publishes data for each State on the percent of need met for primary care, dental care, and mental health providers, with a lower percentage indicating a lower availability of providers. It should be noted that the types of mental health providers counted in HPSAs are set in regulation, and based on the regulations, HRSA allows State Primary Care Offices to choose whether to count: psychiatrists only, core mental health professionals (psychiatrists, clinical psychologists, clinical social workers, psychiatric nurse specialists, and marriage and family therapists), or a combination of all types. As of December 31, 2023, there is significant variation among States in the percent of need met for mental health care, with a low of 9 percent and a high of 63 percent.[557] This variation in availability of mental health care providers may suggest that populations of individuals with behavioral health disorders in some States may have greater difficulty accessing behavioral health services or accessing transportation to a behavioral health provider than those populations in other States. There may also be significant variability between States with regard to behavioral health outcomes and mortality. For example, in 2021 the age-adjusted drug overdose mortality rate by State had significant variation, from a low of 11 per 100,000 to a high of 90 per 100,000.[558] These differences between populations of individuals with behavioral health disorders in different States may suggest that the degree to which a State's population of individuals with behavioral health disorders meets the four criteria may be variable.

This evidence indicates that an exception to the clinic services four walls requirement could be warranted, based on State-specific circumstances, for clinics that are primarily organized for the care and treatment of outpatients with a behavioral health disorder, as these clinics might primarily serve a patient population that may be more likely than other groups to meet more of the four criteria we described in the proposed rule. The evidence also suggests that this patient population is less likely to meet as many of the criteria as consistently nationwide as patients served by IHS/Tribal clinics. Under the proposal, a State could determine that individuals with a behavioral health disorder in that State should be engaged by behavioral health clinic personnel where they are located due to their challenges accessing services, including lack of transportation and geographic distance from services, historic mistrust and stigmatization in the health care system, and poor health outcomes.

We considered proposing that, to qualify for the proposed exception, clinic services would have to be provided specifically to individuals with a behavioral health disorder, in addition to being provided by personnel of a behavioral health clinic. However, we believe that such a requirement would be too operationally burdensome and that instead behavioral health clinics can serve as a proxy for a population that generally consists of individuals with a behavioral health disorder. We recognize there may be circumstances in which a behavioral health clinic furnishes services to an individual who does not have a behavioral health disorder, but it is our understanding that behavioral health clinics generally serve a patient population that consists primarily of individuals with behavioral health disorders (including individuals with a formal behavioral health disorder diagnosis and those with an undiagnosed behavioral health disorder). Thus, these clinics can serve as a proxy for a patient population that is more likely to have such a disorder—and thus, that includes people who are more likely to meet more of the four criteria. In addition, we believe that requiring clinics or States to verify that a clinic patient has a behavioral health disorder and to deny coverage of Medicaid clinic services provided outside the four walls if the patient does not, would be too operationally burdensome. For example, an individual might experience or present their behavioral health symptoms in an uncommon way, an individual might be misdiagnosed, or an individual might be experiencing a crisis where services are needed urgently and verifying that they have a behavioral health disorder might delay needed care. Because we believe that behavioral health clinics can serve as a proxy for individuals with behavioral health disorders, and because we do not want to make this exception too operationally burdensome, we did not propose that to qualify for the proposed exception, clinic services must be provided by a behavioral health clinic specifically to an individual with a behavioral health disorder.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Most commenters expressed support for our proposed exception to the Medicaid clinic services benefit four walls requirement for behavioral health clinics at § 440.90(d). Commenters indicated that individuals with behavioral health needs would benefit from receiving care in environments where they feel most comfortable rather than solely within the four walls of a clinic. One commenter noted that an exception to the four walls requirement for behavioral health clinics might lead to earlier diagnosis, better adherence to

''Access to Health Care and Nonemergency Medical Transportation: Two Missing Links.'' *Transportation Research Record* 1924 (January): 76–84. *https://doi.org/10.3141/1924-10*.

[554] Knaak, Stephanie, Ed Mantler, and Andrew Szeto. 2017. ''Mental Illness-Related Stigma in Healthcare.'' *Healthcare Management Forum* 30 (2): 111–16. *https://doi.org/10.1177/0840470416679413*.

[555] Iturralde, Esti, Natalie Slama, Andrea H. Kline-Simon, Kelly C. Young-Wolff, Don Mordecai, and Stacy A. Sterling. 2021. ''Premature Mortality Associated with Severe Mental Illness or Substance Use Disorder in an Integrated Health Care System.'' *General Hospital Psychiatry* 68 (January): 1–6. *https://doi.org/10.1016/j.genhosppsych.2020.11.002*.

[556] Health Resources & Services Administration (HRSA), ''What is Shortage Designation?'' HRSA Health Workforce, June 2023, *https://bhw.hrsa.gov/workforce-shortage-areas/shortage-designation*.

[557] HRSA, Designated Health Professional Shortage Areas Statistics, Designated HPSA Quarterly Summary, (Rockville, MD, 2024), *https://data.hrsa.gov/Default/GenerateHPSAQuarterlyReport*.

[558] CDC, NCHS, ''Drug Overdose Mortality by State,'' CDC, March 1, 2022, *https://www.cdc.gov/nchs/pressroom/sosmap/drug_poisoning_mortality/drug_poisoning.htm*.

treatment plans, and improved outcomes for beneficiaries with behavioral health needs. Many commenters explained that beneficiaries that receive services from behavioral health clinics often experience transportation, financial, safety, behavioral health, or physical health challenges that impede their ability to travel to behavioral health clinics.

Several commenters expressed that telehealth flexibilities adopted by States under section 1135 waivers during the COVID–19 public health emergency (PHE) to allow coverage of Medicaid clinic services outside of the four walls (when neither the clinic practitioner nor beneficiary was present at the clinic) increased access to services furnished by behavioral health clinics, and that a permanent exception to the four walls requirement for behavioral health clinics would increase access to care. Many commenters indicated that CMS's current interpretation of how the four walls requirement applies when Medicaid clinic services are furnished via telehealth, under which clinic services furnished via telehealth are covered only when either the clinic practitioner or the beneficiary is physically onsite at the clinic facility, is burdensome for behavioral health clinics.

In addition, several commenters noted that there are national behavioral health workforce shortages and allowing an exception to the four walls requirement for behavioral health clinics would increase clinic practitioner recruitment and retention rates.

Response: We appreciate the comments in support of our proposed exception to the Medicaid clinic services benefit four walls requirement for behavioral health clinics. We thank the commenters for sharing additional information on how the population served by behavioral health clinics may benefit from an exception to the four walls requirement and how an exception could lead to better workforce recruitment and retention rates. We also agree that an exception to the four walls requirement for behavioral health clinics could increase access to care. Finally, we agree with the commenters that noted that an exception to the four walls requirement for behavioral health clinics might increase clinic practitioner recruitment and retention rates.

We acknowledge the commenters' concerns regarding our current interpretation of how the four walls requirement applies when Medicaid clinic services are furnished via telehealth. We note that upon the effective date of this rule, if a State adopts exceptions to the four walls requirement for behavioral health clinics and/or clinics located in rural areas, then neither the beneficiary nor the clinic practitioner would need to be present in such a clinic for services to be delivered via telehealth. In addition, IHS/Tribal clinic services can be delivered via telehealth without the beneficiary or clinic practitioner present in the clinic upon the effective date of this final rule with comment period. Finally, we will take these comments into consideration as we contemplate issuing sub-regulatory guidance regarding our interpretation of how the four walls requirement applies when Medicaid clinic services are delivered via telehealth.

Comment: One commenter inquired whether psychiatric outpatient clinics are considered behavioral health clinics, for purposes of the proposed exception for behavioral health clinics at § 440.90(d).

Response: The proposed exception for behavioral health clinics applies to services furnished outside of a clinic that is primarily organized for the care and treatment of outpatients with behavioral health disorders, including mental health and substance use disorders, by clinic personnel under the direction of a physician. As we discussed in the proposed rule preamble, the types of behavioral health clinics within a State may vary, so we are not proposing to limit this exception to specific types of behavioral health clinics, and States that choose to adopt this exception would describe the types of behavioral health clinics to which the exception applies in their Medicaid State plans. All such clinics would have to be primarily organized to treat outpatients with behavioral health disorders regardless of the patient mix of the clinic. Additionally, per § 440.90, Medicaid clinic services must be furnished by a facility that is not part of a hospital but that is organized and operated to provide medical care to outpatients.

Comment: Many commenters expressed support for including behavioral health clinic types that are recognized nationally, such as Community Mental Health Centers (CMHCs), and other behavioral health clinics organized in a State as behavioral health clinics at § 440.90(d).

Response: We remind the commenters that the States implementing this exception will determine which clinics are subject to it. As we discussed in the proposed rule preamble, States that choose to adopt this exception would describe the types of behavioral health clinics to which the exception applies in their Medicaid State plans, provided that such clinics are primarily organized to treat outpatients with behavioral health disorders. However, as we indicated in the proposed rule preamble, we expect all States that opt to implement this exception to include behavioral health clinic types that are recognized nationally.

Comment: Many commenters expressed support for CMS's proposal to allow the behavioral health clinic exception at § 440.90(d) to apply to any services furnished by behavioral health clinics and not just behavioral health services.

Response: We appreciate the comments in support of our proposal to allow the exception to the four walls for behavioral health clinics to apply to any services furnished by behavioral health clinics.

Comment: Many commenters agreed with CMS that the behavioral health population meets more of the four criteria we described in the proposed rule than other groups that are not the focus of an exception in this rulemaking and that an exception to the four walls requirement is justified for behavioral health clinics. One commenter noted that there is evidence that individuals with behavioral health conditions have increased difficulties establishing trust relationships with practitioners, which leads to a mistrust of the health care system. In addition, the commenter explained that behavioral health conditions can make navigating public transit more difficult, which creates transportation barriers for individuals with behavioral health conditions.

Response: We appreciate the comments in support of the evidence we presented that the behavioral health population meets more of the four criteria we described in the proposed rule than other groups that are not the focus of an exception in this rulemaking and that an exception to the four walls requirement is justified for behavioral health clinics.

Comment: Two commenters recommended that CMS not limit the exception for behavioral health clinics at § 440.90(d) to only include clinics that are primarily organized for the treatment of outpatients with behavioral health disorders. One commenter recommended that CMS consider an application or appeals process to allow clinics which serve a behavioral health population that meets the four criteria we described in the proposed rule (but do not fall under the proposed exception) to also furnish services outside of the four walls.

Another commenter expressed that in rural and frontier areas, individuals with behavioral health disorders may

have access to behavioral health services only through primary care clinics or other clinics that are not primarily organized for the care and treatment of outpatients with behavioral health disorders. The commenter recommended that the proposed exception at § 440.90(d) include any clinic that furnishes behavioral health services.

Response: We decline to expand the exception to include non-behavioral health clinics that furnish behavioral health services. As we noted in section XVIII.B of the proposed rule (89 FR 59186), behavioral health clinics can serve as a proxy for a patient population that is more likely to have a behavioral health disorder—and thus, that includes people who are more likely to meet more of the four criteria we described in the proposed rule. It is our understanding that non-behavioral health clinics do not generally serve a patient population that consists primarily of individuals with behavioral health disorders. We do not believe that non-behavioral health clinics that furnish behavioral health services can serve as a proxy for such a population. We would also note that we included an exception at § 440.90(e) for clinics located in rural areas and are not limiting the types of services that those clinics may furnish outside of the four walls under that exception.

Comment: One commenter encouraged CMS to require States to establish a robust referral system, including ongoing transportation support, to ensure that individuals who receive services from behavioral health clinics can get connected to and receive care for any additional health needs outside of the clinic.

Response: We decline to amend the regulation to require States to establish a referral system. Federal Medicaid regulations governing transportation and case management services are beyond the scope of this rulemaking. However, we understand the critical role that transportation to services can play in improving the health outcomes of Medicaid beneficiaries, and note that per section 1902(a)(4)(A) of the Act and 42 CFR 431.53, State Medicaid plans must specify that the Medicaid agency will ensure necessary transportation for beneficiaries to and from providers. CMS issued guidance on the Medicaid transportation assurance in the form of a State Medicaid Director letter (SMD) 23–006 that introduces the Medicaid Transportation Coverage Guide. Case management services are optional in the Medicaid program under sections 1905(a)(19) and 1915(g) of the Act and 42 CFR 440.169, and States may choose to implement case management services under a variety of authorities. We acknowledge the role that case management can play in linking individuals to needed medical, behavioral health, and other services.

Comment: Two commenters recommended that CMS implement the proposed exception at § 440.90(d) at the beneficiary level (in addition to the clinic level) to ensure that the entire behavioral population that meets the four criteria we described in the proposed rule is able to access clinic services outside the four walls.

Response: We understand the commenters to be recommending application of this exception to any Medicaid beneficiary with a behavioral health condition, regardless of the type of clinic. We thank the commenters for their recommendation that we implement the proposed exception at § 440.90(d) at the beneficiary level (in addition to the clinic level) to ensure that the entire behavioral health population that meets the four criteria we described in the proposed rule is able to access clinic services outside the four walls; however, we will not be making changes in the final rule to allow States to apply the exception at § 440.90(d) at the beneficiary level. As we noted in section XVIII.B of the proposed rule (89 FR 59186), behavioral health clinics can serve as a proxy for a patient population that is more likely to have a behavioral health disorder—and thus, that includes people who are more likely to meet more of the four criteria we described in the proposed rule. In addition, we believe that requiring clinics or States to verify that a clinic patient has a behavioral health disorder and to deny coverage of Medicaid clinic services provided outside the four walls if the patient does not, would be too operationally burdensome.

After consideration of the public comments we received, we are finalizing, without modification, an exception to the Medicaid clinic services four walls requirement at § 440.90(d) for clinics that are primarily organized for the care and treatment of outpatients with behavioral health disorders, including mental health and substance use disorders.

5. Clinics Located in Rural Areas

We proposed to add a new paragraph (e) to § 440.90 to authorize an exception to the four walls requirement for clinic services provided outside the four walls by personnel of clinics located in rural areas, but that are not RHCs as referenced in section 1905(a)(2)(B) of the Act and § 440.20(b). This exception would not be mandatory in States that opt to cover the clinic services benefit, but could be implemented at State option. Just like our proposed exception for IHS/Tribal clinics and behavioral health clinics, we proposed to include language in this exception specifying that services subject to the exception would have to be under the direction of a physician.

Per SAMHSA data, rates of mental illness and substance use disorders are similar in rural and urban areas.[559] However, individuals in rural areas with a mental illness or substance use disorder are less likely to receive treatment than individuals in urban areas due to more limited access to providers, as rural areas are more likely to lack trained and specialized behavioral health providers.[560] For example, in 2021 the number of psychologists per 100,000 people in rural counties was less than half of the number in urban counties.[561] A recent study found that rural individuals on average are 22 percent less likely than urban individuals to utilize primary and specialty clinic services.[562] Studies have found that lack of transportation and distance to providers is a common barrier to rural individuals accessing health care services.[563] Furthermore, a recent Government Accountability Office (GAO) report found that rural individuals need to travel 40 miles on average to access specialty services.[564] With regards to mistrust of the health care system, research has found that rural individuals have historically mistrusted the health care at higher

[559] SAMHSA, ''2022 NSDUH Detailed Tables,'' SAMHSA, November 13, 2023, *https://www.samhsa.gov/data/report/2022-nsduh-detailed-tables.*

[560] Morales, Dawn A., Crystal L. Barksdale, and Andrea C. Beckel-Mitchener. 2020. ''A Call to Action to Address Rural Mental Health Disparities.'' *Journal of Clinical and Translational Science* 4 (5): 1–20. *https://doi.org/10.1017/cts.2020.42.*

[561] WWAMI Rural Health Research Center, University of Washington. *Changes in the Supply and Rural-Urban Distribution of Psychologists in the U.S., 2014–2021.* 2022. *https://familymedicine.uw.edu/rhrc/wp-content/uploads/sites/4/2022/10/RHRC_DBOCT2022_PSYCHOLOGIST_Andrilla.pdf.*

[562] Nuako, Akua, Jingxia Liu, Giang Pham, Nina Smock, Aimee James, Timothy Baker, Laura Bierut, Graham Colditz, and Li-Shiun Chen. 2022. ''Quantifying Rural Disparity in Healthcare Utilization in the United States: Analysis of a Large Midwestern Healthcare System.'' Edited by Nickolas D. Zaller. *PLOS ONE* 17 (2): e0263718. *https://doi.org/10.1371/journal.pone.0263718.*

[563] Arcury, Thomas A., John S. Preisser, Wilbert M. Gesler, and James M. Powers. 2005. ''Access to Transportation and Health Care Utilization in a Rural Region.'' *The Journal of Rural Health* 21 (1): 31–38. *https://doi.org/10.1111/j.1748-0361.2005.tb00059.x.*

[564] GAO, *Rural Hospital Closures,* GAO–21–93, (Washington, DC, 2020), *https://www.gao.gov/assets/gao-21-93.pdf.*

rates, and that some of this mistrust comes from a perception that the health care system prioritizes urban communities over rural communities.[565] Per the CDC, rural individuals are at greater risk of poor health outcomes as they tend to be older and sicker than urban individuals.[566] Finally, according to a CDC National Center for Health Statistics (NCHS) study, age-adjusted mortality rates are higher for rural individuals, with the mortality gap increasing since 1999 between rural and urban individuals.[567]

State-specific circumstances may affect the degree to which a State's population of individuals in rural areas meets the four criteria described in the proposed rule. A study found that 21 percent of adults without access to a vehicle or public transit reported skipping needed medical care compared to only 9 percent who did not own a vehicle but had access to public transit.[568] According to a Federal Highway Administration publication, just under 90 percent of passenger trips in rural areas occur in personal vehicles.[569] For the rural individuals who lack access to a personal vehicle, public transit is generally less available, with an approximate 40 percent of rural individuals living in an area without public transit.[570] However, some States establish rural public transit systems that guarantee service coverage to all residents.[571] This variation between States in their rural populations' access to public transit may suggest that the degree to which a State's rural population is able to access transportation to medical services may differ from State to State. There may also be significant variability between States with regards to health outcomes and mortality. For example, a CDC report found that the percentage of excess mortality from heart disease in rural counties varied significantly between States in the northeast and the south with a 13 percent excess rate for the northeast States and 56 percent for the southern States.[572] These differences between State populations of individuals in rural areas may suggest that the degree to which a State's rural population meets the four criteria may be variable.

This evidence indicates that an exception to the clinic services four walls requirement could be warranted, based on State-specific circumstances, for services furnished by clinics located in rural areas that are not RHCs, as these clinics might primarily serve a patient population that may be more likely than other groups to meet more of the four criteria we identified in the proposed rule. The evidence also suggests that this patient population is less likely to meet as many of the criteria as consistently nationwide as patients served by IHS/Tribal clinics. Under the proposal, a State could determine that individuals who reside in rural areas in that State should be engaged where they are located by personnel of a clinic located in a rural area, due to their challenges accessing behavioral health services, overall health care access challenges stemming from lack of transportation and distance from providers, historic mistrust of the health care system, and poor health outcomes. We note that clinics located in rural areas providing optional services as authorized under sections 1902(a)(10) and 1905(a)(9) of the Act and 42 CFR 440.90 are distinct from RHCs providing mandatory services as authorized under sections 1902(a)(10) and 1905(a)(2)(B) of the Act and 42 CFR 440.20(b). RHC services are a separate Medicaid benefit provided by a type of facility that is referenced in section 1905(a)(2)(B) of the Act and 42 CFR 440.20(b), and a four walls requirement does not apply to that benefit under Federal Medicaid law.

We considered proposing that, to qualify for the proposed exception, clinic services would have to be provided specifically to individuals who reside in rural areas, in addition to being provided by personnel of a clinic located in a rural area. However, we believe clinics located in rural areas can serve as a proxy for a population that generally consists of individuals who reside in rural areas, and that such a requirement would be too operationally burdensome. We recognize there may be circumstances in which a clinic located in a rural area furnishes services to an individual who does not reside in a rural area, but it is our understanding that clinics located in rural areas generally serve a patient population that consists primarily of individuals who reside in rural areas. Thus, these clinics can serve as a proxy for a patient population that is more likely to reside in a rural area—and thus, that includes people who are more likely to meet more of the four criteria. In addition, we believe that requiring clinics or States to verify that a clinic patient lives in a rural area, and to deny coverage of Medicaid clinic services provided outside the four walls if the patient does not, would be too operationally burdensome. For example, an individual's address might change frequently, an individual might refuse to provide their address, or the clinic might be located in a rural area that borders a non-rural area. Because we believe that clinics located in rural areas can serve as a proxy for individuals who reside in rural areas, and because we do not want to make this exception too operationally burdensome, we did not propose that to qualify for the proposed exception, clinic services must be provided by a clinic located in a rural area specifically to an individual who resides in a rural area.

We did not include a definition of ''rural'' in our proposed rule text, but we considered defining that term in the final rule and we considered various approaches to doing so, on which we sought comment. There are many Federal and State definitions of rural for various programs, and no single definition precisely identifies all rural areas. The Rural Health Information Hub provides a non-official tool that could be used to help identify if a specific location is considered a rural location based on various definitions.[573] Some rural definitions may categorize areas that are generally recognized as suburban as rural, while other

[565] Lister, Jamey J., and Paul J. Joudrey. 2022. ''Rural Mistrust of Public Health Interventions in the United States: A Call for Taking the Long View to Improve Adoption.'' *The Journal of Rural Health* 39 (1): 18–20. *https://doi.org/10.1111/jrh.12684.*

[566] CDC, ''About Rural Health,'' CDC, May 16, 2024, *https://www.cdc.gov/rural-health/php/about/?CDC_AAref_Val=https://www.cdc.gov/ruralhealth/about.html.*

[567] CDC, NCHS, *Trends in death rates in urban and rural areas: United States, 1999–2019,* by Sally C. Curtin and Merianne Rose Spencer, NCHS Data Brief No. 417, (Hyattsville, MD, 2021), *https://dx.doi.org/10.15620/cdc:109049.*

[568] Smith, Laura Berrie, Michael Karpman, Dulce Gonzalez, and Sarah Morriss, ''More than One in Five Adults with Limited Public Transit Access Forgo Health Care Because of Transportation Barriers,'' Robert Wood Johnson Foundation, April 26, 2023, *https://www.rwjf.org/en/insights/our-research/2023/04/more-than-one-in-five-adults-with-limited-public-transit-access-forgo-healthcare-because-of-transportation-barriers.html.*

[569] U.S. Department of Transportation (DOT), Federal Highway Administration (FHWA), *Chapter 11: Rural America, Status of the Nation's Highways, Bridges, and Transit Conditions and Performance Report,* 24th Edition (Washington, DC, 2021), *https://www.fhwa.dot.gov/policy/24cpr/pdf/Chapter11.pdf.*

[570] Id.

[571] Id.

[572] CDC, *Potentially Excess Deaths from the Five Leading Cause of Death in Metropolitan and Nonmetropolitan Counties—United States, 2010–2017,* by Macarena C. Garcia, Lauren M. Rossen, Brigham Bastian, Mark Faul, Nicole F. Dowling, Cheryll C. Thomas, Linda Schieb, Yuling Hong, Paula W. Yoon, and Michael F. Iademarco, Morbidity and Mortality Weekly Report Vol. 68, No. 10, (Atlanta, GA, 2019), *https://www.cdc.gov/mmwr/volumes/68/ss/pdfs/ss6810a1-H.pdf.*

[573] ''Am I Rural?—Tool,'' Rural Health Information Hub, accessed May 7, 2024, *https://www.ruralhealthinfo.org/am-i-rural.* This tool is not official and should not be relied upon as a formal Federal determination that a location is rural.

definitions may classify sparsely populated remote areas as urban. For example, the population residing in rural areas identified by a more limited rural definition may more closely meet more of the four criteria identified in the proposed rule than the population residing in rural areas identified under a broader definition. Definitions of rural adopted and used by Federal governmental agencies for programmatic purposes include the definition used by the Census Bureau, the definition used by the Office of Management and Budget (OMB), and the definition used by HRSA's Federal Office of Rural Health Policy (FORHP).[574] [575] In addition, we believe that State-level variations may also affect whether certain ways of defining rural are appropriate in specific States. States may have their own definitions of rural under State law or regulation for various programmatic purposes, such as definitions adopted by State primary care offices or State Offices of Rural Health.

Under any definition of rural, the specific areas identified as rural may change over time and that would have a direct impact on the scope of clinics eligible for this four walls exception. For example, areas identified as rural under the Census definition may change after the decennial census, which may result in some clinics no longer being located in rural areas under that updated definition.

We considered the following approaches to defining rural: adopting one of the commonly used definitions of rural adopted by the Federal governmental agencies referenced previously, permitting a State to adopt a definition of rural that is adopted and used by a Federal governmental agency for programmatic purposes, permitting a State to adopt a definition of rural that is adopted and used by a State governmental agency with a role in setting State rural health policy, or not adopting any definition of rural.

We note that the research, data, and reports cited earlier in this section do not all use the same definition of rural, and for four of the citations it is unclear what definition of rural was used. The SAMHSA data, the study on primary and specialty care utilization, and NCHS study use the OMB definition while the CDC health outcomes research uses the Census Bureau definition and the GAO report uses the FORHP definition of rural.

We explained that if we were to adopt a Federal definition, we would finalize in rulemaking that for the purposes of this exception rural is defined as the definition of rural adopted or used by the Census Bureau, OMB, or FORHP (we would adopt only one of these definitions). The benefits to adopting a Federal definition include that the definition would be consistent for all States electing to implement the exception and all clinics located in rural areas in such States. However, if we adopted a specific Federal definition of rural then States could not consider the variation in which their rural populations under different rural definitions meet the four criteria we describe in the proposed rule. In addition, CMS does not directly control any of these Federal definitions, so if we adopted a specific Federal definition then future rulemaking might be necessary to align our rule with another Federal agency's changes to that Federal definition.

The Census Bureau does not specifically define rural but considers any area that is not urban as rural. An urban area must meet certain density standards and contain at least 2,000 housing units or at least 5,000 people. There are 2,644 urban areas defined by the Census Bureau following the 2020 Census. Over 80 percent of the Census-defined urban areas (2,134 urban areas) have populations of less than 50,000 people while the remaining 19 percent (510 urban areas) have populations of 50,000 people or more.[576] Following the 2020 Census, the Census Bureau does not sub-categorize urban areas as Urbanized Areas or Urban Clusters.[577] If we adopted the Census Bureau definition, then we would finalize in rulemaking that a rural area is defined as an area identified by the Census Bureau in ''Urban Area Criteria for the 2020 Census-Final Criteria,'' 87 FR 16706, as not being an urban area. The advantage to the Census Bureau definition of rural is that it is a widely recognized definition, which may make it an easier definition to implement for purposes of an exception to the clinic services four walls requirement. A disadvantage to the Census Bureau definition is that the Census Bureau's urban area boundaries do not follow other administrative units, such as county or municipality borders, and may be complex to operationalize. The Census Bureau provides TIGERweb Decennial online mapping tools for urban area boundaries at *https://tigerweb.geo.census.gov/* that may be helpful for interested parties considering what it would have meant for CMS to finalize a rule that defines rural according to the U.S. Census Bureau's definition. The CDC research on health outcomes we cite elsewhere in this section used the Census Bureau definition, which demonstrates that this definition can be linked to the four criteria described in the proposed rule. However, the Census Bureau definition is broad, and some policy experts point out that the definition classifies many suburban areas as rural while also classifying towns and small cities with populations of less than 50,000 people as non-rural.[578]

OMB also does not specifically define rural, but designates areas as metropolitan, micropolitan, or neither (also known as noncore).[579] A metropolitan area consists of an urban core of 50,000 or more individuals, a micropolitan area consists of an urban core of 10,000 to 49,999 individuals, and all other areas are considered neither. Areas that are micropolitan or neither are considered rural while metropolitan areas are considered urban.[580] If we adopted the OMB definition, then we would finalize in regulation text that a rural area is defined as an area not identified as metropolitan by OMB, as described in ''2020 Standards for Delineating Core Based Statistical Areas,'' 86 FR 37770. Like the Census Bureau definition of rural, the OMB definition is a widely recognized definition that may be an easier definition to implement for purposes of an exception to the clinic services four walls requirement. For example, the study on primary and specialty care utilization and the NCHS study on mortality we cite elsewhere in this section use the OMB definition, which demonstrates that this definition

[574] HRSA, ''Defining Rural Population,'' Health Resources & Services Administration, January 2024, *https://www.hrsa.gov/rural-health/about-us/what-is-rural.*

[575] Response to Comments on Revised Geographic Eligibility for Federal Office of Rural Health Policy Grants, 86 FR 2418 (January 12, 2021). See, *https://www.federalregister.gov/documents/2021/01/12/2021-00443/response-to-comments-on-revised-geographic-eligibility-for-federal-office-of-rural-health-policy.*

[576] Census Bureau, ''Urban and Rural,'' United States Census Bureau, September 2023, *https://www.census.gov/programs-surveys/geography/guidance/geo-areas/urban-rural.html.*

[577] Urban Area Criteria for the 2020 Census-Final Criteria, 87 FR 16706 (Mar. 24, 2022). See, *https://www.federalregister.gov/documents/2022/03/24/2022-06180/urban-area-criteria-for-the-2020-census-final-criteria.*

[578] Revised Geographic Eligibility for Federal Office of Rural Health Policy Grants, 85 FR 59806 (Oct. 23, 2020). See, *https://www.federalregister.gov/documents/2020/09/23/2020-20971/revised-geographic-eligibility-for-federal-office-of-rural-health-policy-grants.*

[579] 2020 Standards for Delineating Core Based Statistical Areas, 86 FR 37770 (July 16, 2021). See, *https://www.federalregister.gov/documents/2021/07/16/2021-15159/2020-standards-for-delineating-core-based-statistical-areas.*

[580] HRSA, Defining Rural Population.

can be linked to the four criteria described in the proposed rule. In addition, the NCHS Urban-Rural Classification Scheme for Counties follows the OMB definition of rural and is widely used in health research.[581] However, the OMB definition is considered by some policy experts to be too narrow as areas OMB defines as metropolitan include areas that are often considered to be rural, like for example the Grand Canyon.[582]

The last Federal definition of rural we considered was the FORHP definition, which consists of all non-metropolitan counties, all metropolitan census tracts with Rural-Urban Commuting Area (RUCA) codes four through ten, large area census tracts of at least 400 square miles in area with population density of 35 or less per square mile with RUCA codes two to three, and all outlying metropolitan counties without an Urbanized Area.[583] [584] If we adopted the FORHP definition, then we would finalize in regulation text that a rural area is defined as an area identified as rural by FORHP, as described in ''Response to Comments on Revised Geographic Eligibility for Federal Office of Rural Health Policy Grants,'' 86 FR 2418. We recognized that the FORHP definition uses terminology that has not yet been updated to align with the latest Census Bureau terminology, that is, FORHP currently refers to urbanized area, but we still considered the FORHP definition, as is, based on its wide use and the benefits described in this paragraph. We noted that FORHP is proposing to update the FORHP definition to incorporate the U.S. Department of Agriculture's Economic Research Service (ERS) Road Ruggedness Scale (RRS) measure of rugged terrain into the existing definition, specifically for census tracts of at least 20 square miles in area in metro counties with RRS 5 and RUCA code 2 or 3. In addition, if finalized, the update would have aligned the FORHP definition's use of Census Bureau terminology with the current Census Bureau definition.[585] [586] We explained that if the proposed update to the FORHP definition were finalized, we would then consider the updated FORHP definition for the final rule over the existing FORHP definition. The advantage to the FORHP definition is that it is more precise, as it is narrower than the Census Bureau definition and broader than the OMB definition. In addition, as described elsewhere in this section, the GAO report that identified rural individuals needing to travel 40 miles on average to access specialty care used the FORHP definition in effect at the time of the report, which demonstrates that this definition can be linked to the four criteria we describe in the proposed rule. However, some have criticized the FORHP definition for excluding some areas that used to be considered rural while others consider the definition to be too expansive.[587]

Instead of specifying a uniform definition of rural nationwide for this exception, we also considered allowing States to adopt a definition of rural that has been adopted by a Federal governmental agency. If we permitted States to adopt a definition of rural that is adopted by a Federal governmental agency for programmatic purposes, then we would finalize in regulation text that a rural area is defined by the State based upon a reasonable definition adopted by a Federal governmental agency for programmatic purposes. We would not specifically list out the Federal definitions of rural that we consider reasonable in the regulation text. In addition to the Census, OMB, and FORHP definitions, we would consider rural definitions developed by the U.S. Department of Agriculture's Economic Research Service (ERS) to be reasonable definitions for a State to select if we adopted this option in the final rule (this would include RUCAs, Rural-Urban Continuum Codes, Urban-Influence Codes, and Frontier and Remote Area Codes).[588] We did not consider adopting any of the ERS definitions as one of the Federal definitions we considered (as described previously) because it is our understanding that the ERS definitions are less commonly used on their own (that is, not in conjunction with other Federal definitions) in identifying rural areas in health care. However, the ERS definitions could be used by States if we opted to permit States to identify a Federal definition. While we do not believe that any of the ERS definitions should be adopted as one definition for all States to follow, if we provided States with the flexibility to adopt a Federal definition, then we wanted to ensure that we are not too prescriptive in the definitions they may choose from. It is possible that a State could determine that one of the ERS definitions better captures the population of rural individuals that meets the four criteria described in the proposed rule. Under such an approach, States that elect this exception would identify the specific Federal definition of rural (that is, Census Bureau, OMB, FORHP definition, or one of the ERS definitions) they are adopting in their State plan and attest that the selected definition best captures the population of rural individuals that meets more of the four criteria described in the proposal. The benefits to this approach include that each State can consider which Federal definition of rural best captures the population of rural individuals that meet more of the four criteria described in the proposed rule for that State (and States would attest to this in their State plan), while also being required to adopt a rural definition commonly accepted as a legitimate definition for programmatic purposes at the national level. Requiring the State to attest that the selected Federal definition best captures the population of rural individuals that meets more of the four criteria would help to ensure that there is an explanation for any variations in the definitions selected by different States. However, even if the variations in the definitions chosen by different States can be explained, it might burden or cause confusion for some beneficiaries if the States that elect this exception have different definitions of rural. For example, a beneficiary that moves from a State that has adopted this exception with a broader definition of rural to another State that has adopted the exception but has a narrower definition of rural might lose access to clinic services provided outside of the four walls. In addition, if we finalized the proposal, clinics that operate in different States that have adopted this exception might find it confusing or burdensome to track each such State's definition of rural.

If we permitted States to adopt a definition of rural that is adopted by a State governmental agency with a role

[581] CDC, NCHS, ''NCHS Urban-Rural Classification Scheme for Counties,'' CDC, June 1, 2017, *https://www.cdc.gov/nchs/data-analysis-tools/urban-rural.html?CDC_AAref_Val=https://www.cdc.gov/nchs/data_access/urban_rural.htm.*

[582] Revised Geographic Eligibility for Federal Office of Rural Health Policy Grants, 85 FR 59806 (Oct. 23, 2020).

[583] Response to Comments on Revised Geographic Eligibility for Federal Office of Rural Health Policy Grants, 86 FR 2418 (January 12, 2021).

[584] HRSA, Defining Rural Population.

[585] Proposed Inclusion of Terrain Factors in the Definition of Rural Area for Federal Office of Rural Health Policy Grants, 89 FR 32451 (April 26, 2024). See, *https://www.federalregister.gov/documents/2024/04/26/2024-08931/proposed-inclusion-of-terrain-factors-in-the-definition-of-rural-area-for-federal-office-of-rural.*

[586] As of November 27, 2024, HRSA has not finalized these proposed changes to FORHP's definition of rural.

[587] Response to Comments on Revised Geographic Eligibility for Federal Office of Rural Health Policy Grants, 86 FR 2418 (January 12, 2021).

[588] U.S. Department of Agriculture (USDA), Economic Research Services (ERS), ''Rural Classifications,'' USDA, September 8, 2023, *https://www.ers.usda.gov/topics/rural-economy-population/rural-classifications/.*

in setting State rural health policy, then we would finalize in regulation text that a rural area is defined by the State based upon a rural definition adopted by a State governmental agency with a role in setting State rural health policy. Under such an approach, a State that elects this exception would describe in its State plan the specific definition of rural that it is adopting, attest that this definition has been adopted by a State governmental agency with a role in setting State rural health policy (such as a State primary care office or State Office of Rural Health), and attest that the selected definition best captures the population of rural individuals that meets more of the four criteria described in the proposal. The benefits to this approach include that States may consider a State definition of rural that best identifies the population of rural individuals that meet more of the four criteria described in the proposed rule, and attest to in their State plan that the definition does so. Requiring the State to attest that the selected definition best captures the population of rural individuals that meets more of the four criteria would help to ensure that there is an explanation for any variations in the definitions selected by different States. In addition, under this approach to defining rural, the State would adopt a rural definition commonly accepted and used to manage State programs, which thus may be a more familiar definition to providers and be easier for a State to implement since that definition is also used for other health policy purposes in that State. However, even if the variations in the definitions chosen by different States can be explained, it might burden or cause confusion for some beneficiaries if the States that elect this exception have different definitions of rural. For example, a beneficiary that moves from a State that has adopted this exception with a broader definition of rural to another State that has adopted the exception but has a narrower definition of rural may lose access to clinic services provided outside of the four walls. In addition, if we finalized the proposal, clinics that operate in different States that have adopted this exception might find it confusing or burdensome to track each such State's definition of rural.

Finally, we explained that if we chose not to define rural in the final rule, then we would finalize proposed regulation text with no definition of rural. Under this approach, a State that elects this exception would choose any definition of rural that can be linked to the four criteria we describe in the proposed rule and meets its program needs, but would not identify the definition in the State plan or submit it to CMS for review and approval. We would require and finalize in rule text that the State would publish its rural definition on a website maintained by the State that is accessible to the public. The benefits to not adopting a definition of rural under the final rule would include that States can consider which definition of rural best captures the population of rural individuals that meets more of the four criteria described in the proposed rule. This approach also recognizes that States may have the best information and data to determine the definition of rural that best meets their operational needs. However, under this approach CMS would not be reviewing State definitions of rural, and a State might adopt a definition of rural that could be considered to be overly broad or overly narrow. For example, a State might adopt a definition of rural that encompasses large urban areas, such as a populous city. As we stated in the proposed rule, we are aware that there are many definitions of rural, so the other approaches we considered could potentially leave out reasonable definitions of rural, although we are not currently aware of any such reasonable definitions. In our proposed rule, we invited comment on which approach to defining rural we should adopt if the rule were finalized.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Most commenters expressed support for our proposed exception to the Medicaid clinic services benefit four walls requirement for clinics located in rural areas at § 440.90(e). Many commenters indicated that rural areas are experiencing provider shortages and that an exception to the four walls requirement for clinics located in rural areas would improve access to care for individuals in rural areas. Several commenters noted that in rural areas experiencing provider shortages individuals often have to travel long distances to receive services, and that initiatives aimed at meeting individuals in rural areas where they are located have found success in improving access to care. In addition, a few commenters noted that an exception to the four walls requirement for clinics located in rural areas could alleviate transportation barriers, reduce missed appointments, and lead to more timely care.

Response: We appreciate the comments in support of our proposed exception to the Medicaid clinic services benefit four walls requirement for clinics located in rural areas. We agree that this exception may improve access to care for the population served by clinics located in rural areas.

Comment: Many commenters agreed with CMS that the rural population meets more of the four criteria we described in the proposed rule than other groups that are not the focus of an exception in this rulemaking and that an exception to the four walls requirement is justified for clinics located in rural areas.

Response: We appreciate the comments in support of the evidence we presented that the rural population meets more of the four criteria we described in the proposed rule than other groups that are not the focus of an exception in this rulemaking and that an exception to the four walls requirement is justified for clinics located in rural areas.

Comment: Two commenters recommended that CMS implement the proposed exception at § 440.90(e) at the beneficiary level (in addition to the clinic level) to ensure that the entire rural population that meets the four criteria we described in the proposed rule is able to access clinic services outside the four walls.

Response: We understand the commenters to be recommending application of this exception to any Medicaid beneficiary who resides in a rural area, regardless of the type of clinic. We thank the commenters for their recommendation that we implement the proposed exception at § 440.90(e) at the beneficiary level (in addition to the clinic level) to ensure that the entire rural population that meets the four criteria we described in the proposed rule is able to access clinic services outside the four walls; however, we will not be making changes in the final rule to allow States to apply the exception at § 440.90(e) at the beneficiary level. As we noted in section XVIII.B of the proposed rule (89 FR 59186), clinics located in rural areas can serve as a proxy for a patient population that is more likely to live in a rural area—and thus, that includes people who are more likely to meet more of the four criteria we described in the proposed rule. In addition, we believe that requiring clinics or States to verify that a clinic patient lives in a rural area and to deny coverage of Medicaid clinic services provided outside the four walls if the patient does not, would be too operationally burdensome.

Comment: Many commenters recommended that CMS not adopt a definition of rural at § 440.90(e) in the final rule in response to CMS's

solicitation of comments on the best approach to defining rural in the final rule. However, many other commenters recommended that CMS allow States to choose any State or Federal definition of rural. These commenters believed States were best equipped to determine the extent to which a specific definition best captures the rural population that meet the four criteria we described in the proposed rule and that this would recognize each States' unique geographic needs. Several of these commenters expressed concerns that if CMS were to adopt a Federal definition of rural, that this would create a one-size-fits-all approach that would create barriers for beneficiaries and providers. A few of the commenters indicated that in other instances where a Federal program adopted a single definition of rural that it created barriers and hardships for them by not recognizing their States' unique geographic differences. Finally, one commenter explained that under some of the Federal definitions of rural a small city with no access to roads and that is surrounded by rural areas was classified as urban.

Three commenters recommended that CMS define rural with a definition that is adopted and used by a Federal governmental agency for programmatic purposes. One of the two commenters recommended CMS adopt the Census definition of rural in the final rule, as they believed the Census definition is the broadest definition, and that CMS should adopt a definition of rural that is applied consistently. Another commenter recommended that CMS adopt the FORHP definition of rural, as they believed this definition best captures the rural populations that meet the four criteria we described in the proposed rule. Finally, the third commenter recommended that CMS adopt a Federal definition of rural, although they did not specify which definition, as they were concerned that if a State adopted a definition of rural that it might adopt a definition of rural that arbitrarily excludes certain clinics.

Another commenter recommended CMS adopt a definition of rural that is adopted by a State governmental agency with a role in setting rural health policy.

Finally, one commenter, in addition to recommending that CMS adopt a broad definition of rural, recommended that any clinic that furnishes services to individuals in rural areas under a range of definitions be allowed to qualify for the exception.

Response: We thank the commenters for sharing their recommendations on how we should approach defining rural in the final rule. As we noted in section XVIII.B of the proposed rule (89 FR 59186), there are many Federal and State definitions of rural for various programs, no single definition precisely identifies all rural areas, and different definitions might more accurately target a population meeting more of the criteria described in the proposed rule in different States. Some rural definitions may categorize areas that are generally recognized as suburban as rural, while other definitions may classify sparsely populated remote areas as urban. We believe that State-level variations may also affect whether certain ways of defining rural are appropriate in specific States. Further, under any definition of rural, the specific areas identified as rural may change over time and that would have a direct impact on the scope of clinics eligible for our proposed four walls exception.

We solicited comments on the following approaches to defining rural in the final rule: adopting one of the commonly used definitions of rural adopted by the Federal governmental agencies referenced previously, permitting a State to adopt a definition of rural that is adopted and used by a Federal governmental agency for programmatic purposes, permitting a State to adopt a definition of rural that is adopted and used by a State governmental agency with a role in setting State rural health policy, or not adopting any definition of rural. We appreciate all the different perspectives that commenters shared with us. We note, however, that the overwhelming majority of commenters recommended that CMS either not adopt a definition of rural or allow States to choose either a State or Federal definition of rural that best captures the rural population that meets the four criteria we described in the proposed rule.

Taking these comments into account, we believe that the best approach is to permit States to choose either a State or Federal definition of rural that best captures the State's rural population that meets the four criteria. Specifically, under the final rule, States implementing the exception must include in their State plans a definition of rural area. This definition must be either a definition adopted and used by a Federal governmental agency for programmatic purposes, or a definition adopted by a State governmental agency with a role in setting State rural health policy. As part of their State plan submission, States will need to attest that the selected definition falls into one of the two described categories and that it best captures the population of rural individuals that meets more of the four criteria described in this final rule. This approach gives States the flexibility to choose a definition that best targets the exception to a rural population that meets more of the four criteria we describe in this final rule. It also helps to ensure that States are using a definition that is commonly accepted and used in relevant contexts and generally accepted as a legitimate definition. States will be more likely to adopt a definition that may be more familiar to providers and be easier for a State to implement, since these definitions are also used for other purposes. We also agree with the concerns that commenters raised about how adopting a single Federal definition of rural could create barriers for beneficiaries and providers. This approach also recognizes that States may have the best information and data to determine the definition of rural that best meets the goals identified in the final rule, as well as the definition that best meets their operational needs. If, as some commenters requested, we instead finalized a Federal definition of rural that would apply in every State opting to implement this exception, that would not have accounted for State-specific variations in the degree to which different definitions might be better at targeting rural populations that meet more of the four criteria identified in the proposed rule in different States. Finally, because the definition will be identified in the State plan, it will be changed through the State plan amendment process, which gives CMS and the public notice of the change.

In the proposed rule, we did not include among the discussed options for defining rural an option under which any clinic that furnishes services to individuals in rural areas under a range of definitions would qualify for the exception, and are thus not including such an approach in this final rule. It is not clear to us how such an approach would effectively target a population that meets more of the criteria described in the proposed rule. Under the approach we are finalizing, in contrast, States will attest that the Federal or State definition of rural area that they are adopting best captures the population of rural individuals that meets more of the four criteria we described in the proposed rule.

After consideration of the public comments we received, we are finalizing an exception to the Medicaid clinic services four walls requirement at § 440.90(e) for clinics located in rural areas, with a modification that a State must include a definition of rural area in its State plan that must be either a definition adopted and used by a

Federal governmental agency for programmatic purposes, or a definition adopted by a State governmental agency with a role in setting State rural health policy.

6. Additional Four Walls Considerations

We proposed that the proposed exception to the four walls requirement for IHS/Tribal clinics would be a mandatory component of the clinic services benefit for States electing to cover that benefit. We proposed that the proposed exceptions for behavioral health clinics and clinics located in rural areas would be optional for States covering that benefit. In addition, we proposed to codify in regulation text our longstanding interpretation (discussed in section XVIII.A of the proposed rule) that existing § 440.90(a) and (b) are mandatory components of the clinic services benefit for States that elect to cover that benefit. Finally, we proposed to delete the word ''eligible'' from existing regulation text at § 440.90(b) because there is no Federal authority for States to provide Medicaid-covered services to individuals who are ineligible for Medicaid, so we believe it is unnecessary to specify that the individuals who would receive services under this exception are eligible.

We proposed to make the exception for IHS/Tribal clinics mandatory because the population served by IHS/Tribal clinics more consistently meets the four criteria described previously, both within and across States, than the populations targeted by the optional exceptions, especially given the degree of State variability in whether the populations targeted by the optional exceptions meet those criteria. Further, Medicaid is the largest source of third-party payment for services billed by IHS facilities, accounting for nearly two-thirds of health coverage payments to these facilities.[589] Given the significant role of Medicaid as a payer for IHS/Tribal clinic services, any reduction in the Medicaid payments IHS/Tribal clinics receive for services (such as a reduction in payment from the AIR to a professional services rate for services furnished outside the four walls by the clinic) might uniquely burden IHS/Tribal clinics. These clinics might need to curtail their available services, or no longer provide services outside the four walls, which could significantly impede their ability to serve their patients. For these reasons, we proposed a mandatory exception to the clinic services four walls requirement for IHS/Tribal clinics.

In contrast to the exception for IHS/Tribal clinics, we believe that the exceptions for behavioral health clinics and clinics located in rural areas should be optional because there may be geographic variability in the degree to which the populations served by these clinics meet the four criteria we described previously, and thus there may be State-specific variation in the degree to which these populations have the four characteristics described in the proposed rule. For example, the populations served by behavioral health clinics and clinics located in rural areas may not as consistently face transportation challenges nationwide, to the extent that Tribal populations do. In addition, it is our understanding that Medicaid funding is less often the largest source of payment for behavioral health clinics and clinics located in rural areas, compared to IHS/Tribal clinics. We believe it best to let each State assess the degree to which these two exceptions might be warranted based on the State's specific circumstances. In making this assessment, each State should consider the degree to which individuals located in rural areas of the State and/or individuals with behavioral health disorders in the State meet the four criteria described in the proposed rule. We solicited comment on the arguments made in the CY 2025 OPPS/ASC proposed rule in support of the mandatory and optional exceptions, and on whether the optional exceptions should also be mandatory for States opting to cover the clinic services benefit.

We explained that if we finalized the exceptions as proposed, then upon the effective date of the final rule, services qualifying for the exception for IHS/Tribal clinics must be paid for as Medicaid clinic services in States that opt to cover that benefit. Accordingly, we would require States that cover the clinic services benefit to submit a State plan amendment (SPA), as applicable, to attest to coverage of IHS/Tribal clinic services under the exception. Similarly, we explained that if we finalized the proposed rule as proposed, then no earlier than the effective date of a SPA or SPAs implementing one or both of the optional exceptions, services provided outside the four walls under the exceptions may be paid for as Medicaid clinic services. Under any of the exceptions, the excepted services could be paid for using a facility-based Medicaid clinic services payment methodology, which for most IHS/Tribal clinics is the AIR.

We did not propose any additional exceptions to the clinic services four walls requirement. It is our understanding that other populations are better able than those targeted by the proposed exceptions to access services through Medicaid benefits to which a four walls requirement does not apply under Federal Medicaid law (for example, FQHC services, RHC services, outpatient hospital services, etc.). As described in the proposed rule, States have considerable discretion regarding the types of clinics they opt to cover under the clinic services benefit. There are no specific Federal Medicaid credentialling requirements, such as licensure or certification, for providers of the Medicaid clinic services benefit like there are for other Medicaid facility State plan benefits, such as hospitals and nursing facilities. This leads to considerable variability in the types of clinics providing services that a State may cover under the clinic services benefit. We invited comment on whether there are additional populations that are likely to meet the four criteria described in the CY 2025 OPPS/ASC proposed rule and that have no alternative access to services through Medicaid benefits not subject to a four walls requirement under Federal Medicaid law, and on whether there are additional types of clinics that might serve as a proxy for such a population.

We did not receive any comments on our proposal to codify in regulation text our longstanding interpretation that existing § 440.90(a) and (b) are mandatory components of the clinic services benefit for States that elect to cover that benefit or on our proposal to delete the word ''eligible'' from existing regulation text at § 440.90(b). We received public comments on the following proposals: that the exception to the four walls requirement for IHS/Tribal clinics would be a mandatory component of the clinic services benefit for States electing to cover that benefit; that the exceptions for behavioral health clinics and clinics located in rural areas would be optional for States covering that benefit; and that we would not propose any additional exceptions to the clinic services four walls requirement. The following is a summary of the comments we received and our responses.

Comment: Most commenters expressed support for CMS's proposal at § 440.90 to make the IHS/Tribal clinic four walls exception mandatory for States that cover the clinic services benefit. In addition, many commenters supported CMS's proposal at § 440.90

[589] Assistant Secretary of Planning and Evaluation (ASPE), *How Increased Funding Can Advance the Mission of the Indian Health Service to Improve Health Outcomes for American Indians and Alaska Natives,* Report No. HP–2022–21, (Washington, DC, 2022), *https://aspe.hhs.gov/sites/default/files/documents/e7b3d02affdda1949c215f57b65b5541/aspe-ihs-funding-disparities-report.pdf.*

for the exceptions to the four walls requirement for behavioral health clinics at § 440.90(d) and clinics located in rural areas at § 440.90(e) to be at State option. Commenters noted that this would allow States to meet each State's unique populations, provider landscape, and program needs. A few commenters noted that States are in the best position to assess the extent to which their behavioral health and rural populations meet the four criteria we described in the proposed rule. In addition, one commenter noted that behavioral health services can be covered under several benefit categories under section 1905(a) of the Act; and that CMS's proposal that an exception for behavioral health clinics at § 440.90(d) be at State option would allow States to cover behavioral health services in a tailored way to recognize the unique needs of each States' behavioral health population.

However, many commenters also urged CMS to make the exception for behavioral health clinics at § 440.90(d) mandatory rather than optional for States that cover the clinic services benefit. The commenters explained that making the exception to the four walls requirement for behavioral health clinics mandatory would make services more accessible, strengthen States' behavioral health workforces, and more effectively enable providers to meet individuals where they are in need. Several commenters noted that the behavioral health provider shortage is at a crisis point nationally and therefore, an exception to the four walls requirement for behavioral health clinics should be mandatory.

Finally, two commenters recommended that CMS amend § 440.90 to make the exception for clinics located in rural areas at § 440.90(e) mandatory for States that cover the clinic services benefit. The commenters indicated that individuals in rural areas experience barriers in accessing health care within and across States, and they disagreed that there was State variation.

Response: We thank the commenters for their support for our proposal at § 440.90 to make the IHS/Tribal clinic four walls exception mandatory for States that cover the clinic services benefit. In addition, we thank the commenters who shared their recommendations on whether the exceptions for behavioral health clinics and clinics located in rural areas should be at State option or mandatory.

As we noted in section XVIII.B of the proposed rule (89 FR 59186), our proposal to make the IHS/Tribal clinic four walls exception mandatory and the exceptions for behavioral health clinics and clinics located in rural areas optional was based on the population served by IHS/Tribal clinics more consistently meeting the four criteria described in the proposed rule, both within and across States, than the populations served by behavioral health clinics or clinics located in rural areas. We indicated that this is especially true given the degree of State variability in whether the populations served by behavioral health clinics or clinics located in rural areas meet those criteria. Medicaid is the largest source of third-party payment for services billed by IHS/Tribal facilities; it is our understanding that Medicaid funding is less often the largest source of payment for behavioral health clinics and clinics located in rural areas compared to IHS/Tribal clinics.

While we appreciate the evidence and information that some commenters shared that there is a national behavioral health provider shortage and that a mandatory exception to the four walls requirement for behavioral health clinics could make services more accessible, strengthen States' behavioral health workforces, and more effectively enable providers to meet individuals where they are in need, we do not believe that the evidence or information included in some public comments contradicts our assumptions described in the preceding paragraph. The evidence and information shared by the commenters did not contradict our understanding that the population served by IHS/Tribal clinics more consistently meets the four criteria described in the proposed rule, that there is considerable State variability in the degree to which the behavioral health population meets the four criteria, and that Medicaid is less often the largest source of payment for behavioral health clinics than for IHS/Tribal clinics. The commenters supporting a mandatory exception to the four walls requirement for clinics located in rural areas did not share any data or evidence in support of their recommendation. We continue to believe, based on the information available to us, that the assumptions we describe in the preceding paragraph are accurate. We are therefore finalizing our proposal at § 440.90 to make the IHS/Tribal clinic four walls exception mandatory and the exceptions for behavioral health clinics and clinics located in rural areas at State option for States that cover the clinic services benefit.

Comment: Many commenters recommended CMS consider additional exceptions to the four walls requirement at § 440.90 in response to CMS's solicitation of comments on whether there are additional populations that are likely to meet the four criteria described in the proposed rule and that have no alternative access to services through Medicaid benefits not subject to a four walls requirement under Federal Medicaid law, and on whether there are additional types of clinics that might serve as a proxy for such a population. Most of the commenters that recommended additional exceptions to the four walls requirement at § 440.90 indicated that CMS's current interpretation of how the four walls requirement applies to Medicaid clinic services delivered via telehealth creates access to care issues for these populations.

Most of the commenters recommending that CMS include additional exceptions to the four walls requirement at § 440.90 advocated for exceptions for underserved and high-risk populations including racial and ethnic minorities, individuals with disabilities, LGBTQ+ individuals, low-income individuals, women, and individuals who are elderly; the commenters indicated they believed that these populations also meet the four criteria described in the proposed rule. A few commenters noted that transportation and access to care issues are also experienced in suburban and urban areas and that the populations served by clinics in these areas may also benefit from an exception from the four walls requirement.

One commenter recommended additional exceptions for specific types of services including maternity care, behavioral health care, urgent care, and emergency care, regardless of the type of clinic or population.

A few commenters requested that CMS include additional exceptions in the final rule for populations served by specific types of clinics. One commenter requested that CMS include an exception for school-based services that are covered in Medicaid as clinic services. Another commenter requested that CMS include a mandatory exception for essential community providers that operate as clinics and furnish services to underserved populations; the commenter indicated that they believe these underserved populations meet the four criteria described in the proposed rule, are more likely to meet the four criteria than other populations, and that Medicaid is a significant payer for essential community providers. A commenter requested that CMS include an additional exception to the four walls for clinics that are grandfathered by section 6411(g) of the Omnibus Budget Reconciliation Act of 1989 to provide

habilitation services under the clinic services benefit, to help individuals in hard-to-serve areas.

Finally, two commenters recommended an additional exception to the four walls requirement for UIOs and indicated they believe the population served by UIOs meets the four criteria described in the proposed rule. One of the commenters agreed with CMS's understanding that most UIOs participate in Medicaid as FQHCs while the other commenter disagreed with CMS and indicated that most UIOs do not participate in Medicaid as FQHCs.

Response: We thank the commenters that shared their recommendations for additional exceptions to the clinic services benefit four walls requirement at § 440.90 and acknowledge the concerns commenters raised regarding our current interpretation of how the four walls requirement applies to Medicaid clinic services delivered via telehealth. We also thank the commenters that took the time to describe why they believe additional exceptions may be warranted based on the four criteria described in the proposed rule.

As we noted in section XVIII.B of the proposed rule (89 FR 59186), it was our understanding that other populations are better able than those targeted by the proposed exceptions to access services through Medicaid benefits to which a four walls requirement does not apply under Federal Medicaid law (for example, FQHC services, RHC services, outpatient hospital services, etc.). We invited comment on whether there are additional populations that are likely to meet the four criteria described in the proposed rule and that have no alternative access to services through Medicaid benefits not subject to a four walls requirement under Federal Medicaid law, and on whether there are additional types of clinics that might serve as a proxy for such a population.

At this time, we believe that including additional exceptions to the four walls requirement would require additional consideration and discussion with the public beyond what could be finalized in this current rule. We will take these recommendations into consideration when determining whether possible future rulemaking on additional exceptions to the four walls requirement is warranted. We continue to believe that most UIOs participate in Medicaid as FQHCs, based on the information available to us, including the information shared by the two commenters. Finally, we will take these comments into consideration as we contemplate issuing sub-regulatory guidance regarding our interpretation of how the four walls requirement applies when Medicaid clinic services are delivered via telehealth.

After consideration of the public comments we received, we are finalizing, without modification, our proposals at § 440.90 that the exception to the four walls requirement for IHS/Tribal clinics would be a mandatory component of the clinic services benefit for States electing to cover that benefit, and that the exceptions for behavioral health clinics and clinics located in rural areas would be optional for States covering that benefit. In addition, we are finalizing that the existing regulation text at § 440.90(a) and (b) are mandatory components of the clinic services benefit for States that elect to cover that benefit and the deletion of the word ''eligible'' from existing regulation text at § 440.90(b).

XIX. Changes to the Review Timeframes for the Hospital Outpatient Department (OPD) Prior Authorization Process

The CMS Interoperability and Prior Authorization final rule (89 FR 8758) (Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program) creates, improves, or shortens prior authorization timeframes for certain payers such as Medicare Advantage organizations and applicable integrated plans, CHIP FFS programs, Medicaid managed care plans, and CHIP managed care entities to respond to prior authorization requests for covered items and services, excluding drugs (89 FR 8878). The final rule requires impacted payers (excluding Qualified Health Plan issuers on the Federally-Facilitated Exchanges) to send prior authorization decisions as expeditiously as the enrollee's health condition requires or as the beneficiary's health condition requires but no later than 72 hours for expedited (that is, urgent) requests and 7-calendar days for standard (that is, non-urgent) requests.

As part of the CY 2020 OPPS/ASC final rule with comment period (84 FR 61446 through 61456), CMS established a nationwide prior authorization process and requirements for certain OPD services. OPD providers must submit to the Medicare Administrative Contractor (MAC) a prior authorization request for any service on the list of outpatient department services that require prior authorization. CMS currently requires prior authorization for the following services: blepharoplasty, rhinoplasty, botulinum toxin injections, panniculectomy, vein ablation, cervical fusion with disc removal, implanted spinal neurostimulators, and facet joint interventions. Upon receipt of the prior authorization request, the MAC should review it and issue a decision within specific timeframes, which are listed in the regulation text at § 419.82(d)(1)(iii) and (d)(2). These timeframes ensure providers receive timely responses and beneficiaries get appropriate care.

While Medicare FFS is not an impacted payer under the CMS Interoperability and Prior Authorization final rule, we proposed to align our Medicare FFS prior authorization review timeframe for standard review requests for hospital outpatient department services with the timeframe in this final rule. This change would not only streamline the prior authorization processes so that they are the same across payers but would also help to reduce provider burden by having the same timeframe and reducing the potential for delays in care by decreasing the time beneficiaries and providers wait for prior authorization decisions on standard requests in FFS Medicare. We proposed to change the current review timeframe for provisionally affirmed or non-affirmed standard review requests for these services from 10-business days to 7-calendar days in § 419.82(d)(1)(iii). For example, if a standard request is submitted on a Tuesday, June 2, under the new timeframe, a decision must be rendered by the next Monday, June 8, whereas under the old timeframe, the decision must be rendered by Monday, June 15.

We are still considering the impact of aligning our expedited review decision timeframe with the expedited review decision timeframe in the CMS Interoperability and Prior Authorization final rule because, depending on when the expedited request is submitted, it may take longer for OPD provider to receive a decision using the 72-hour timeframe than our current expedited timeframe of 2-business days. The goal of changing the standard review timeframe is not only to align the timeframe across the prior authorization programs but also to reduce the time

beneficiaries wait to access the care they need. Since changing the expedited review decision timeframe from 2-business days to 72 hours would not reduce beneficiaries' wait time in all circumstances, we did not propose to conform that timeframe with the one in the CMS Interoperability and Prior Authorization final rule at this time, but we may address this issue in future rulemaking.

We received 94 comments on the proposal, including comments from healthcare providers, professional, and trade organizations. The following is a summary of the comments we received and our responses.

Comment: We received comments in support of aligning the prior authorization review timeframe for the standard review requests with the timeframe in the Interoperability and Prior Authorization final rule.

Response: We appreciate the positive responses. This change would not only streamline the prior authorization standard timeframe so that it is the same across payers but would also help to reduce provider burden and beneficiaries' waiting time to receive care in FFS Medicare.

Comment: We received comments requesting that the standard timeframe and expedited timeframe be shorter than what we proposed. Another commenter asked CMS to clarify specific scenarios where it may take longer for an HOPD provider to receive an expedited decision using the CMS Interoperability and Prior Authorization final rule's 72-hour timeframe versus the current two-business day timeframe. Additionally, a commenter requested that CMS address prior authorization requests that occur immediately preceding a holiday or weekend.

Response: We thank the commenters for the feedback. As noted above, our proposed change to the standard timeframe aligns with the timeframe regulated in the CMS Interoperability and Prior Authorization final rule, and we believe that the 7-day timeframe for obtaining a decision on a prior authorization request is reasonable, considering that these are non-emergency procedures that typically require the beneficiary to undergo conservative treatment prior to the procedure. Changing the expedited review decision timeframe from 2-business days to 72 hours would not reduce beneficiaries' wait time in all circumstances. If an expedited request is submitted on Monday, August 5, at 8 a.m., under a 72-hour timeframe, a decision must be rendered by 8 a.m. on Thursday, August 8, whereas under the current timeframe of two business days, the decision must be rendered by the end of the business day on Tuesday, August 6. In contrast, when Monday is a Federal holiday and an expedited request is submitted on Saturday, August 10, at 8 a.m., under a 72-hour timeframe, the decision must be rendered by 8 a.m. on Tuesday, August 13, whereas under the current timeframe of 2-business days, the decision must be rendered by Wednesday, August 14. Our decision not to propose changes to the current timeframe for expedited requests was based on our recognition that a change to 72-hours will not always benefit beneficiaries.

Comment: Several commenters suggested that ''gold carding'' be approved for providers that have a history of prior authorization approval. We also received comments from mental health organizations concerning prior authorization requirements for mental health and substance use services, specifically that their comprehensive treatment plan is more restrictive and complex compared to the assessment for medical-surgical healthcare services. These commenters suggested updating comprehensive treatment plans that would help to improve beneficiary access to services.

Response: Thank you for the comment. We note that under the regulation at 42 CFR 419.83(c), we may elect to exempt a provider from the prior authorization process upon the providers' demonstration of compliance with Medicare coverage, coding, and payment rules. This exemption would remain in effect until we elect to withdraw the exemption. Providers who are exempt do not need to submit prior authorization requests. Additionally, mental health and substance use services do not require prior authorization under Medicare FFS. Also, and as we noted above, our prior authorization policy does not create any new documentation requirements.

Comment: Some commenters suggested that we remove implanted spinal neurostimulators and facet joint interventions from OPD prior authorization as they are contrary to efforts to promote non-opioid alternatives to pain management. One commenter stated that trends showed that utilization for facet joint interventions was decreasing without need for prior authorization requirements.

Response: We thank the commenters for their comments. We are committed to evaluating and adjusting our current guidelines and payment rules, if necessary, in order to ensure appropriate care for beneficiaries amid the current opioid epidemic. We acknowledge the benefits that implanted spinal neurostimulators and facet joint intervention services offer for chronic pain. At the same time, we reiterate the fact that these are non-emergency procedures that require the beneficiary to undergo conservative treatment prior to the procedure. Providers may also request expedited review of a prior authorization request, where the processing of the request must be expedited due to the beneficiary's life, health, or ability to regain maximum function being in jeopardy. To show the changes in the utilization of the services on the prior authorization list, we have posted statistics on the CMS OPD Prior Authorization and Pre-claim Review Initiatives website.[590] The statistics show the total number of prior authorization requests received and reviewed, the number of requests affirmed or non-affirmed, appeals and accuracy rates. We continue to analyze data associated with the services that require prior authorization and hopes to share additional data in the future.

We refer the commenters to the CY 2023 OPPS/ASC[591] and CY 2021 OPPS/ASC[592] final rules with comment period for our rationale on requiring prior authorization for facet joint interventions and implanted spinal neurostimulators.

Comment: We received comments requesting that CMS do more to streamline and automate the prior authorization process.

Response: Thank you for your comment. We recognize the value of automation in shortening the time between receipt of prior authorization requests and our responses. Finalizing the proposal to reduce the timeframe that beneficiaries wait to receive prior authorization decisions is one way to streamline the overall prior authorization process. We are aware that not all providers have the same level of technology and thus we allow various methods of submission of a prior authorization request. With regard to the hospital OPD prior authorization process, most providers submit requests and medical documentation to the MACs via individual MAC portals. Other providers submit the requests through the United States (U.S.) postal service, facsimile, or medical documentation (esMD) system. We continue to monitor and implement

[590] *https://www.cms.gov/research-statistics-data-systems/medicare-fee-service-compliance-programs/prior-authorization-and-pre-claim-review-initiatives/prior-authorization-certain-hospital-outpatient-department-opd-services.*

[591] See 87 FR 72225 and 72226.

[592] See 85 FR 86237 and 86238.

other Federal and industry initiatives in order to improve the efficiency of our prior authorization processes, including increasing the number of requests submitted electronically in order to reduce provider burden, decrease delays in patient care, and promote high-quality, affordable health care.

Comment: Some commenters suggested that we eliminate outpatient hospital services prior authorization requirements as a way to improve patient access and reduce physician administrative burden. There were also concerns about prior authorization creating delays in patient care.

Response: Thank you for your comment. We remain fully committed to the agency's initiative to reduce unnecessary burdens while protecting our programs' sustainability by serving as a responsible steward of public funds. We believe that we have structured the prior authorization processes to effectively account for concerns associated with processing timeframes, patient care, and other administrative concerns. Finalizing the new timeframe should further alleviate the providers' burden and enable hospitals to receive timely provisional affirmations. Additionally, our prior authorization policy does not create any new documentation or administrative requirements. Instead, it just requires the same documents that are currently required to be submitted earlier in the process. Therefore, hospital OPDs should not need to divert resources from patient care. We note that prior authorization has the added benefit of giving hospitals some assurance of payment for services for which they received a provisional affirmation. In addition, beneficiaries have information regarding coverage prior to receiving the service and benefit by knowing in advance of receiving the service if they will incur financial liability for non-covered services. CMS will continue tracking MAC timeliness metrics and is confident that the MACs will continue to meet the required review and decision timeframes so as not to cause an additional burden for OPD providers or delay medically necessary services.

Comment: One commenter posed concerns about the time it takes to obtain prior authorization with Medicare Advantage plans, which often leads to delayed access to care.

Response: Thank you for the comment. While Medicare Advantage plans are outside the scope of the proposal, under the CMS Interoperability and Prior Authorization final rule, beginning January 1, 2026, Medicare Advantage organizations and applicable integrated plans must provide notice of prior authorization decisions as expeditiously as a patient's health condition requires, but no later than 7-calendar days for standard requests.

Comment: We received comments asking whether section 1833(t)(2)(F) of the Act grants CMS the authority to establish a prior authorization process.

Response: As we conveyed in the CY 2020 OPPS/ASC, CY 2021 OPPS/ASC, and CY 2023 OPPS/ASC final rules with comment periods, section 1833(t)(2)(F) of the Act gives us the discretion to determine the appropriate methods to control unnecessary increases in the volume of covered OPD services.

Comment: We received comments with concerns about unclear reasons for denial, challenges in understanding the prior authorization process, and that prior authorization could be discriminatory and worsen health disparities.

Response: CMS maintains a robust oversight process to ensure the accuracy and consistency of MACs' review decisions. In all Medicare Fee-for-Service medical review programs, we require that MACs utilize clinicians, specifically registered nurses when reviewing medical documentation. We also require the oversight of a medical director and additional clinician engagement if necessary to ensure that review decisions are accurate and written in plain language. We are committed to ensuring transparency of the prior authorization process. CMS publishes any changes to the prior authorization process, a list of services requiring prior authorization, an operational guide, frequently asked questions, and, as we already noted, program statistics on the CMS OPD Prior Authorization and Pre-Claim Review Initiatives website. Although specific data is not available to determine the actual impacts on underserved communities, CMS believes that finalizing the proposal to reduce the timeframe will help beneficiaries who meet Medicare requirements for services under prior authorization receive those services in a timelier manner. Also, CMS allows multiple methods to submit prior authorization requests to the MACs (for example, electronic, fax, mail) to account for differences in the utilization of technology among different providers. CMS continues to monitor to ensure that this OPD prior authorization program does not disproportionately impact underserved populations and works to advance health equity by operationalizing policies and programs that support health for all beneficiaries.

After consideration of the public comments we received, we are finalizing our proposal to change the current review timeframe for provisionally affirmed or non-affirmed standard review requests for covered OPD services subject to prior authorization from 10-business days to 7-calendar days and making this change in regulation text at § 419.82(d)(1)(iii).

XX. Provisions Related to Medicaid and the Children's Health Insurance Program (CHIP)

A. Continuous Eligibility in Medicaid and CHIP (42 CFR 435.926 and 457.342)

Prior to January 1, 2024, States had the option to provide up to 12 months of continuous coverage to children under age 19 enrolled in Medicaid or CHIP, regardless of changes in circumstances that otherwise would impact their eligibility for these programs. This option has been available to State Medicaid programs under section 1902(e)(12) of the Act and Federal regulations at § 435.926; and to States' separate CHIP programs through Federal regulations at § 457.342. Under this option, States had the option to elect an age limit under age 19 and/or continuous eligibility (CE) periods shorter than 12 months. However, except for the limited exceptions defined in the regulations, states could not terminate the coverage of children during a CE period.

Section 5112 of Title V, subtitle B of the Consolidated Appropriations Act, 2023 (CAA, 2023) amended section 1902(e)(12) of the Act to make the previously optional CE policy a requirement under the state plan or waiver of the state plan for children enrolled in Medicaid. The CAA, 2023 also added a new paragraph (K) to section 2107(e)(1) of the Act, adopting by reference Medicaid's CE policy into CHIP. Thus, effective January 1, 2024, States are required to provide a 12-month period of CE that offers continuous coverage to children under the age of 19 in Medicaid and CHIP, with limited exceptions.

B. Summary of the Proposed Provisions, Public Comments and Responses to Comments on Medicaid and CHIP continuous eligibility

We proposed to update the Medicaid regulations at § 435.926 to conform to changes to the CE policy effectuated by the CAA, 2023 amendments to section 1902(e)(12) of the Act, which are adopted by reference into the CHIP regulations at § 457.342(a). Specifically, we proposed to revise § 435.926(b) to specify that a State must provide CE for

the period specified in paragraph (c) (12 months). We also proposed to revise § 435.926(b)(1) to remove the option to limit CE to an age younger than 19. We further proposed to revise § 435.926(c)(1) to remove the option to limit CE to a period of time of less than 12 months. Finally, we proposed to revise § 435.926(d)(1) to remove the option of ending a CE period for a person when they reach the State-specified maximum age, as now all States must provide CE to children until they reach age 19. We also proposed to remove the option in § 457.342(b) to disenroll children from separate CHIP coverage for failure to pay required premiums or enrollment fees during a continuous eligibility period.

The existing Medicaid continuous eligibility regulation includes three exceptions that were unaffected by the CAA, 2023, and we did not propose changes to those exceptions. These exceptions permit States to terminate coverage for children during a CE period in specific circumstances that do not involve a re-determination of eligibility based on a change in the beneficiary's circumstances during the CE period. Those situations arise if the child or child's representative requests a voluntary termination of eligibility; the agency determines that eligibility was erroneously granted at the most recent determination, redetermination, or renewal of eligibility because of agency error or fraud, abuse, or perjury attributed to the child or the child's representative; or the child is deceased. The CAA, 2023 amended section 1902(e)(12) of the Act to make the CE option mandatory for state Medicaid programs, but it did not foreclose termination of coverage in these situations, which are important to maintain program integrity. The death or voluntary termination of a child does not involve the State's evaluation of eligibility at all, and therefore is not barred by the prohibition on reassessing eligibility based on changed circumstances during a CE period. Indeed, it is unclear how coverage could continue when the child has died or is voluntarily removed from the program. Similarly, a decision that coverage was improperly provided to begin with (based on mistake, fraud, abuse, or perjury) is a decision about eligibility *before* the CE period began, not a re-determination about eligibility based on changed circumstances during the CE period. We described our intention to retain these exceptions in CMS State Health Official (SHO) Letter #23–004, Section 5112 Requirement for all States to Provide Continuous Eligibility to Children in Medicaid and CHIP under the Consolidated Appropriations Act, 2023, which was issued on September 29, 2023.

For a full discussion of these proposals, please see the CY 2025 OPPS/ASC proposed rule (89 FR 59487).

We received over 70 timely comments on the proposals to require 12-months of continuous eligibility in Medicaid and CHIP and to eliminate nonpayment of premiums as an optional exception to continuous eligibility in CHIP, in accordance with sections 1902(e)(12) and 2107(e)(1)(K) of the Act as amended by CAA, 2023. A summary of the public comments and our responses is below.

1. Requiring 12 Months of Continuous Eligibility in Medicaid and CHIP

Comment: The vast majority of commenters were supportive of the Medicaid and CHIP Continuous Eligibility proposal published in the CY 2025 OPPS/ASC proposed rule. Commenters noted that individuals with continuous coverage experience fewer unmet health care needs and better health outcomes than individuals with gaps in coverage. In addition, commenters noted that uninterrupted health coverage may promote access to preventive care, necessary treatments for acute health needs, and continuity of care. Other commenters noted that individuals with chronic or serious health needs require consistent access to health care and that any gap in coverage, even for as little as 1 month, may put individuals at risk of delays in care and declining health. Commenters also noted that these provisions will reduce coverage gaps that may occur when individuals transition from Medicaid or CHIP to Marketplace coverage and reduce the rates of churning on and off coverage.

Response: We appreciate the support from these commenters. We are finalizing the Medicaid and CHIP continuous eligibility provisions as proposed.

Comment: One commenter suggested that CMS track rates of churn for children to help evaluate the effectiveness of the continuous eligibility policy.

Response: We appreciate the commenter's suggestion. We currently utilize data from the Transformed Medicaid Statistical Information System (T–MSIS) Analytic Files (TAF) to monitor churn across several eligibility groups. We will continue to monitor churn to inform the impact of this continuous eligibility policy.

Comment: A few commenters suggested that CMS extend the continuous eligibility requirements to populations not explicitly addressed by the CAA, 2023. Specifically, one commenter discussed the importance of continuous eligibility in ensuring that patients will not lose coverage mid-treatment or immediately following treatment. This commenter suggested that CMS finalize its proposal and consider future extensions of this policy for patients undergoing active treatment for serious illnesses. Another commenter suggested expanding continuous eligibility to vulnerable adults, including pregnant women or adults with disabilities. Another commenter suggested expanding continuous eligibility to all adults and children covered under any Medicaid eligibility category.

Response: We thank the commenters for these suggestions. At this time, we are only codifying the requirements of the CAA, 2023 related to providing continuous eligibility to children up to age 19 in Medicaid and CHIP.

We note that, with respect to continuing eligibility during acute care treatment, section 1902(e)(7) of the Act and § 435.172 currently protect children enrolled in the mandatory Medicaid eligibility group for infants and children under age 19 (described at § 435.118) who are receiving inpatient services when they age out of coverage in their eligibility group and would otherwise remain eligible for coverage. This provision requires that states provide these children with continued eligibility, despite exceeding the maximum age for the group, until the end of their inpatient stay.

For pregnant women, under section 1902(e)(6) of the Act and § 435.170(c), most pregnant Medicaid beneficiaries are eligible for coverage under the state plan through the end of the month in which a 60-day period, beginning on the last day of pregnancy, ends (referred to as the ''60-day postpartum period''), regardless of changes in household income. States also have the option to extend CHIP eligibility to ''targeted low-income pregnant women'' through the end of the 60-day postpartum period, similar to Medicaid. States have the option under the state plan to provide 12 months of continuous postpartum coverage, regardless of any changes in circumstances, to all pregnant women in Medicaid and CHIP. Section 1902(e)(16) of the Act provides this authority in Medicaid, which is extended to CHIP through cross-reference at section 2107(e)(1)(J) of the Act. When the State elects this option in Medicaid, it must also make the same election in a separate CHIP, as required by section 1902(e)(16)(C) of the Act and cross-referenced in section 2107(e)(1)(J) of the

Act. As of September 2024, 46 States, the District of Columbia, and the U.S. Virgin Islands have elected to extend continuous postpartum coverage to 12 months. For more information on coverage options for pregnant women, please see the December 7, 2021 CMS State Health Official Letter #21–0007, ''Re: Improving Maternal Health and Expanding Postpartum Coverage in Medicaid and the Children's Health Insurance Program (CHIP).'' [593]

We encourage States that may be interested in extending continuous eligibility to other populations in Medicaid and CHIP or for children for longer than periods of 12 months to contact their section 1115 demonstration project officers to discuss options for doing so.

Comment: One commenter requested clarification regarding the start date of a child's continuous eligibility period and how the continuous eligibility period aligns with their renewal cycle. The commenter expressed concern that States may be setting renewal dates based on the date of the child's first approved application, rather than the application that led to the child's current coverage, which could result in a child losing coverage in under 12 months.

Response: As discussed in the September 29, 2023, State Health Official Letter #23–004, under 42 CFR 435.926 and 457.342, the 12-month continuous eligibility period begins on the effective date of the child's eligibility or most recent renewal of eligibility.

Because almost all children have 12-month eligibility periods and the 12-month CE period begins on the effective date of the child's most recent determination or redetermination of eligibility, a child's CE period generally will align with their renewal cycle, which is based on the child's current coverage period. Each time a child's eligibility is renewed in Medicaid or CHIP, the state must provide a new 12-month CE period. A child's coverage may not be terminated during the CE period, unless the child meets one of the exceptions to continuous eligibility enumerated at 42 CFR 435.926(d).

2. Removing Nonpayment of Premiums as an Optional Exception to Continuous Eligibility in CHIP

Comment: The majority of commenters supported removing nonpayment of premiums as an optional exception to continuous eligibility in CHIP. Commenters noted that requiring financial contributions from individuals may be a barrier to care for lower-income populations. Other commenters noted that removing this exception to continuous eligibility will allow children to have access to health care when they need it, regardless of the financial hardships families may face month to month.

Response: We appreciate the support from these commenters. We are finalizing this policy as proposed.

Comment: Several commenters suggested that CMS monitor States' responses to the elimination of the option to disenroll individuals due to nonpayment of premiums, which could create incentives for States or health plans to increase CHIP premiums to make up for lost revenue due to nonpayment. Another commenter expressed concern that CHIP managed care organizations could potentially place families in collections for the outstanding premiums. Another commenter requested strong monitoring and enforcement mechanisms to prevent unauthorized disenrollment practices and to ensure state compliance with this requirement.

Response: We appreciate the commenters' suggestions. We note that under section 2105(d)(3) of the Act, States shall not have in effect eligibility standards, methodologies, or procedures under a CHIP State plan or waiver of a State plan that are more restrictive than the eligibility standards, methodologies, or procedures under such plan (or waiver) as in effect on March 23, 2010. This requirement applies to children in families whose income does not exceed 300 percent of the Federal poverty level (FPL) and remains in effect through September 30, 2029.[594] These requirements are referred to as the ''maintenance of effort'' or MOE provisions. In the February 25, 2011, State Medicaid Director Letter #11–001,[595] CMS clarified that for CHIP, increases to existing premiums or the imposition of new premiums to existing eligibility groups are not consistent with MOE. States may only adopt, through State plan or demonstration amendments, certain inflation-related adjustments to premium levels. These adjustments must be based on (and no more than) the percentage increase in the Consumer Price Index (CPI) trended forward using the applicable CPI for Medical Care (or another State specific index submitted by the State and approved by CMS). Therefore, States may not increase their premiums to account for nonpayment of premiums, beyond the amounts charged on March 23, 2010, other than by an inflation-related adjustment, at least through September 30, 2029.

We also note that the CHIP statute and these regulations do not prohibit States or health plans from pursuing the collection of past due premiums. However, States can prohibit the CHIP managed care organizations from placing families in collections for the outstanding premiums through their contractual arrangements with the plans, and attempt to collect any past due premiums through other means.

With regards to enforcement, all States will be required to submit a CHIP State plan amendment (SPA) to demonstrate compliance with the provision of this final rule regarding removing nonpayment of premiums as an exception to continuous eligibility in CHIP. Most States are already in compliance with this provision and have submitted SPAs to demonstrate compliance. CMS will provide technical assistance to any State that needs assistance coming into compliance with the requirements of this provision. As noted above, we will also be using TAF data to monitor churn and expect to see modest drops in churn for states newly adopting continuous eligibility.

Comment: One commenter suggested that CMS further reduce barriers to coverage by eliminating premiums or the ability to disenroll children due to nonpayment of premiums in Medicaid and CHIP.

Response: For CHIP, Section 2103(e) of the Act allows for the imposition of premiums, subject to the limitations described in section 2103(e)(3). For children with family income below 150 percent of the FPL, premiums may not exceed the maximum monthly charge permitted consistent with standards established to carry out section 1916(b)(1) of the Act (with respect to individuals described in such section). For children with family income above 150 percent of the FPL, total aggregate cost-sharing (including premiums) may not exceed 5 percent of the family's income for the year. In Medicaid, sections 1902(a)(14), 1916, and 1916A of the Act permit States to require certain beneficiaries to share in the costs of providing medical assistance through premiums and cost sharing. Most premiums for children assessed in Medicaid are subject to the aggregate cost sharing limit of 5 percent of family income.

In the absence of a statutory requirement preventing disenrollment,

[593] *https://www.medicaid.gov/federal-policy-guidance/downloads/sho21007.pdf.*

[594] The same requirement applies to state Medicaid agencies. 1902(a)(74) and (gg)(2) of the Act.

[595] *https://downloads.cms.gov/cmsgov/archived-downloads/SMDL/downloads/smd11001.pdf.*

like the continuous eligibility requirement under section 1902(e)(12) and 2107(e)(1)(K) of the Act, we do not believe the Medicaid and CHIP statutes limit states' ability to disenroll children due to nonpayment of premiums at the end of a CE period provided required procedures are followed.

Comment: A few commenters requested specific technical assistance from CMS regarding these policies. One commenter noted that CHIP health plans may collect premiums from beneficiaries and that CMS should release guidance for States on working with CHIP health plans that are collecting premiums, if there is an instance of non-payment during a continuous eligibility period. The commenter emphasized the importance of standardizing implementation across states and reducing administrative and financial burden for CHIP health plans. Another commenter suggested CMS provide States with template notices to send to beneficiaries in order to alleviate enrollee confusion and administrative burden for States. Another commenter requested that CMS provide outreach and education efforts to inform beneficiaries of these policy changes and provide technical assistance to states in implementing these changes.

Response: We appreciate the suggestions and are working on additional guidance regarding implementation of the policies in this final rule. States with technical assistance needs regarding notices or other implementation areas should reach out to their Medicaid State leads or CHIP project officers for assistance.

Comment: Two commenters were unsupportive of removing nonpayment of premiums as an optional exception to continuous eligibility in CHIP. Specifically, these commenters requested clarity regarding the authority under which CMS can remove this previously optional exception and cited concerns regarding the potential increased costs to states or health plans if premiums are unpaid. One commenter stated the CAA, 2023 does not require CMS to remove nonpayment of premiums as an exception to continuous eligibility in CHIP. One commenter was concerned that removing nonpayment of premiums as an optional exception to continuous eligibility in CHIP would render CHIP an entitlement program.

Response: Under prior law, the Medicaid statute gave States the option to include in their State plans a ''continuous eligibility'' period of up to 12 months for children under 19. During this period, a child ''determined to be eligible for benefits under'' a State plan generally had to remain ''eligible for those benefits.'' In 2016, CMS promulgated a regulation implementing this section of the Medicaid statute. The regulation specified that ''[a] child's [Medicaid] eligibility may not be terminated during a continuous eligibility period, regardless of any changes in circumstances, unless'' one of five exceptions was met: (1) the child attains the maximum age specified in accordance with § 435.926(b)(1); (2) the child or child's representative requests a voluntary termination of eligibility; (3) the child ceases to be a resident of the State; (4) the agency determines that eligibility was erroneously granted at the most recent determination, redetermination or renewal of eligibility because of agency error or fraud, abuse, or perjury attributed to the child or the child's representative; or (5) the child dies. Notably, this regulation did not permit termination of Medicaid coverage for nonpayment of premiums during periods of continuous eligibility, consistent with then-applicable (and the amended) version of section 1902(e)(12) of the Act and preexisting Medicaid regulations in 42 CFR 435.930(b), which provides that states ''must . . . [c]ontinue to furnish Medicaid regularly to all eligible individuals until they are found to be ineligible.''

At the same time, CMS also issued a regulation permitting states to include a similar period of continuous eligibility in their CHIP plans, under 42 CFR 457.342. This regulation stated that, ''[i]n addition to the reasons provided at § 435.926(d) of this chapter''—that is, the five exceptions set forth above permitting termination of Medicaid eligibility—an additional exception applied in the CHIP context, where ''a child may be terminated during the continuous eligibility period for failure to pay required premiums or enrollment fees required under the State plan,'' id. § 457.342(b). This exception did not apply to Medicaid—it was unique to CHIP. Notably, prior to the amendments made by the CAA, 2023, there was no statutory provision specifically addressing provision of continuous eligibility under CHIP; this option was implemented through regulations only.

The CAA, 2023 made two fundamental changes relevant to continuous eligibility. First, it amended section 1902(e)(12) of the Medicaid statute to provide that State plans ''shall'' include a 12-month continuous eligibility period, which had previously been optional. Second, it amended the CHIP statute to adopt this Medicaid continuous eligibility requirement by reference. As a result, the CHIP statute now reads that section 1902(e)(12) of the Medicaid statute, as amended by section 5112(a) of the CAA, ''shall apply to States under this subchapter [*i.e.,* CHIP] in the same manner as [it] appl[ies] to a State under subchapter XIX [*i.e.,* Medicaid].'' The sole exception to this ''in the same manner'' directive is that CHIP coverage may end if a child ''becomes eligible for full benefits'' and is ''transferred to the [state's] Medicaid program . . . for the remaining duration of the 12-month continuous eligibility period.''

Accordingly, Congress made clear that the 12-month period of continuous eligibility under Medicaid must apply ''in the same manner'' with respect to CHIP coverage. And termination of coverage for nonpayment of premiums is not permitted during periods of continuous eligibility under Medicaid. Thus, termination for nonpayment of premiums is not permitted during a 12-month period of continuous eligibility under CHIP either. When Congress required that continuous eligibility be applied ''in the same manner'' in the two programs, Congress necessarily understood that CHIP beneficiaries would now receive uninterrupted coverage during the continuous eligibility period, as Medicaid beneficiaries already did. Therefore, the CAA, 2023 compels CMS to remove nonpayment of premiums as an exception to continuous eligibility in CHIP, just as nonpayment of premiums previously did not serve as an exception to the continuous eligibility option provided under the Medicaid statute. We also note that continuous eligibility can lead to more efficient care and better health outcomes, by stabilizing health coverage. In order to achieve this, unnecessary exceptions to continuous eligibility that are not provided for by statute, such as the exception for nonpayment of premiums, must be eliminated.

Regarding costs to States or managed care organizations (MCOs), States are not prohibited from entering or renegotiating contract 'per-member, per-month' (PMPM) amounts that take into consideration that supplemental MCO revenue could be reduced if the MCO is not able to collect 100 percent of premiums, which could result in an increase in state expenditures to cover the MCO's PMPM cost of care. However, the state may only claim FFP for the expenses set out in section 2105(a)(1)(A) through (D) of the Act. Uncollected premiums are not themselves considered an 'expense' within the meaning of section 2105. Although States may have decreased revenue due to unpaid premiums, States may find

administrative costs savings or reduced administrative burden, as a result of fewer children churning on and off coverage. Continuous eligibility, including eliminating disenrollment for failure to pay premiums, can reduce the need for repeatedly reviewing eligibility, disenrolling children, and then re-enrolling them.[596]

Removing nonpayment of premiums as an exception to continuous eligibility in CHIP does not render CHIP an entitlement program. States are not prohibited from charging and pursuing the collection of past-due premiums or from requiring an initial premium or enrollment fee to be paid prior to an individual enrolling in coverage. Rather, States simply may not disenroll individuals due to nonpayment of premiums during the continuous eligibility period.

Comment: One commenter questioned if removing this optional exception conflicted with the CHIP premium grace period requirements. Another commenter asked if individuals can be disenrolled after nonpayment of one premium or multiple premiums.

Response: Removing nonpayment of premiums as an exception to continuous eligibility does not conflict with the CHIP premium grace period requirements addressed in section 2103(e)(3)(C) of the Act. Under section 2103(e)(3)(C)(ii) of the Act, the State must provide the child with a grace period of ''at least 30 days from the beginning of a new coverage period to make premium payments before the individual's coverage'' may be terminated. Section 2103(e)(3)(C)(ii)(II) of the Act defines ''new coverage period'' as ''the month immediately following the last month for which the premium has been paid.'' Section 2103(e)(3)(C)(ii) of the Act also requires the State to provide notice no later than 7 days after the first day of the grace period (typically 7 days after the premium payment was due) that failure to make a premium payment within the grace period will result in termination of coverage and when such termination will be effective.

Disenrollment may occur at the end of the continuous eligibility period after nonpayment of one or multiple premiums, depending on how the State has structured their premium policies. States may disenroll individuals at the end of the continuous eligibility period for nonpayment of premiums during the continuous eligibility period, provided the State has afforded the enrollee a minimum of 30 days to pay the past-due premiums. If a State requires monthly premiums that are due in advance of the month of coverage, it is possible that an individual may be disenrolled at the end of the continuous eligibility period after nonpayment of only one premium payment.

Example: Jose is enrolled in CHIP with a 12-month continuous eligibility period of January 1, 2024, through December 31, 2024. The State requires that any unpaid premiums owed for one or more months in a child's current CE period must be paid prior to the end of the CE period in order to avoid termination at the end of the CE period. Jose's family paid the monthly premiums from January through November, due on the 1st of each respective month. However, the family did not pay the required premiums due for December.

Consistent with its renewal process, the State initiates the ex parte process for Jose's renewal on October 1, 2024. The State is unable to determine Jose's eligibility based on available information. The State therefore sends the family a pre-populated renewal form on November 1 and provides the family with 30 days to respond. Jose's family returns the renewal form (along with any requested documentation) later that month, and the State begins to process the information received. On December 7, the State sends Jose's family the notice required under section 2103(e)(3)(C)(ii) of the Act that Jose's coverage will end on December 31, 2024, if the family does not pay the December premium by that date. On December 10, the State completes processing Jose's renewal and determines that Jose continues to meet the other eligibility requirements. However, because Jose's family failed to pay the December premium, the State will not send Jose's family a notice that his eligibility is being renewed. Rather, the State would send Jose's family a notice explaining that: (1) it has determined that Jose meets the other eligibility requirements to have his coverage renewed but; (2) in order for Jose's coverage to be renewed for another 12 months effective January 1, 2025, the family must pay the December premium by December 31. If the State requires that the premium for January 2025 be paid prior to renewing Jose's coverage, the notice must include this information as well.

If the family pays the outstanding premium by December 31, 2024, Jose cannot be terminated due to failure to pay the premium. If Jose's coverage is erroneously terminated (for example, because the family did not submit the premium until December 31 and the State was unable to reverse the termination), the State must reinstate his coverage effective January 1, 2025. Conversely, if the family does not pay the outstanding premium by December 31, Jose can be terminated effective January 1, 2025, due to failure to pay the premium.

Comment: One commenter questioned if States could require CHIP enrollees to pay an initial premium or enrollment fee prior to enrolling in coverage, given this is prohibited in Medicaid. This commenter suggested that if continuous eligibility is to apply in the same manner in CHIP as it does in Medicaid, this practice may be prohibited.

Response: States have long had the option to require individuals who are determined eligible for separate CHIP coverage to pay an initial premium or enrollment fee prior to enrolling the individual in coverage. This rule does not preclude States from continuing this practice. Rather, this rule requires that once enrolled in coverage and the continuous eligibility period begins, States may not disenroll individuals from coverage due to nonpayment of premiums during the continuous eligibility period.

In Medicaid, section 1916(c)(3) of the Act specifies that a state shall not require prepayment of a premium imposed. Additionally, section 1902(a)(8) of the Act specifies that the State must provide that all individuals wishing to make application for medical assistance under the plan shall have opportunity to do so, and that such assistance shall be furnished with reasonable promptness to all eligible individuals. These statutory requirements do not apply to CHIP, and thus, States may be permitted to require the payment of an initial premium or enrollment fee prior to enrolling a child in CHIP. Once the period of continuous eligibility begins, however, that period applies ''in the same manner'' as in Medicaid, and therefore coverage cannot be terminated for nonpayment of premiums.

Comment: One commenter stated their State law requires disenrollment for failure to pay premiums. The commenter questioned if these regulations could apply to State programs that were grandfathered into CHIP, when it was created in 1997.

[596] Georgetown University. (2021). Advancing Health Equity for Children and Adults with a Critical Tool: Medicaid and Children's Health Insurance Program Continuous Coverage. Retrieved from *https://ccf.georgetown.edu/wp-content/uploads/2021/10/continuity-of-coverage-final.pdf.*

Response: We recognize that certain changes in this final rule, including eliminating failure to pay premiums as an optional exception to continuous eligibility, may require updates to information technology systems or changes in State laws. However, the vast majority of States have already implemented the Medicaid and CHIP continuous eligibility provisions in this final rule as of January 1, 2024, the effective date of the provisions under the CAA, 2023. Moreover, these regulations will be effective January 1, 2025, which provides additional time for States to make necessary changes. As previously mentioned, CMS is available to assist States with any technical assistance needs related to implementation of these provisions.

These regulations do apply to States whose programs were grandfathered into CHIP when it was created in 1997. CHIP regulations in § 457.410(a)(3) specify that States may offer health benefits coverage in the form of an existing comprehensive State-based coverage, in accordance with § 457.440. These two regulations describe the requirements regarding the benefits grandfathered health plans must provide but do not relieve States from complying with other programmatic requirements, such as requirements related to eligibility for coverage. As described above, CMS is available to provide technical assistance to States on these requirements.

After consideration of the public comments we received, we are finalizing our proposed revisions to Medicaid and CHIP regulations to codify the requirement within the CAA, 2023 to require States to provide 12 months of continuous eligibility to children under the age of 19 in Medicaid and CHIP, with limited exceptions. We are also finalizing our proposal to remove nonpayment of premiums as an optional exception to continuous eligibility in CHIP.

XXI. Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals

A. Background and Statutory Authority

CMS has broad statutory authority to establish health and safety regulations, which includes the authority to establish requirements that protect the health and safety of pregnant, postpartum, and birthing patients. Several statutes applicable to specific provider and supplier types explicitly give CMS the authority to enact regulations that the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in an institution, while others give CMS the authority to prescribe regulations as may be necessary to carry out the administration of the program.

Sections 1861(e)(1) through (8) of the Social Security Act (the Act) provide that a hospital participating in the Medicare program must meet certain specified requirements. Section 1861(e)(9) of the Act specifies that a hospital also must meet such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals furnished services in the institution. Under this authority, the Secretary has established regulatory requirements that a hospital must meet to participate in Medicare at 42 CFR part 482, ''Conditions of Participation [CoPs] for Hospitals.'' Section 1905(a) of the Act provides that Medicaid payments from States may be applied to hospital services. Under regulations at 42 CFR 440.10(a)(3)(iii) and 440.20(a)(3)(ii), Medicaid-participating hospitals are required to meet the Medicare CoPs in order to participate in Medicaid.

Sections 1820 and 1861(mm) of the Act, as amended by section 4201 of the Balanced Budget Act (BBA) of 1997, replaced the EACH/RPCH program with the Medicare Rural Hospital Flexibility Program (MRHFP), under which a qualifying facility can be designated and certified as a critical access hospital (CAH). CAHs participating in the MRHFP must meet the conditions for designation specified in the statute under section 1820(c)(2)(B) of the Act, and to be certified must also meet other criteria the Secretary may require, under section 1820(e)(3) of the Act. Under this authority, the Secretary has established regulatory requirements that a CAH must meet to participate in Medicare at 42 CFR part 485, subpart F.

The CoPs for hospitals and CAHs are organized according to the categories of services a hospital or CAH may offer, and include specific, process-oriented requirements for each hospital or CAH service or department. The purposes of these CoPs are to protect patient health and safety and to ensure that quality care is furnished to all patients in Medicare-participating hospitals and CAHs. In accordance with section 1864 of the Act, State surveyors assess hospital and CAH compliance with the conditions as part of the process of determining whether a hospital qualifies for a provider agreement under Medicare. However, under section 1865 of the Act, hospitals and CAHs can elect to be reviewed instead by private accrediting organizations approved by CMS as having standards that meet or exceed the applicable Medicare standards and survey procedures comparable to those CMS requires for State survey agencies.

B. The U.S. Maternal Health Crisis

The U.S. is currently facing a maternal health crisis which has not only led to a maternal mortality rate that is among the highest in high-income countries, but also disproportionately affects racial and ethnic minorities. In 2022, the most recent year for which there is data, there were 22 maternal deaths for every 100,000 live births in the U.S. which is more than double the rate for most other high-income countries. For example, in 2022, Canada, France, the United Kingdom, Germany, and Japan had maternal death rates of 8.6 deaths per 100,000 live births or lower.[597] Over 80 percent of pregnancy-related deaths are considered preventable.[598] Approximately 13 percent of all pregnancy-related deaths (a death during pregnancy or within 1 year of the end of pregnancy from a pregnancy complication, a chain of events initiated by pregnancy, or the aggravation of an unrelated condition by the physiologic effects of pregnancy) occur at the time of delivery, and nearly 12 percent occur between 1 and 6 days after the end of pregnancy.[599]

Native Hawaiian and Pacific Islander women, Black women, and American Indian/Alaska Native (AI/AN) women are two to four times more likely to suffer a pregnancy-related death than non-Hispanic White women.[600] Black and AI/AN women experience severe maternal morbidity rates that are more than two times higher than their White counterparts.[601] [602] Systemic societal barriers, including a patient's social determinants of health, have meant that these individuals experience a greater

[597] Munira Gunja et al., Insights into the U.S. Maternal Mortality Crisis: An International Comparison (Commonwealth Fund, June 2024). *https://doi.org/10.26099/cthn-st75.*

[598] *https://www.cdc.gov/maternal-mortality/media/pdfs/Pregnancy-Related-Deaths-Data-MMRCs-2017-2019-H.pdf.*

[599] *https://www.cdc.gov/maternal-mortality/media/pdfs/Pregnancy-Related-Deaths-Data-MMRCs-2017-2019-H.pdf.*

[600] *https://www.cms.gov/files/document/maternal-health-may-2022.pdf.*

[601] Centers for Disease Control and Prevention. Pregnancy Mortality Surveillance System. Available at: *https://www.cdc.gov/maternal-mortality/php/pregnancy-mortality-surveillance/index.html/* Accessed June 5th, 2024.

[602] *https://www.commonwealthfund.org/publications/issue-briefs/2021/oct/severe-maternal-morbidity-united-states-primer#:~:text=Approximately%20140%20of%2010%2C000%20women,severe%20maternal%20morbidity%20every%20year.*

share of these poor maternal health outcomes.[603] [604] [605]

Pregnant women who live in rural communities are about 60 percent more likely to die before, during, or following birth than women in urban communities.[606] Pregnant women with disabilities receive lower quality maternity care, experience a higher risk of pregnancy and birth-related complications, and are eleven times more likely to experience maternal death than people without disabilities.[607] [608]

Based on the issues regarding the delivery of maternity care referenced, we proposed a new OB services CoP, including proposed requirements for the organization, staffing, and delivery of OB services and staff training. We also proposed revisions to the current hospital and CAH QAPI requirements, hospital and CAH emergency services requirements, and hospital discharge planning requirements. We also solicited comments on whether these proposed requirements should also apply to REHs.

C. Summary of the Proposed Provisions, Public Comments and Responses to Comments on Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals

In response to these proposals, we received 153 total comments. A broad range of individuals, groups, and organizations responded to the proposed rule. Commenters included hospitals, healthcare systems, hospital associations, medical associations and societies, professional trade organizations, patient advocacy organizations, and individuals, among others.

Our goal is to establish new requirements for the provision of obstetrical services to protect the health and safety of pregnant, birthing, and post-partum patients. These requirements are designed to establish baseline standards for obstetrical care and, in many cases, mirror existing optional services in other areas of the Conditions of Participation for hospitals, which helps to minimize burden. These requirements do not dictate standards of care or otherwise require hospitals to offer any specific type of care to patients. We believe that these requirements are balanced and will drive improved care for pregnant, birthing, and post-partum patients.

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and an explanation for changes in the policies that we are finalizing.

1. General Comments

Comment: Many commenters expressed strong support for the proposed CoPs and CMS' efforts to improve maternal health with many commenters acknowledging the importance of addressing health disparities and social determinants of health. These commenters largely supported the overall goal of the proposed requirements and applauded these requirements as a major and historic step to improving maternal health outcomes. Some commenters also stated that these requirements were essential in addressing maternal health disparities. A few commenters also observed that these requirements will improve health equity by establishing standards and procedures across all hospitals, ensuring that facilities are held to a consistent standard of high-quality care. Additionally, a commenter noted that these requirements are a crucial step to transforming the health care system to be more responsive to the peri-natal needs of high-risk patients and communities. A few commenters also expressed support for the use of standardized practices for health care, quality measures, training, and assessments. Further, a commenter recommended future continuous evaluation of the standards to further positively impact patient care.

Response: We thank commenters for their support. We believe these requirements are an important component of the agency's efforts to improve maternal health and advance health equity. CMS routinely reviews new evidence, research, and information and may consider the possibility of revising the standards in the future if additional updates would be appropriate to improve quality and further protect the health and safety of patients.

Comment: Some commenters expressed support for these proposals, indicating their beliefs that the new requirements would promote consistent, high-quality maternal health care across the country, especially following the *Dobbs* v. *Jackson Women's Health Organization* (597 U.S. 215 (2022)) decision and related State policy changes restricting access to reproductive health care and its impact on the provision of emergency services. With this, many commenters recommended that CMS strengthen or reinforce the Emergency Medical Treatment and Labor Act (EMTALA) protections for patients experiencing pregnancy-related emergencies to reduce maternal morbidity and mortality. A commenter expressed concern that there is lack of clarity between the Federal requirements under EMTALA and State abortion restrictions. This commenter expressed concern that without EMTALA protections patients may face delays in accessing medically necessary emergency care. In addition, other commenters recommended that CMS remind hospitals of their legal responsibility to provide stabilizing treatment to pregnant women and requested that CMS work with policymakers and stakeholders to uphold EMTALA protections related to maternity care, especially in States with laws restricting women's health care. Further, commenters stated that these requirements were urgently needed given the nationwide shortage in OB providers, particularly in rural areas and southern States and would ensure timely and effective treatment for pregnant women regardless of their geographic location.

Response: We appreciate support for these requirements. With these requirements, we aim to support the provision of timely, effective, and high-quality maternal care. Of note, these requirements do not dictate standards of care or otherwise require hospitals to offer any specific type of care to patients. Rather, we proposed to require hospitals to have appropriate protocols and adequate provisions in place to meet the needs of patients with emergency conditions, including but not limited to patients who are experiencing obstetrical emergencies, complications, and immediate post-delivery care in alignment with the facility's complexity

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[603] *https://www.whitehouse.gov/wp-content/uploads/2022/06/Maternal-Health-Blueprint.pdf.*

[604] Taylor, J., Novoa, C., Hamm, K., & Phadke, S. (2021, December 3). Eliminating Racial Disparities in Maternal and Infant Mortality. Center for American Progress. *https://www.americanprogress.org/article/eliminating-racial-disparities-maternal-infant-mortality/.*

[605] Hoffman KM, Trawalter S, Axt JR, Oliver MN. Racial bias in pain assessment and treatment recommendations, and false beliefs about biological differences between blacks and whites. Proc Natl Acad Sci U S A. 2016;113(16):4296–4301. doi:10.1073/pnas.1516047113 *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4843483/.*

[606] White House Fact Sheet: Vice President Kamala Harris Announces Call to Action to Reduce Maternal Mortality and Morbidity. *https://www.whitehouse.gov/briefing-room/statements-releases/2021/12/07/fact-sheet-vice-president-kamala-harris-announces-call-to-action-to-reduce-maternal-mortality-and-morbidity/.*

[607] Gleason JL, Grewal J, Chen Z, Cernich AN, Grantz KL. Risk of Adverse Maternal Outcomes in Pregnant Women With Disabilities. JAMA Netw Open. 2021;4(12):e2138414.doi:10.1001/jama networkopen.2021.38414.

[608] Willi Horner-Johnson *et.al.* Perinatal Health Risks and Outcomes Among US Women With Self-Reported Disability, 41 Health Aff. 2011 (September. 2022), *https://doi.org/10.1377/hlthaff.2022.00497.*

and scope of services. Hospitals will have the flexibility to develop their own protocols consistent with evidence-based, nationally recognized guidelines.

Other laws, such as the Emergency Medical Treatment and Labor Act (EMTALA), require certain facilities with emergency departments to provide an appropriate medical screening exam and, if an emergency medical condition exists, offer stabilizing treatment or, under certain circumstances, appropriate transfer for a patient to receive stabilizing care. HHS reaffirmed its commitment supporting hospitals in complying with Federal requirements under EMTALA, consistent with binding court orders, and enforcing these requirements as recently as July 2, 2024.[609] Following the Supreme Court's decision in *Moyle* v. *United States,* HHS and CMS leadership jointly sent a letter to hospitals and provider associations reminding them of relevant facilities' legal responsibilities under EMTALA.[610] HHS will continue to partner with hospital and provider associations to disseminate training on facilities' obligations under EMTALA and maintain a team of HHS experts to support hospitals in complying with EMTALA.[611] Further, HHS and CMS also introduced a new EMTALA complaint form in both English and Spanish and issued updated model signage for hospitals, to help further educate patients about their rights under EMTALA.[612] [613] The electronic EMTALA form is also now available on the CMS website.[614] We emphasize that EMTALA requirements are separate and distinct from these requirements. Rather, these rules will require hospitals to adopt protocols and procedures so as to be adequately prepared to meet both the emergency and non-emergency needs of all patients, including those with obstetrical emergencies.

Comment: Many commenters recommended that CMS withdraw the proposed CoPs for OB services and the proposed revisions to the current CoPs. Some stated that CMS should engage in additional public outreach, such as working with hospitals and other interested parties to adopt guidelines, prior to developing policies for improving maternal health. Many commenters did not support the adoption of CoPs related to maternal health because of the belief that CoPs are not the appropriate mechanism to achieve change, and their view that the potential risk of losing Medicare certification for not meeting the proposed CoPs is excessively punitive for hospitals. These commenters stated that adoption of CoPs may limit flexibility for hospitals to address the needs of their patient populations. Some of these commenters suggested alternative mechanisms to achieve change including technical assistance programs, learning collaboratives, and well-tested quality metrics within the CMS Quality Reporting programs. Commenters stated that by engaging interested parties, CMS will have an opportunity to better understand the positive and negative impacts of potential policies. Lastly, a commenter stated that because the number of Medicare patients seeking maternity care is low, a more targeted approach through Medicaid would be more appropriate to implement these changes.

Response: As we previously noted, the U.S. is currently facing a maternal health crisis which has not only led to a maternal mortality rate that is amongst the highest in high-income countries, but also disproportionately affects racial and ethnic minorities. After analyzing the issue of high rates of maternal mortality and morbidity in the U.S., receiving feedback from various stakeholders on improving maternal health care, and reviewing available resources and current requirements, we believe that it is necessary to establish new baseline requirements for the provision of obstetrical services to protect the health and safety of pregnant, birthing, and postpartum patients. Doing so would be part of a multi-pronged HHS-wide approach to address the maternal health crisis and would hold hospitals and CAHs accountable to a consistent set of high-quality requirements that would improve outcomes for pregnant, birthing, and postpartum patients. We therefore are finalizing our proposals, with the modifications discussed below.

We also note that the role of the CoPs is to establish health and safety standards that health care providers and suppliers (in this case hospitals and CAHs) must meet to participate in the Medicare and Medicaid programs. These standards are foundational for improving quality and protecting the health and safety of all patients seeking care from these facilities including pregnant, postpartum, and birthing patients. As noted above, these requirements do not dictate standards of care or otherwise require hospitals to offer any specific type of care to patients. As discussed in the CY 2025 OPPS/ASC proposed rule (89 FR 59488) some of these patients are currently not receiving consistent high quality, safe care. Therefore, it is appropriate to expand the CoPs to ensure that the care provided to these patients meets minimum quality standards, in alignment with the facility's complexity and scope of services. We note that the CoPs apply to all patients in facilities, not only those covered by Medicare and Medicaid.

We appreciate commenters' suggestions regarding other channels for improving the quality and safety of obstetric services. We recognize that updating the CoPs for hospitals and CAHs is not a complete solution to the maternal health crisis and that updating the CoPs for hospitals and CAHs is one element of the HHS-wide approach to strengthening maternal health, among other activities.[615] Across the Department, other relevant activities include developing and implementing a strategy to improve maternal mental health care,[616] to extend postpartum coverage,[617] and to support innovative programs to address racial equity for postpartum patients enrolled in Medicaid.[618] Within CMS, as part of our

[609] *https://www.hhs.gov/about/news/2024/07/02/biden-harris-administration-reaffirms-commitment-emtala-enforcement.html.*

[610] *https://www.hhs.gov/about/news/2024/07/02/biden-harris-administration-reaffirms-commitment-emtala-enforcement.html.*

[611] CMS, CMS Announces New Actions to Help Hospitals Meet Obligations under EMTALA, January 22, 2024. Available at: *https://www.cms.gov/newsroom/press-releases/cms-announces-new-actions-help-hospitals-meet-obligations-under-emtala#:~:text=Today%2C%20the%20Department%20of%20Health,meet%20their%20obligations%20under%20the.*

[612] *https://www.cms.gov/priorities/your-patient-rights/emergency-room-rights/complaint-form.*

[613] *https://www.cms.gov/medicare/health-safety-standards/quality-safety-oversight-general-information/policy-memos-states/updated-model-signage-emergency-medical-treatment-and-labor-act-emtala.*

[614] *https://www.cms.gov/priorities/your-patient-rights/emergency-room-rights/how-to-file-complaint#:~:text=There%20are%202%20ways%20to%20file%20a%20complaint,complaint%20and%20might%20share%20it%20with%20the%20state.*

[615] U.S. Department of Health and Human Services, Strengthening Maternal Health. Available at: *https://www.hhs.gov/healthcare/maternal-health/index.html.*

[616] Task Force on Maternal Mental Health, National Strategy to Improve Maternal Mental Health Care. Available at: *https://www.samhsa.gov/sites/default/files/mmh-strategy.pdf.*

[617] U.S. Department of Health and Human Services, December 2021, HHS Announces Efforts to Help Expand Nationwide Access and Coverage for High-quality Maternal Health Services. Available at *https://www.cms.gov/newsroom/press-releases/hhs-announces-efforts-help-expand-nationwide-access-and-coverage-high-quality-maternal-health.*

[618] U.S. Department of Health and Human Services, February 14, 2024, HHS Announces Final Phase Winners in Challenge to Address Racial Equity in Postpartum Care. Available at: *https://www.hhs.gov/about/news/2024/02/14/hhs-announces-final-phase-winners-challenge-address-racial-equity-postpartum-care.html.*

Maternity Care Action Plan,[619] we have established the ''birthing friendly'' designation [620] for hospitals and have established funding through CMS' Innovation Center model (the Transforming Maternal Health Model) focused developing whole-person approaches to pregnancy, childbirth, and postpartum care.[621] In addition, the Maternal Morbidity Structural Measure requires hospitals participating in the Hospital Inpatient Quality Reporting Program (IQR) to assess whether or not a hospital participates in a statewide or national Perinatal Quality Improvement (QI) Collaborative initiative, and implements patient safety practices and/or bundles related to maternal morbidity from that QI Collaborative.[622] We note in our current QAPI proposal that participating in Perinatal QI Collaborative would be consistent with meeting this new requirement. Other specific hospital IQR maternal health quality measures include: (1) measurement of severe obstetric complications (which describes the number of inpatient hospitalizations for patients with severe complications occurring during the delivery hospitalization, such as hemorrhage), and (2) measurement of low-risk Cesarean section rates, which describes the share of patients with low-risk pregnancies who give birth via a Cesarean section.[623] Given that a significant portion (42 percent) of U.S. births are covered by the Medicaid, the Medicaid program has also prioritized improving maternal and infant health care quality. This includes the Maternal and Infant Health Initiative (MIHI), which has supportive tools such as a webinar series, affinity groups, and a quality improvement resource list.[624]

While we understand commenters' concern that failure to comply with the Medicare CoPs may result in loss of certification, we note that if a surveyor identifies deficiencies during their survey, the initial step is for the hospital or CAH to develop a Plan of Correction (PoC) to remedy the deficiency. This activity is intended to ensure that the hospital or CAH becomes compliant with the CoPs instead of requiring that CMS terminate the hospital from its programs. CMS remains committed to collaborating with hospitals and CAHs, including by providing technical assistance and issuing interpretive guidance to help hospitals and CAHs come into compliance with the CoPs.

With regards to comments on public outreach, we note that public outreach is a vital element of understanding the potential impacts of policies on facilities and their patients, and we did so when developing these proposed updates to the CoPs. As part of that outreach, in 2022 we solicited public input on a wide range of maternal health issues (86 FR 44774) and published the responses in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49290 through 49292). We then conducted a systematic literature review to inform development of the proposed CoPs. We also held listening sessions with industry groups, patient advocacy groups, and health care professionals to further understand the potential impacts of possible updates to the CoPs, including an obstetrical services CoP. Finally, we issued an RFI in the FY 2025 IPPS proposed rule (89 FR 35934) and included a summary of these comments in the CY 2025 OPPS/ASC proposed rule (89 FR 59186, 59490). We evaluated input from a wide range of interested parties including advocacy groups, industry associations, State health departments, labor unions, professional organizations, among others who responded to this RFI in developing our current requirements. Commenters who provided feedback in prior rulemaking were supportive of CoPs for obstetrical care services noted that establishing CoPs for obstetrical care would enhance the quality and safety of maternal care. These commenters also stated that obstetrical services CoPs regarding organization and staffing would promote multi-disciplinary, team-based care with specialists, among others providing care to pregnant women. Other commenters stated that establishing obstetrical training standards for hospitals and CAHs could improve maternal health outcomes and also supported staff training on equitable-person centered care, cultural competency, and trauma-informed care. Some commenters supported requiring facilities to report directly to the Maternal Mortality Review Committee (MMRC) and others supported specific transfer protocol requirements. Because we have engaged in extensive public outreach as part of developing our plan for improving maternal health, we do not believe that it would be appropriate to further delay these important updates. However, we continually monitor the effectiveness of the CoPs and we will continue to collaborate with interested parties and make any necessary updates in the future if new information warrants revisions or additional requirements.

Comment: Several commenters recommended monitoring the impact of these CoPs to ensure that hospitals can effectively implement the new requirements while maintaining high-quality care and essential services. A commenter recommended establishing minimum baseline standards, in accordance with State regulations, to reduce hardships small or under-resourced facilities experience in meeting these requirements.

Response: We continually monitor the effectiveness of the CoPs on advancing patient health and safety. We understand the commenters' concerns regarding small and under-resourced facilities and have opted to provide additional time for facilities to come into compliance with these requirements to reduce any potential implementation burden or unintended consequences (see section XXI.A.7 of this final rule with comment period). We acknowledge that these requirements will require a robust review of existing programs and would necessitate changes to ensure full compliance with the new requirements. We anticipate that additional time will be needed to develop revised interpretive guidance for surveyors and survey processes, conduct surveyor training on the changes, and implement the software changes in the Quality Indicator Survey (QIS) system. We believe that these updates to the CoPs will ensure that providers deliver care that is consistent with evidence-based standards, which is a vital part of providing high quality, safe care.

Comment: A few commenters recommended that CMS collaborate with affected parties, including providers and communities, in the development of subregulatory guidance for compliance with the CoPs.

Response: As discussed in the CY 2025 OPPS/ASC proposed rule, we engaged in public collaboration and outreach while developing these

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[619] CMS, July 26, 2022, CMS Releases Maternity Care Action Plan to Implement Biden-Harris Maternal Health Blueprint; Launches Industry Call to Action. Available at: *https://www.cms.gov/files/document/cms-maternity-care-action-plan.pdf.*

[620] CMS, August 1, 2022, New CMS Rule Increases Payments for Acute Care Hospitals and Advances Health Equity, Maternal Health. Available at *https://www.cms.gov/newsroom/press-releases/new-cms-rule-increases-payments-acute-care-hospitals-and-advances-health-equity-maternal-health.*

[621] CMS, Transforming Maternal Health (TMaH) Model. Available at: *https://www.cms.gov/priorities/innovation/innovation-models/transforming-maternal-health-tmah-model.*

[622] *https://www.cms.gov/files/document/maternal-morbidity-structural-measure-specifications.pdf.*

[623] *https://www.cms.gov/newsroom/fact-sheets/fiscal-year-fy-2022-medicare-hospital-inpatient-prospective-payment-system-ipps-and-long-term-care-0.*

[624] Medicaid.gov, Maternal & Infant Health Care Quality. Available at: *https://www.medicaid.gov/medicaid/quality-of-care/quality-improvement-initiatives/maternal-infant-health-care-quality/index.html.*

policies (89 FR 59489). As with all regulations regarding the CoPs, the interpretive guidance will be updated once this final rule is published. The development of the interpretive guidance is a subregulatory process intended to clarify the regulatory requirement as described in the preamble of the final rule. However, CMS will consult with clinical subject matter experts in developing the subregulatory process and notify the public as we move forward with the guidance process.

Comment: A few commenters expressed concern that there has been insufficient time and analysis to adopt what they characterize as far-reaching CoPs. These commenters stated that there was insufficient time to properly analyze public input on the RFI published in the FY 2025 IPPS final rule. Several commenters stated that there is a lack of evidence that the specific structures and associated processes in the proposed CoPs will contribute to improved patient outcomes.

Response: As discussed previously, we engaged in extensive public outreach and information collection and worked with the public as we developed these updated requirements; This research and outreach included analyzing and evaluating the evidence base for each proposal. We also conducted a thorough analysis of the comments on the most recent RFI on maternal health to determine whether the concerns expressed by commenters offset the benefits of adopting CoPs to reduce maternal morbidity and mortality and improve care for patients. As discussed in the CY 2025 OPPS/ASC proposed rule, commenters supportive of CoPs for obstetrical care services noted that establishing CoPs for obstetrical care would enhance the quality and safety of maternal care and provide the opportunity to standardize services across various health care settings. On prior rulemaking, these commenters also stated that obstetrical services CoPs regarding organization and staffing would promote multi-disciplinary, team-based care with specialists, among others providing care to pregnant women. Other commenters stated that establishing obstetrical training standards for hospital and CAHs can help improve maternal health outcomes and also supported staff training on equitable person-centered care, cultural competency, and trauma-informed care. Some commenters supported requiring facilities to report directly to the MMRC and others supported specific transfer protocol requirements. Following that evaluation and discussed throughout this final rule, we determined that there was sufficient information to develop and support finalization of these requirements. To the extent possible, we allow hospitals and CAHs flexibility to adopt evidence-based structures and processes consistent with nationally recognized standards. We address more specific concerns related to the evidence base for individual requirements in the respective section of these comment responses. The obstetrical services CoPs are just one component of a multipronged approach to addressing the maternal health crisis and are complementary to other HHS maternal health initiatives.

Comment: Many commenters expressed concern that the burden of complying with new CoPs could potentially cause hospitals to choose to no longer offer OB services which would exacerbate disparities and increase access challenges as hospitals do not have sufficient resources to implement some best practices. Commenters cited ongoing OB staff shortages and provider burnout, particularly in rural areas, for these reasons, the commenter urged CMS to delay implementing these requirements. Additionally, a commenter stated that there would be additional burden for hospitals to meet these proposed standards even if the hospitals were already meeting the accreditation standards set by organizations such as the Joint Commission (TJC). These commenters recommended that CMS provide monetary assistance to hospitals to meet the proposed CoPs or implement other financial incentives or supports. Many commenters also recommended that CMS offer technical assistance, resource guides, and a FAQ document to help hospitals improve OB care explaining that these resources would help hospitals comply with the proposed CoPs. Conversely, other commenters recommended offering these resources as a more supportive way to improve OB care without updating the CoPs.

Some commenters stated that because these services are optional, and some of the proposed new CoPs only apply to hospitals with OB services, hospitals may choose to close these units as opposed to complying with new regulations. Other commenters stated that even for hospitals that do not close their OB units, there is the potential for resources to be drawn away from providing care to focus on complying with regulations. These commenters stated that this would worsen outcomes for patients. Some commenters stated that these closures could have a disproportionate effect on rural communities or communities of color. Some commenters recommended that CMS exempt rural hospitals and CAHs to ensure that access is not limited due to potential closures. A few commenters recommended that CMS conduct a study of OB unit closures and their impact on equity and revise the proposed CoPs based on the results of that study to ensure CoPs do not strain OB units.

Response: We thank commenters for expressing their concerns and we understand the challenges that new requirements may present for some facilities. We are implementing these requirements in response to the ongoing maternal health crisis, which has led to a U.S. maternal mortality rate that is among the highest across high-income countries and disproportionately affects racial and ethnic minorities as well as those living in rural areas and those with disabilities. Ensuring that all hospitals and CAHs participating in the Medicare and Medicaid programs meet or exceed evidence-based standards of care will lead to an overall improvement in care for all patients. We also note that we proposed these CoPs to provide flexibility to hospitals and CAHs, recognizing that hospitals and CAHs already adhere to complementary accrediting organization requirements and may also utilize guidelines from expert organizations. We believe that these requirements are balanced and would drive improved care for pregnant and post-partum women. Moreover, these proposed CoPs are only one component of an HHS-wide strategy to address the maternal health crisis. To alleviate burden, we have revised some of our requirements and will also allow for a phased-in implementation. Please refer to section XXI.A.7 of this final rule with comment period for more information on the implementation delay.

HHS has taken a comprehensive approach to addressing health care worker staffing shortages. For example, HRSA has several programs that support women's health, including the National Health Service Corps.[625] The National Health Service Corps uses both Health Professional Shortage Areas (HPSAs) and designated Maternity Care Target Area (MCTA) scoring to distribute maternity care health professionals.[626] In addition, HRSA recently announced nearly $100 million in awards to grow, support, and strengthen the health

[625] *https://bhw.hrsa.gov/data-research/projecting-health-workforce-supply-demand#:~:text=Women's%20health,future%20shortage%20of%20OB%2DGYNs.*

[626] *https://nhsc.hrsa.gov/loan-repayment/nhsc-loan-repayment-program.*

workforce and improve access to quality care in high-need areas across the country. These awards will enhance and expand the number of nurses and primary care physicians.[627] In 2023, HHS launched the HHS Health Workforce Initiative with the goal of supporting, strengthening, and growing the health workforce by leveraging programs across the Department. The Initiative includes a coordinated Department-wide effort to identify opportunities to improve health workforce recruitment and retention, and career advancement, with equity at the center of its work.[628] We discuss organization, staffing, and delivery of services requirements further in section XXI.A.2 of this final rule with comment period.

While payment policy is not within the scope of the CoPs we agree with commenters regarding the importance of providing resources to support hospitals in improving OB care. We note that HHS generally, and CMS specifically, are engaged in a long-term, multi-agency effort to improve the quality of maternal health care across the full continuum of care. For example, some specific resources we refer readers to include the HHS resources on Strengthening Maternal Health,[629] the CMS Maternity Care Action Plan,[630] and the Medicaid Maternal and Infant Health Initiative resources.[631] Additionally as we implement these new requirements, we will continue to provide resources for hospitals, State survey agencies, and accreditation organizations, including subregulatory guidance. We note that accreditation organizations (such as the Joint Commission) [632] and expert organizations (such as ACOG) [633] have resources available to support maternal health quality improvement efforts. Further, CMS will collaborate with HHS partners to monitor the impact of OB unit closures and consider further analysis and evaluation of this issue.

Comment: Many commenters stated that the CoPs do not address the underlying issues with high quality maternity and neonatal care. Some commenters stated that many of the reasons for poor maternal outcomes are not associated with obstetrical care that patients receive in the hospital but are associated with social determinants of health (SDOH) or non-obstetric health concerns such as substance use disorder (SUD) or mental health conditions. These commenters recommended that CMS consider solutions that address the continuum of maternal health care rather than focus on inpatient OB care.

Response: We agree with commenters that improving maternal health outcomes is a complex, multifaceted issue. While the proposed updates to the CoPs for hospitals and CAHs are only one element of our multi-agency effort to improve the quality of maternal health care across the health care continuum, we believe these new standards will advance patient health and safety and compliment the activities of other agencies. There are currently no minimum care standards that hospitals and CAHs must comply with pertaining to emergency readiness, transfer protocols, and organization, staffing, and delivery of services. These requirements hold hospitals and CAHs to minimum, baseline standards to ensure facilities are held accountable for delivering care that meets or exceeds evidence-based standards of care. Examples of specific resources include HHS' resources on Strengthening Maternal Health,[634] the CMS Maternity Care Action Plan,[635] the Medicaid Maternal and Infant Health Initiative resources,[636] and the Alliance for Innovation on Maternal Health (AIM) bundles.[637] Some of these initiatives are focused on maternal mental health [638] and others involve financial support to address maternal health equity.[639] We appreciate the comments on funding resources and payment policy, though they are beyond the scope of the CoPs.

Comment: Many commenters stated that the proposed CoPs would duplicate existing regulations and guidelines including existing CoPs (specifically the QAPI requirements), State regulations, and clinical guidelines produced by expert organizations. A commenter recommended allowing States to regulate OB care.

Response: We disagree that the proposed requirements duplicate existing CoPs. While the updates have similarities to the existing CoPs, there are currently no CoPs specific to the organization, staffing, and delivery of OB services; to staff training on evidence-based best practices to improve the delivery of maternal care within a facility; emergency services readiness; or to OB transfer protocols. We also note that we proposed these CoPs to provide flexibility to hospitals and CAHs, recognizing that hospitals and CAHs already adhere to complementary State regulations and may also utilize guidelines from expert organizations. By establishing a baseline through the CoPs, we will ensure that all hospitals and CAHs meet a minimum standard of quality and safety.

We acknowledge that these CoPs may include new requirements beyond those currently adopted by the Joint Commission (TJC) and other CMS-approved accrediting organizations. In the CY 2025 OPPS/ASC proposed rule, we also stated that we are aware that accrediting organizations may also have additional requirements that exceed the Medicare CoP requirements as part of their CMS-approved deeming program (89 FR 59533), so there would not be a significant burden for hospitals that are accredited by these other organizations. In our cost estimates, we did not assume that TJC-accredited facilities would already be meeting any of the proposed requirements beyond the requirement

[627] *https://www.hhs.gov/about/news/2024/09/17/biden-harris-administration-announces-nearly-100-million-grow-health-workforce.html.*

[628] *https://www.hhs.gov/about/news/2023/07/06/new-hhs-initiative-aims-strengthen-nations-health-workforce.html.*

[629] U.S. Department of Health and Human Services, Strengthening Maternal Health. Available at: *https://www.hhs.gov/healthcare/maternal-health/index.html.*

[630] CMS, July 26, 2022, CMS Releases Maternity Care Action Plan to Implement Biden-Harris Maternal Health Blueprint; Launches Industry Call to Action. Available at: *https://www.cms.gov/files/document/cms-maternity-care-action-plan.pdf.*

[631] Medicaid.gov, Maternal & Infant Health Care Quality. Available at: *https://www.medicaid.gov/medicaid/quality-of-care/quality-improvement-initiatives/maternal-infant-health-care-quality/index.html.*

[632] The Joint Commission, Focus on Maternal Health to Help Reduce Mortality and Morbidity, January 17, 2023. Available at: *https://www.jointcommission.org/resources/news-and-multimedia/news/2023/01/new-alerts-from-the-joint-commission-focus-on-maternal-health-to-help-reduce-mortality-and-morbidity/.*

[633] See, for example, ACOG, Levels of Maternal Care. Available at: *https://www.acog.org/programs/lomc.*

[634] U.S. Department of Health and Human Services, Strengthening Maternal Health. Available at: *https://www.hhs.gov/healthcare/maternal-health/index.html.*

[635] CMS, July 26, 2022, CMS Releases Maternity Care Action Plan to Implement Biden-Harris Maternal Health Blueprint; Launches Industry Call to Action. Available at: *https://www.cms.gov/files/document/cms-maternity-care-action-plan.pdf.*

[636] *Medicaid.gov*, Maternal & Infant Health Care Quality. Available at: *https://www.medicaid.gov/medicaid/quality-of-care/quality-improvement-initiatives/maternal-infant-health-care-quality/index.html.*

[637] For example, Alliance for Maternal Health. Available at: *https://mchb.hrsa.gov/programs-impact/programs/alliance-innovation-maternal-health#:~:text=AIM%20%E2%80%9C%20patient%20safety%20bundles%20%E2%80%9D%20are%20sets,reduce%20preventable%20deaths%20and%20severe%20maternal%20morbidity%20%28SMM%29.*

[638] For example, the Maternal Mental Health Strategy. Available at: *https://www.samhsa.gov/sites/default/files/mmh-strategy.pdf.*

[639] For example, the Challenge to Address Racial Equity in Postpartum Care. Available at: *https://www.challenge.gov/?challenge=hhs-postpartum-equity-in-care-challenge.*

that if a hospital or Critical Access Hospital (CAH) provides OB services, such services must be well-organized and in accordance with nationally recognized acceptable standards of practices for physical and behavioral health of pregnant, birthing, and postpartum patients and included the costs for TJC-accredited facilities to meet the other requirements for the purposes of our impact analysis.

It is the role of CMS to ensure access to high quality, safe care for patients seeking care in facilities that participate in our programs across the nation. We note that rates of maternal mortality vary significantly across States by as much as four times as many maternal deaths per 100,000 live births as the best performing State.[640] By establishing uniform baseline requirements we aim to improve access to high quality care for all patients, regardless of State residence.

Comment: Several commenters expressed concern about the potential unintended consequences of new OB CoPs following the Supreme Court's decision in *Dobbs* v. *Jackson Women's Health Organization* (597 U.S. 215 (2022)), stating that State restrictions on abortion may potentially compound the existing maternal health crisis. For example, a commenter noted that training and educational curricula will suffer due to the limited scope of patient care being administered. In addition, a commenter expressed concern that the CoPs related to OB services, may enable inappropriate monitoring and scrutiny of hospitals' reproductive and obstetrical care standards and activities as well as additional undue oversight of OB providers and patients.

Response: As previously noted, we believe that the proposed CoPs are a critical step in addressing the maternal health crisis and part of HHS's comprehensive strategy to improve the quality of maternal health services. The CoPs require hospitals and CAHs to have appropriate protocols and adequate provisions and structures in place to meet the needs of obstetrical and emergency services patients. Hospitals have the flexibility to develop their own protocols consistent with evidence-based, nationally recognized guidelines and with the complexity and scope of services offered by the facility. The CoPs do not dictate specific standards of care or otherwise require hospitals to offer any specific type of care to patients or stock particular medications or supplies. HHS has no reason to expect inappropriate monitoring and scrutiny because of these CoPs. HHS will monitor for and investigate any concerns about inappropriate monitoring and scrutiny of hospitals' reproductive and obstetrical care standards and activities. We note that the vast majority of hospitals participate in the Medicare program through deemed status with an accrediting organization [641] and are therefore surveyed by their accrediting organization rather than a State agency, which in any case would survey for Federal, not State standards. We further note that patients' reproductive care protected health information (PHI) is protected under the recently finalized Privacy Rule (89 FR 32976).

Comment: Several commenters expressed that, in trying to maintain flexibility, the CoPs are vague which may contribute to implementation and compliance burden. A few commenters specifically noted that words including ''protocol,'' ''practice,'' ''staff,'' ''training'' and ''equipment'' are all subject to interpretation. A few commenters recommended that CMS define what services fall under the term ''obstetric services.''

Response: As commenters noted, we have intentionally not defined some terms or requirements to allow hospitals and CAHs to meet the requirements while addressing the needs of their patient population and adhering to State regulations or other requirements. To maintain this flexibility, we will provide interpretive guidance through subregulatory channels, including updates to the State Operations Manual (SOM), with respect to these new requirements and how facilities can achieve compliance. As noted in the CY 2025 OPPS/ASC proposed rule, CMS considers a facility to ''offer obstetrical services'' when the facility ''[holds itself] out to the public (by name, posted signs, advertising, or other means) as a place that provides care for obstetrical medical conditions.'' (89 FR 59496) This is similar to how emergency departments are defined in EMTALA (42 CFR 489.24(b), definition of ''dedicated emergency department'', paragraph (2)).

Comment: Several commenters recommended that CMS collaborate with AHRQ to establish a Consumer Assessment of Healthcare Providers & Systems (CAHPS) survey that specifically focuses on prenatal and childbirth care.

Response: We thank commenters for their feedback and will continue to collaborate with our HHS partners to improve maternal health care.

Comment: A commenter recommended that CMS promote alternative delivery sites, such as birthing centers, for low-risk pregnancies. Another commenter recommended that CMS ensure safety standards at these sites.

Response: In alignment with our National Quality Strategy (NQS) goals, we seek a person-centered approach to improving quality.[642] Therefore, we encourage patients to work with their clinicians to make the most appropriate choice for their individual situation, including selecting the delivery site most appropriate to their personal values and clinical needs. We understand that there are a variety of regulations that apply to alternative delivery sites, however CMS does not currently have the statutory authority under the CoPs to regulate entities such as birthing centers.

Comment: A few commenters recommended that CMS expand the CoPs to reduce the risk to patients of pregnancy criminalization. These commenters stated that by ensuring informed consent for drug testing and educating providers about treatment for pregnant patients with SUDs, the CoPs could be enhanced to increase patient trust in the health care system and increase use of prenatal care.

Response: We appreciate commenters' concern, however potential criminalization related to OB care with respect to drug testing and mandatory reporting and note that this is outside the scope of this final rule with comment period. We remind facilities that patients' reproductive care PHI is protected under the recently finalized Privacy Rule (89 FR 32976).

Comment: A few commenters recommended that CMS clarify policies related to telehealth for maternal health services, the use of which increased during the COVID–19 pandemic. These commenters stated telehealth has improved access to care without detrimental effects on care quality.

Response: Revisions to telehealth regulations are beyond the scope of these requirements, and we refer readers to HHS' Telehealth for Maternal Health Services guide [643] to support providers

[640] CDC, Maternal Mortality from 2018 through 2022. Available at: *https://www.cdc.gov/nchs/maternal-mortality/mmr-2018-2022-state-data.pdf.*

[641] *https://www.jointcommission.org/resources/news-and-multimedia/fact-sheets/facts-about-hospital-accreditation/.*

[642] CMS, The CMS National Quality Strategy: A Person-Centered Approach to Improving Quality, June 06, 2022. Available at: *https://www.cms.gov/blog/cms-national-quality-strategy-person-centered-approach-improving-quality.*

[643] HHS, Telehealth for maternal health services. Available at: *https://telehealth.hhs.gov/providers/*

Continued

in using telehealth for maternal health services. We note that for each State's Medicaid program, the State determines which services that can be provided through telehealth.[644]

2. Organization, Staffing, and Delivery of Services (§§ 482.59 and 485.649)

We proposed at new §§ 482.59 and 485.649 new CoPs for hospitals and CAHs offering obstetrical services outside of an ED. Specifically, we proposed to require that if a hospital or a CAH offers obstetrical services, the services must be well organized and provided in accordance with nationally recognized acceptable standards of practice for physical and behavioral health care of pregnant, birthing, and postpartum patients (inclusive of both mental health and substance use disorders). We proposed that, if outpatient obstetrical services are offered, the services must be consistent in quality with inpatient care in accordance with the complexity of services offered. We noted that nationally recognized acceptable standards of practice may be based on medical professional society and/or accrediting organization standards and that, while these CoPs would not require adherence to a specific organization's guideline or recommendations, we would expect that facilities be able to articulate their standards and the source(s) and demonstrate that their standards are based on evidence and nationally recognized sources. This overarching requirement for obstetric services is consistent with other hospital and CAH CoPs and is foundational to ensuring high-quality safe care.

At new §§ 482.59(a) and 485.649(a), we proposed that the organization of the obstetrical services be appropriate to the scope of services offered by the facility and integrated with other departments of the facility. At §§ 482.59(a)(1) and 485.649(a)(1), we proposed that the OB patient care units (that is, labor rooms, delivery rooms, including rooms for operative delivery, and post-partum/recovery rooms whether combined or separate) be supervised by an individual with the necessary education and training, and specified that that person be an experienced registered nurse, certified nurse midwife, nurse practitioner, physician assistant, or a doctor of medicine or osteopathy.

At §§ 482.59(a)(2) and 485.649(a)(2), we proposed that obstetrical privileges be delineated for all practitioners providing obstetrical care in accordance with the competencies of each practitioner. The obstetrical service would be required to maintain a roster of practitioners specifying the privileges of each practitioner. We noted that all hospitals are already required, at § 482.22(c)(6), to have medical staff bylaws that include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges. Our proposed CoP would add additional specificity for an obstetrics service. The proposed obstetric services CoPs at §§ 482.59(a)(2) and 485.649(a)(2) recognize that practitioners other than physicians are important to delivering obstetric services. We again remind hospitals that existing CoPs allow for the privileging and credentialling of practitioners other than physicians, including nurse midwives (§ 482.12(a) and (c); § 482.22).

At new §§ 482.59(b) and 485.649(b), ''Delivery of services'', we proposed to require that OB services must be consistent with the needs and resources of the facility and that policies governing obstetrical care be designed to assure the achievement and maintenance of high standards of medical practice and patient care and safety. We additionally proposed at §§ 482.59(b)(1) and 485.649(b)(1) that labor and delivery room suites have certain basic equipment readily available, including a call-in-system, cardiac monitor, and fetal doppler or monitor. We welcomed public comment on what is an appropriate minimum set of equipment that takes into account the varied levels of services provided for all hospitals offering obstetric services.

At §§ 482.59(b)(2) and 485.649(b)(2) we proposed that the service ensure that it has protocols, consistent with evidence-based, nationally recognized guidelines, that equipment and personnel be ''readily available'' (that is, necessary supplies and equipment are on the unit or are in close proximity and easily accessed by unit personnel) for obstetrical emergencies, complications, immediate post-delivery care, and other patient health and safety events as identified as part of the facility's QAPI program. While this requirement does not require any specific items, we would expect provisions to include, in addition to the equipment required under §§ 482.59(b)(1) and 485.649(b)(1), equipment, supplies, blood, and medication used in treating emergency cases. As discussed in section XXI.B.2 of this final rule with comment period, obstetric readiness is a concern in avoiding preventable maternal morbidity and mortality. Provisions and protocols, as we proposed to require, are one step towards addressing those concerns and improving perinatal outcomes.

We solicited public comments on these proposals, including whether these proposed requirements should be applicable to REHs. We address those comments, and our responses below:

Comment: Many commenters generally supported the establishment of CoPs for the organization, staffing, and delivery of obstetrical services. These commenters also supported the requirement that OB services be provided in accordance with nationally recognized standards of practice for maternal health care. A commenter supported the proposed CoPs to require obstetrical services to be organized appropriate to the scope of the services offered. The commenter stated that the proposed policy would also allow flexibility for hospitals and CAHs without creating undue burden. Other commenters also recommended that the standards cover the full continuum of maternity care, including prenatal, labor, delivery, and postpartum periods. Commenters also stated that it is necessary to integrate OB services with other departments to address chronic conditions such as cardiovascular disease, hypertension, substance use, mental health conditions, and kidney disease.

Response: We appreciate the commenters support of these proposals. We continue to believe that establishing standards for obstetrical services supports the provision of high-quality maternity care and protects the health and safety of patients. We agree that it is important for all Medicare and Medicaid participating hospitals and CAHs that offer these services to be held to a consistent set of requirements. With regard to the commenters recommendation that the standards cover the full continuum of maternity care, as previously noted in the CY 2025 OPPS/ASC proposed rule at 89 FR 59490, for the purposes of these requirements, obstetrical services include labor and delivery, prenatal and post-partum care, and care for newborn infants. This care may be provided in obstetrical units, inpatient units, emergency departments, hospital outpatient departments. We specifically require at §§ 482.59 and 485.649 that, if the hospital or CAH offers obstetrical services, and if outpatient obstetrical services are also offered, the outpatient services must be consistent in quality

best-practice-guides/telehealth-for-maternal-health-services.

[644] CMS, State Medicaid & CHIP Telehealth Toolkit, February 2024. Available at: *https://www.medicaid.gov/medicaid/benefits/downloads/telehealth-toolkt.pdf.*

with inpatient care in accordance with the complexity of services offered. In facilities that do not provide inpatient obstetric services, but rather only outpatient prenatal, maternity, and/or postpartum care, those hospital or CAH outpatient departments remain subject to all applicable existing hospital and CAH CoPs, including the hospital CoP for Outpatient Services at § 482.54. We remind facilities that the existing QAPI standards at §§ 482.21 (for hospitals) and 485.641 (for CAHs) require that the QAPI program involve ''all hospital/CAH departments and services.'' Finally, with regard to comments on the integration of OB services with other departments or services, we also agree that this is essential in order to provide quality, comprehensive care and ensure good communication and collaboration with other services. We included specific requirements for the integration of OB services at §§ 482.59(a) and 485.649(a).

Comment: We received several comments that did not support the establishment of CoPs related to organization, staffing, and delivery of obstetrical services. Some commenters stated that they did not believe that adopting new CoPs would be the most appropriate method to improve maternal health. A few commenters stated that the organization, staffing, and delivery of maternity services should be organized at a regional or state level, and that Federal regulations would be duplicative or conflict with existing regulations. Commenters also expressed concerns regarding enforcement actions, including potential loss of Medicare certification program if facilities are unable to comply with the proposed requirements.

Response: We thank the commenters for this input. As previously noted, we believe that the establishment of CoPs for the organization, staffing, and delivery of obstetric services is a critical step in addressing the maternal health crisis that the country continues to face. It is one part of a comprehensive strategy that HHS is undertaking to improve the quality of maternal health services. We agree that it is important for States and regions to develop standards and guidance for OB services that takes into account the unique circumstances of their respective environments, in ways that do not conflict with the national minimum requirements set forth in this rule. However, we continue to believe that establishing national minimum requirements for OB services helps to ensure that all patients receiving obstetrical care in Medicare and Medicaid participating hospitals and CAHs are receiving safe, quality care. We believe that the proposed standards are achievable, and we have provided flexibilities, including additional time to come into compliance, and clarifications in this final rule to facilitate compliance with these requirements. In addition, as noted above, if a surveyor identifies deficiencies during their survey, the initial step is for the hospital to develop a Plan of Correction (PoC) to remedy the deficiency. This activity is intended to ensure that the hospital or CAH becomes compliant with the CoPs prior to the loss of certification.

Comment: Some commenters requested that we provide clarification regarding the term ''well organized'' in reference to the proposed condition statement for hospitals and CAHs at §§ 482.59 and 485.649, respectively, that if the hospital or CAH offers obstetrical services, the services must be well organized and provided in accordance with nationally recognized acceptable standards of practice for the health care (including physical and behavioral health) of pregnant, birthing, postpartum patients.

Response: As stated in the CY 2025 OPPS/ASC proposed rule, the requirements that we proposed for the organization, staffing, and delivery of obstetrical services, are similar to or consistent with the current requirements for other services that hospitals and CAHs may opt to provide, such as surgical services. The interpretive guidance, published in the State Operation Manual (SOM), provides further detail regarding the expectations for ''well-organized'' surgical services that we believe can provides additional context for the proposed obstetrical services requirements. Similar to the description of the organization of surgical services provided in Appendix A of the SOM at A–0940,[645] obstetrical services should be organized and staffed in such a manner to ensure the health and safety of patients. Additionally, similar to the interpretive guidance provided in the SOM, acceptable standards of practice for obstetrical services would also include maintaining compliance with applicable Federal and State laws, regulations and guidelines governing obstetrical services or obstetrical service locations, as well as any standards and recommendations promoted by or established by nationally recognized professional organizations. We maintain that this overarching requirement for obstetrical services in hospitals and CAHs is foundational to ensuring high-quality, safe care. We also believe that providers need the flexibility to determine how to organize the obstetrical services in their facility in a way that best aligns with the services provided, characteristics of their facility, and needs of their patient population and therefore we do not require adherence to a specific set of standards. Lastly, we also expect to provide interpretive guidance specific to obstetrical services in the SOM in the future which would further detail how providers can assure compliance with these regulations.

Comment: A commenter stated that the proposed requirement that outpatient obstetrical services offered be consistent in quality with inpatient obstetrical care in accordance with the complexity of services offered would be difficult for some organizations to achieve because they believe that the proposal is ambiguous. The commenter stated that treatment could be very different between patients. The commenter provided an example, stating that gestational diabetes is not the same as type two diabetes, and treatment of hyper- and hypo-glycemic episode in a pregnant patient versus and 85-year-old male patient generally, cannot be treated similarly and may have different outcomes.

Response: The proposed requirement is specific to the provision of obstetrical services. If a hospital or CAH elects to provide inpatient obstetrical services, we will require that any obstetrical services provided in the outpatient setting must be consistent in quality with any obstetrical services that the hospital or CAH provides to hospital inpatients. While we understand that there may be some variation in the method or duration of treatment provided when an individual receives outpatient treatment versus inpatient treatment, we would expect that the quality of the services provided in either setting would be equivalent.

Comment: With regard to standards of practice for OB staffing, a few commenters recommended that CMS structure the obstetrical service requirements to ensure adequate staffing levels. These commenters suggested resources for establishing recommended staffing levels (specifically the resources developed by the Association of Women's Health, Obstetric and Neonatal Nurses or the ANA). A commenter recommended that staffing models include community health workers and care coordinators.

A commenter recommended that CMS ensure that the requirements do not

[645] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf.*

become overly burdensome, citing physician shortages and burnout as particular challenges. A few commenters urged CMS to study and understand barriers to implementing existing staffing standards prior to finalizing the proposal. A commenter recommended that CMS not refer to the ACOG 2019 Levels of Maternal Care when developing subregulatory guidance, maintaining that the requirement regarding anesthesiologists as opposed to CRNAs will cause negative effects and that CRNAs are proven to be the most cost-effective model for anesthesia delivery. A few commenters expressed concern with the lack of specificity regarding the appropriate guidelines to follow to meet the proposed CoPs, stating that some guidelines and standards will be overly burdensome and mandatory staffing ratios could cause undue hardship.

Response: We thank the commenters for their input. We note that we did not propose any specific standards for staffing levels for OB units in hospitals or CAHs. Both hospitals (at § 482.23(b)) and CAHs (at § 485.635(d)) are already required to provide nursing care to meet patient needs. We strive to balance the need for hospitals and CAHs to tailor the organization, staffing and policies and equipment for delivery of service of their obstetrical service to the unique populations, capabilities, and constraints of that hospital or CAH, while still meeting the overarching health and safety standards established by the CoPs. We agree that the standards mentioned by the commenters are the types of standards that we would expect hospitals and CAHs to reference in meeting these new CoPs. However, as we have done in other CoPs, CMS is not mandating a specific set of standards. We reference the recommended standards of practice for OB services, including OB staffing, in the CY 2025 OPPS/ASC proposed rule as examples (89 FR 59490).

Comment: Another commenter stated that the proposed requirement that obstetrical services be integrated with other departments would be challenging because effective coordination with other departments is not fully within the control of the OB department and that communication challenges often occur when pregnant or postpartum patients are admitted in another unit or department. The commenter recommended that CMS provide best practices and resources to help hospitals improve internal communications across departments.

Response: We thank the commenters for their input. We continue to believe that, while potentially challenging, in order to provide high quality and safe care, it is essential that the OB unit be integrated with other departments in the hospital as applicable. The integration with other departments must be such that the facility can make available the full extent of its patient care resources, such as laboratory, surgery, or anesthesia, to assess and render appropriate care for a patient receiving obstetrical services, particularly in emergency situations. We note that such integration is already specifically required of some of the services that an OB unit would be expected to coordinate with. For example, it is required for hospital outpatient services at § 482.54(a) and emergency services at § 482.55(a)(2). With respect to best practices, in the CY 2025 OPPS/ASC proposed rule, we provide references to the recommended standards for practice for OB services developed by several accrediting bodies and professional medical specialty societies, such as ACOG and Society of Maternal Fetal Medicine (SMFM), which also includes discussions of strategies related to collaboration and communication within the facility as well as with external facilities in order to best treat the patient.[646] We also refer the reader to our HHS resources on Strengthening Maternal Health,[647] the CMS Maternity Care Action Plan,[648] the Medicaid Maternal and Infant Health Initiative resources,[649] and HRSA's Maternal & Child Health Bureau resources.[650]

Comment: A few commenters supported the proposed requirements at §§ 482.59(a)(1) and 485.649(a)(1) for labor and delivery rooms/suites (including labor rooms, delivery rooms (including rooms for operative delivery), and post-partum/recovery rooms whether combined or separate) to be supervised by an experienced registered nurse, certified nurse midwife, nurse practitioner, physician assistant, or a doctor of medicine or osteopathy. These commenters appreciated that we included a broader range of providers to supervise OB units, noting that these providers play an integral role in providing high quality reproductive health care and improving outcomes. A commenter supported inclusion of other caregivers, such as certified nurse midwives, direct entry midwives, Tribal midwives, and doulas in the staffing of labor and delivery units as allowed by State law. Some commenters stated that expanding the role of midwives and doulas could reduce disparities in maternal health outcomes. Another commenter stated that only physicians should supervise OB units.

Other commenters did not support the proposal and stated that CMS underestimated the difficulties involved with recruiting, training, and retaining qualified clinicians to supervise OB units at the proposed levels, particularly for rural hospitals and CAHs, adding that these costs are likely to disproportionately impact facilities most at risk for eliminating labor and delivery services. These commenters stated that the difficulty in retaining staff could result in the closure of OB units and the loss of OB services.

Other commenters suggested that CMS provide an exemption for community hospitals, CAHs, and other small hospitals to the 24/7 supervision requirement and that CMS allow supervision of maternity departments or units as opposed to rooms and suites. A commenter stated that the proposed requirement for having an OB/GYN physically present at all times would reduce their facility's designation from an OB Level III Unit to an OB Level II Unit which could increase the risk of having to transfer high-risk patients.

Response: We appreciate the comments provided. We understand the staffing challenges experienced by a number of facilities, particularly with regard to recruitment and retention in rural and other underserved areas. We note that the proposed requirement does not alter any of the current requirements related to supervision of services in hospitals and CAHs. We also expect that many hospitals and CAHs that currently opt to provide obstetrical services and would therefore be required to comply with these obstetrical services requirements. Additionally, they would have to have practitioners on staff that would perform supervision duties for the OB unit such as overseeing staff, training, overall patient care, and supporting communications within the unit and across the facility. This requirement was intended to recognize that practitioners other than physicians are important to delivering obstetric services and that we considered them when developing these provisions. Also, to clarify, we did not propose a requirement for an OB/GYN or any other practitioner to be physically present at all times, that is, 24/7, in a hospital or CAH to provide supervision of obstetrical services. The current CAH

[646] *https://www.acog.org/-/media/project/acog/acogorg/clinical/files/obstetric-care-consensus/articles/2019/08/levels-of-maternal-care.pdf.*

[647] *https://www.hhs.gov/healthcare/maternal-health/index.html.*

[648] *https://www.cms.gov/files/document/cms-maternity-care-action-plan.pdf.*

[649] *https://www.medicaid.gov/medicaid/quality-of-care/quality-improvement-initiatives/maternal-infant-health-care-quality/index.html.*

[650] *https://mchb.hrsa.gov/.*

CoPs at § 485.618(e), however, require CAHs to establish procedures, in coordination with emergency response systems in the area, under which a doctor of medicine or osteopathy is immediately available by telephone or radio contact on a 24-hours a day basis to receive emergency calls, provide information on treatment of emergency patients, and refer patients to the CAH or other appropriate locations for treatment.

We reiterate that if not otherwise prohibited by State law, a hospital may elect to include advanced practice providers, such as advanced practice registered nurses, clinical nurse specialists, physician assistants, and nurse midwives) as part of their medical staff. Moreover, the hospital CoPs prohibit a hospital from granting staff membership or professional privileges in the hospital solely upon certification, fellowship, or membership in a specialty body or society (§ 482.12(a)(7)). In States that permit nurse midwives to admit patients (in accordance with hospital policy and practitioner privileges), section 1861(e)(4) of the Act requires only Medicare hospital patients of a nurse midwife to be under the care of an MD or DO (§ 482.12(c)(2)). The statute does not require Medicaid nor other non-Medicare patients admitted by a nurse midwife to be under the care of an MD or DO.[376] For CAHs, CMS does not have the authority to remove the physician oversight requirement for inpatients at § 485.631(b)(1)(iv), as this is a statutory requirement and the physician oversight requirement for outpatients at § 485.631(b)(1)(v) is only applicable if required by State law.

With regard to including doulas in the staffing of an obstetrics unit, evidence demonstrates that doulas can improve outcomes, including reducing c-section frequency and improving the patient experience for mothers.[651] Nothing in these CoPs would restrict a hospital from utilizing doulas to support its obstetric patients, consistent with State law and acceptable standards of practice.

Comment: A few commenters requested clarification regarding the terms included in the proposed requirement. Specifically, commenters questioned what the term ''supervision'' means, including what minimum experience, education, or training is required for practitioners to supervise OB units. A few commenters stated that the term ''experienced'' clinician is not clearly defined and could create an arbitrary standard that small rural hospitals and CAHs may be unable to meet. One commenter recommended CMS provide more clarity, especially for smaller hospitals where staff often work in multiple specialties. Another commenter asked CMS to further define what is meant by ''OB patient care unit supervisor,'' noting that this role could include personnel from a shift-by-shift informal role to a formal unit supervisor or director role.

Response: We appreciate the commenters' input. We recognize that meeting this requirement may vary somewhat from facility to facility, based on the scope and complexity of the services offered. Similar to what is expected for surgical services, we would expect an OB unit to be supervised by an experienced registered nurse, certified nurse midwife, nurse practitioner, physician assistant, or a doctor of medicine or osteopathy. The individual supervising the obstetrical unit must demonstrate appropriate education, background working in obstetrical services, and specialized training in the provision of obstetrical services/management of obstetrical service operations. As noted above, we understand that this may vary somewhat based on the complexity and scope of the services offered by the facility. Thus, the hospital should address its required qualifications for the supervisor of the hospital's obstetrical unit in its policies and the supervisor's personnel file should contain information demonstrating compliance with the hospital's established qualifications.

Comment: Some commenters specifically opposed the proposed requirement at §§ 482.59(a)(2) and 485.649(a)(2) that obstetrical privileges be delineated for all practitioners providing obstetrical care in accordance with the competencies of each practitioner. Commenters also opposed the requirement for the obstetrical service to maintain a roster of practitioners and their specific obstetrical privileges, noting that a statement of the duties and privileges of medical staff are currently required in the CoPs regarding medical staff bylaws.

Response: The intent of the proposed regulation was to ensure that practitioners have the necessary education, training, and experience to provide safe, effective obstetrical care and appropriately perform specific procedures. We believed that the proposed CoP would provide additional specificity for obstetric service regarding the privileges of each practitioner on the service. While we anticipated that the proposed requirement would result in minimal additional burden, we appreciate the comments regarding the redundancy of this requirement with the medical staff bylaws at § 482.22(c) that require the inclusion of a statement of the duties and privileges of each category of medical staff as well as the inclusion of criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges. We agree that the information currently required in the medical staff bylaws meets the intended purpose of the proposed regulations. Therefore, we are finalizing the proposed CoP with a modification that references the requirements of the medical staff bylaws at § 482.22(c) for hospitals and the requirements for agreements for credentialing and quality assurance at § 485.616 for CAHs as opposed to finalizing a new requirement for the delineation of obstetrical privileges for all practitioners providing obstetrical care and the maintenance of a roster of practitioners and their specific privileges.

Comment: Some commenters supported the proposals at §§ 482.59(b)(1) and 485.649(b)(1) to require labor and delivery rooms to have certain basic equipment available to the room, including a call-in-system, cardiac monitor, and fetal doppler or monitor and recognized it as an effort to standardize equipment and supplies across facilities providing obstetrical care. One commenter specifically supported the requirements published in the Guidelines for Perinatal Care, 8th Edition, a joint publication by the American Academy of Pediatrics (AAP) and the American College of Obstetricians and Gynecologists (ACOG), in regards to equipment, in addition to the capabilities and equipment recommendations defined in the Levels of Maternal Care Consensus statement first published in 2015 by the American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal-Fetal Medicine (SMFM).

However, other commenters stated concerns about the proposal. Specifically, commenters requested clarity regarding what it means to have this equipment ''available'' and the evidence for proposing to require this equipment. These commenters noted concerns regarding the financial burden of providing the proposed equipment in every room, when it may not be necessary for the patient's treatment. They also stated that smaller or rural

[651] See for example, Sobczak A, Taylor L, Solomon S, Ho J, Kemper S, Phillips B, Jacobson K, Castellano C, Ring A, Castellano B, Jacobs RJ. The Effect of Doulas on Maternal and Birth Outcomes: A Scoping Review. Cureus. 2023 May 24;15(5):e39451. doi: 10.7759/cureus.39451. PMID: 37378162; PMCID: PMC10292163.

hospitals and CAHs with lower patient volume may have this equipment available to the unit, but not in every labor and delivery room, and suggested that CMS instead allow facilities to have the flexibility to provide equipment in accordance with the scope, volume and complexity of services they offer. Commenters were particularly concerned with the requirement to have a cardiac monitor in each room, stating that cardiac monitors are not typically clinically necessary in all labor and delivery settings and that this requirement would impose significant costs for purchasing the devices and for additional staff training, as not all staff are trained in their use. A commenter also asked for clarification as to whether a call-in system described a call button or a telemetry system, stating that a telemetry system in each room would be overly burdensome.

Lastly, other commenters recommended expanding the proposed requirement to include specific additional emergency equipment such as adult and newborn oxygen supplies, infant resuscitation equipment, crash carts, hemorrhage carts, limited obstetric ultrasonography, and equipment that facilitates quantification of blood loss.

Response: We appreciate the comments regarding the proposed requirement for the availability of equipment for the care of obstetrical patients. We understand commenters' concerns regarding financial investment and potential burden associated with providing the proposed equipment to each labor and delivery room or suite, if the facility does not currently have it available. We also understand that certain facilities, particularly smaller facilities or those in underserved areas, including rural areas, may not have the volume of obstetric patients or provide the level or scope of obstetrical care to necessitate the availability of this equipment in every labor and delivery room in order to safely and effectively care for their patients. We would, however, expect that facilities that treat a large volume or high acuity obstetrical patients would have the aforementioned equipment available in every labor and delivery room to meet the needs of their patient population.

Based on these comments and our review of the proposed requirement, we believe that, as a minimum standard, facilities offering OB services must have basic equipment for the care of OB patients readily available to meet the patients' needs. Therefore, we are finalizing §§ 482.59(b)(1) and 485.649(b)(1) with a modification to clarify that basic equipment for treating OB patients (including a call-in-system, cardiac monitor, and fetal doppler/monitor) must be kept at the facility and be readily available to meet the needs of OB patients in accordance with the scope, volume, and complexity of services offered by the facility. This means a large-volume high-acuity OB unit may have this equipment in every L&D room, while a rural hospital with a low-volume of births may have this equipment readily available within the hospital. Of note, by ''call-in system'', we mean a mechanism by which a patient and/or caregiver can alert staff of any emergencies or concerns. Examples may include a call-bell, alarm, or other notification device.

Additionally, at §§ 482.59(b)(2) and 485.649(b)(2), we will finalize the requirement that there must be adequate provisions and protocols, consistent with nationally recognized and evidence-based guidelines, for obstetrical emergencies, complications, immediate post-delivery care. Provisions include equipment (in addition to the equipment required under §§ 482.59(b)(2) and 485.649(b)(1)), supplies, and medication used in treating emergency cases. Such provisions must be kept in the hospital or CAH and be readily available for treating emergency cases. While this requirement does not require specific items, we would expect provisions to include equipment, supplies, blood, and medication used in treating emergency cases. In the proposed rule preamble, we provided examples of such supplies including: resuscitator, defibrillator, aspirator, and airways, endotracheal tubes, ambu bag/valve/mask, oxygen, tourniquets, nasogastric tubes, IV therapy supplies, suction machine, and defibrillator. Example emergency medications could include analgesics, local anesthetics, anti-arrhythmic, cardiac glycosides, antihypertensives, antiepileptics, uterotonics, anticoagulants, antifibrinolytics, electrolytes and replacement solutions. We note that hospitals and CAHs may maintain these and other obstetrical emergency supplies in ''crash carts'', ''obstetrical emergency carts/bags/boxes/kits'',[652] ''OB hemorrhage carts'',[653] or other readily accessible method for use when and where needed.

In response to commenters asking for additional specific emergency equipment, we believe the above finalized emergency supply requirement is comprehensive while allowing facilities flexibility to provide care in line with their scope, volume, and complexity of services. CMS is not prohibiting hospitals from stocking commenters' suggested supplies, but likewise is not mandating specific items given facilities' diverse practice settings and scope of services. Rather CMS will require facilities to stock provisions necessary for the care their obstetrical and neonate patient populations consistent with (1) nationally recognized and evidence-based guidelines as well as (2) the facilities' scope, volume, and complexity of services. This approach is consistent with the new requirement for emergency services readiness (§ 482.55; § 485.618) and existing CAH (§ 485.618(b) and (c)) and REH (§ 485.516(c)(2)) emergency supply standards.

Comment: A commenter requested clarification regarding whether delivery rooms in hospitals and CAHs, specifically rooms for operative delivery, would be required to meet the obstetrical services CoP or continue to be required to meet the surgical services CoPs. The commenter noted that their facility already complies with the surgical services CoPs at § 482.51 for their operative delivery rooms. We note there are also requirements for surgical services provided at CAHs at § 485.639.

Response: In the CY 2025 OPPS/ASC proposed rule, we included proposals for requirements for operative delivery rooms. Specifically, at §§ 482.59(a)(1) and 485.649(a)(1), we proposed to require OB patient care units, described as labor rooms, delivery rooms, including rooms for operative delivery, and post-partum/recovery rooms whether combined or separate, to meet specific requirements regarding supervision. At §§ 482.59(b)(1) and 485.649(b)(1) we proposed that hospitals and CAHs must have specific equipment available to the labor and delivery room suite. The finalized policy requires this equipment to be kept at the hospital and be readily available for treating obstetrical cases to meet the needs of patients. As noted in the interpretive guidance provided in the SOM (A–0940), if a hospital provides any degree of surgical services to its patients, the hospital must comply with all the requirements of the surgical services CoP. Therefore, we expect hospitals and CAHs to continue to comply with the surgical services CoP. Additionally, we expect hospitals and CAHs to meet any requirements specific to obstetrical services that are not delineated in the surgical services CoP. For example, we would expect that

[652] *https://saferbirth.org/aim-obstetric-emergency-readiness-resource-kit/.*

[653] *https://saferbirth.org/wp-content/uploads/3-FINAL_AIM_OERRK_Readiness.pdf.*

hospitals and CAHs providing obstetrical services would ensure that the OB patient care unit, including operative delivery rooms, have the basic equipment relevant to maternal care available in the unit.

Comment: There were supportive comments for the proposed requirement that the obstetric service have protocols and provisions to address obstetrical emergencies, complications, immediate post-delivery care, and other patient health and safety events as identified as part of the facility's QAPI program. One commenter recommended expanding the current list of equipment used in life-saving procedures to include an incubator and another commenter noting that equipment should be available for prenatal as well as neonatal emergencies. A few commenters recommended including protocols for transport as an important part of addressing emergencies, including transfer to a hospital with sufficient blood supply to address significant maternal hemorrhage and the capability to transport neonatal patients.

One commenter did not support the proposal stating that multiple protocols would be appropriate for complex patients, and it would be challenging to identify the appropriate protocol.

Response: We appreciate these recommendations. We reiterate that the proposed requirements at §§ 482.59(b)(2) and 485.649(b)(2) do not require hospitals and CAHs to have any specific items on the unit or in close proximity. The list of emergency equipment and supplies provided in the CY 2025 OPPS/ASC proposed rule (89 FR 59492) included examples of provisions that we would expect facilities to have available in order to quickly and effectively address obstetrical emergencies and other issues. Therefore, at this time, we do not believe that it is necessary to include any additional supplies or medications in this list. Additionally, while we acknowledge that some facilities may experience challenges in establishing protocols to address these issues that anticipate the complexities involved in this care, we believe that these protocols are an important step towards avoiding preventable maternal morbidity and mortality and improving maternal health outcomes. We believe this is an achievable minimum standard. We note that we discuss the policies regarding transfer protocols in section A.XXI.6 of this final rule with comment period.

Comment: In response to our comment solicitation regarding whether the proposed requirements for the organization, staffing, and delivery OB services should be applicable to REHs, we received a variety of comments. A commenter encouraged CMS to apply the organization, delivery, and training requirements to REHs. A few commenters stated that an REH should be staffed by an emergency medicine physician with experience and continuing education requirements in obstetric medicine, and a commenter suggested that emergency physicians who are competent in OB care should be credentialed to perform deliveries.

Response: With respect to applying these proposed requirements to REHs, we appreciate commenters insights and recommendations, as noted above. We will take these comments into consideration for future potential rulemaking.

Final Rule Action: After consideration of the public comments we received, we are finalizing these provisions as discussed below.

For hospitals, we are finalizing the following CoPs as proposed:

Section 482.59 (Condition of participation: Obstetrical services):

- Section 482.59(a) (Standard: Organization and staffing);
- Section 482.59(a)(1);
- Section 482.59(b) (Standard: Delivery of service); and
- Section 482.59(b)(2).

We are finalizing the following CoPs with modifications:

- Section 482.59(a)(2) with a modification to reference the requirements of the medical staff bylaws at § 482.22(c) for hospitals.
- Section 482.59(b)(1) with a modification to clarify that basic equipment, including a call-in-system (we note that for the purposes of this regulation, call-in system describes a call button), cardiac monitor, and fetal doppler or monitor must be kept at the hospital and be readily available for treating obstetrical cases to meet the needs of patients.

For Critical Access Hospitals, we are also finalizing the following CoPs as proposed:

Section 485.649 (Condition of participation: Obstetrical Services):

- Section 485.649(a) (Standard: Organization and staffing);
- Section 485.649(a)(1);
- Section 485.649(b) (Standard: Delivery of service); and
- Section 485.649(b)(2)

We are finalizing the following CoPs with modifications:

- Section 485.649(a)(2) with a modification to reference the requirements for agreements for credentialing and quality assurance at § 485.616 for CAHs.
- Section 485.649(b)(1) with a modification to clarify that basic equipment, including a call-in-system (we note that for the purposes of this regulation, call-in system describes a call button), cardiac monitor, and fetal doppler or monitor must be kept at the hospital and be readily available for treating obstetrical cases to meet the needs of patients.

3. Training for Obstetrical Staff in Hospitals and CAHs (§§ 482.59(c), 485.649(c))

We proposed at new §§ 482.59(c) and 485.649(c) that hospitals and CAHs with OB services would be required to develop policies and procedures that would ensure that relevant obstetrical services staff would be trained on select topics that reflect the scope and complexity of services offered, including but not limited to facility-identified evidence-based best practices and protocols to improve the delivery of maternal care within the facility. We also proposed that any additions, revisions, or updates to topics be informed by the hospital and CAH's QAPI program findings. Additionally, we proposed that governing body to identify and document which staff must complete annual training and that the hospital and CAH must document in the staff personnel records that the training was successfully completed. Further, we proposed that the hospital and CAH be able to demonstrate staff knowledge on the topics identified at §§ 482.59(c)(1) and 485.649(c)(1), respectively. We solicited public comment on these proposals, including whether these proposed staff training requirements should be applicable to REHs. We also solicited public comment on whether CMS should require specific training on person-centered care, trauma-informed care, cultural competency, and/or other topics as part of the evidence-based training.

In the following section we discuss the public comments received and our responses on proposed §§ 482.59(c) and 485.649(c), which would require hospitals and CAHs to train OB staff on key maternal health topics.

Comment: Several commenters supported requiring evidence-based trainings for staff at hospitals with OB services, noting that if properly implemented the proposal will likely lead to significant improvements in health outcomes by ensuring staff are well-trained and that a consistent minimum standard of care is delivered nationwide.

Many commenters also supported the requirement to train OB staff on select topics aimed at improving the delivery of maternal care and recommended several specific topics that OB staff

should be trained on. Several commenters supported requirements for training related to cultural competency, highlighting the negative health outcomes and health inequities that result from a lack of culturally competent care. For example, commenters shared that the lack of cultural competency among non-Tribal providers has contributed to poor quality care for pregnant and birthing Native women. Another commenter underscored the importance of combatting medical misinformation as it contributes to health inequities. For example, the commenters noted that it is still a common belief among medical professional students that Black patients have a higher pain tolerance than white patients. Because of this, Black patients often do not receive proper main management.

A few commenters also supported trauma-informed care (TIC) as a training topic, explaining that TIC training prepares staff to support patients who have experienced trauma. A commenter also supported inclusion of person-centered care training topics because these care models are associated with increased patient satisfaction and trust. Some commenters also recommended training on substance use disorders and related topics including neonatal abstinence, perinatal mood disorders, and managing substance use disorder within pregnant patients. Various other topics included health disparities, care for people with disabilities, and pregnancy criminalization. A few commenters also recommended clinical topics including severe hypertension/preeclampsia, hemorrhage, fetal monitoring, shoulder dystocia, and neonatal resuscitation.

Conversely, a few commenters recommended that CMS not specify training topics within the CoPs, explaining that because hospitals serve diverse patient populations, it is more appropriate for hospitals to determine the most relevant training topics.

Response: We thank commenters for their support and highlighting the improved health care outcomes staff training will lead to as well as providing recommendations on additional topics to improve the delivery of maternal care. These requirements will support clinicians in performing vital tasks consistently through evidence-based standardized practices, which can ultimately reduce errors.[654]

While CMS encourages facilities to train staff on the aforementioned topics, we also recognize that hospitals and CAHs serve diverse populations with unique needs. Therefore, we are providing facilities with the flexibility to select which evidence-based best practices and protocols to train on that reflect the scope and complexity of the services offered within their facility and the needs of their specific patient population. Based on the findings from a facility's QAPI program, a facility may determine that some of the aforementioned topics are important for staff to be trained on in order to improve patient outcomes or address disparities. For example, a CAH's QAPI program may reveal that a significant portion of their obstetrical patients have diagnosed substance use disorders (SUD). Subsequently, this CAH may decide to pursue training for their OB staff on behavioral health and/or medications for opioid use disorder. Another hospital's QAPI findings may reveal that a large percentage of their patient population does not speak English as their first language. To address this, the hospital may pursue training relevant staff on the culturally and linguistically appropriate care and/or person-centered care. While not required, facilities that wish to learn more about culturally competent care and person-centered care may wish to review the following resources among others:

- Think Cultural Health. Health and Human Services. Office of Minority Health, Department of Health and Human Services. *https://thinkculturalhealth.hhs.gov/clas*.
- Addressing Health Literacy. Health Resources and Services Administration. *https://www.hrsa.gov/about/organization/bureaus/ohe/health-literacy/culture-language-and-health-literacy*.
- Behavioral Health Implementation Guide for the National Standards for Culturally and Linguistically Appropriate Services in Health and Health. Office of Minority Health, Department of Health and Human Services. *https://thinkculturalhealth.hhs.gov/assets/pdfs/resource-library/clas-standards.pdf*.
- Fundamentals of the National Standards for Culturally and Linguistically Appropriate Services in Maternal Healthcare, Office of Minority Health, Department of Health and Human Services. *https://thinkculturalhealth.hhs.gov/resources/presentations/1/fundamentals-of-the-national-standards-for-culturally-and-linguistical*.
- Culturally and Linguistically Appropriate Services in Maternal Health Care, Department of Health and Human Services. *https://thinkculturalhealth.hhs.gov/education/maternal-health-care*.

Comment: A few commenters stated that requiring the governing body to identify and document which staff must complete annual training is inconsistent with governing body activities, which typically focus on oversight. Another commenter stated that hospitals' governing bodies may lack the medical expertise to identify which staff must complete annual training. These commenters noted that regulation implementation details are generally determined by service line leadership, and therefore, medical leadership should guide training decisions to ensure effective and relevant instruction.

Response: The hospital governing body performs a broad array of functions and is responsible for a variety of tasks, including but not limited to planning and budgeting, care of patients, managing contracted services, and participating in the QAPI program. Section 482.12(a)(10) requires the hospital governing body to consult directly with the individual assigned the responsibility for the organization and conduct of the hospital's medical staff. In addition, governing bodies have experience appointing individuals for certain roles and also have the ability to grant clinical privileges. For example, § 485.639 states, ''If a CAH provides surgical services, surgical procedures must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body.'' The governing body is also responsible for appointing an individual or individuals to serve as the infection preventionist/infection control professional (§§ 482.42(a)(1), 485.640(a)(1)). Thus, we believe that determining which relevant staff must be trained on maternal health topics is not outside the scope of their capabilities and standard activities. Further, we note that the governing body has the ability to delegate tasks and responsibilities, including to medical staff, but maintains overall responsibility for compliance.

Comment: Some commenters requested CMS provide additional guidance regarding which staff will be required to complete OB training and provided further recommendations for staff that may require additional training. For example, a commenter requested clarification on training for staff without specific maternity credentials and privileges for midwives who do not have formal educational training, while another commenter

[654] *https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2019/10/clinical-guidelines-and-standardization-of-practice-to-improve-outcomes.*

recommended that CMS develop guidance for the training of Nurse Practitioners, Physician Assistants, and direct entry midwives. Some commenters also suggested implementing standards that are developed for non-obstetrical staff, as appropriate, as they may still have interactions with OB patients. The commenter noted that these staff should have basic knowledge on the leading causes of maternal deaths (*e.g.,* hemorrhage, hypertension, and mood disorders).

Response: As outlined in the introductory paragraph of §§ 482.59 and 485.649, ''Condition of participation: Obstetrical services,'' if a hospital or CAH offers OB services, the services must be well organized and provided in accordance with nationally recognized acceptable standards of practice for the health care of pregnant, birthing, and postpartum patients. At §§ 482.59(c)(3) and 485.649(c)(3), we are requiring the governing body of hospitals and CAHs to identify and document which relevant staff must complete the training. While we are providing hospitals and CAHs with the flexibility to determine training topics based on the scope and complexity of their services and also with the flexibility to determine the format to administer the training, we expect facilities to provide high-quality training, consistent with, and tailored to the staff's expected role, with the goal of improving the delivery of obstetrical care.

We recognize that staff outside of OB units may also interact with OB patients. Thus, we are also requiring staff to be trained on transfer protocols (§ 482.43(c)) and emergency services readiness (§§ 482.55(c)(3), 485.618(e)(2)). We refer readers to sections A.XXI.5 and A.XXI.6 of this final rule with comment period for additional details on training on emergency services readiness transfer protocol training, respectively. This requirement does not preclude hospitals or CAHs from training additional staff on maternal health topics.

Comment: Some commenters supported that findings from QAPI programs should be used to inform training needs and updates on an ongoing basis. A commenter requested CMS more clearly define ''ongoing basis'' and instead suggested we incorporate different terminology, such as ''annually.''

Response: Stratified data can produce meaningful measures that can be used to expose health disparities, develop interventions to reduce them, and monitor performance to ensure interventions aimed at improving care do not have unintended consequences for certain patients and improve patient outcomes.[655] Continuous quality improvement depends on a disciplined and well-defined data-driven process that constantly is monitored and improved.[656] Facilities must review findings from their QAPI programs on an ''ongoing basis'' to determine any additions, revisions, or updates to training concepts. That is, facilities should be able to verify that data analyses and collection are occurring over time and are not just one-time events. Hospitals and CAHs should perform follow-up analyses on its remedial actions to determine if its actions were effective in improving performance and quality. We also expect hospitals and CAHs to continuously study and improve their processes and service delivery and take a proactive approach to improve their performance (QSO-23-09-Hospital).[657] We refer readers to section A.XXI.3 of this final rule with comment period for further details on the updated QAPI requirements.

Comment: Some commenters provided recommendations regarding the modality in which staff be trained on pertinent maternal health topics. For example, a commenter recommended that training should be completed in an active learning style which involves staff collaboration. Another commenter recommended against requiring simulation training. Lastly, a few commenters recommended that staff be trained upon hire or complete an orientation program.

Response: While we acknowledge the benefits of training in a collaborative environment that encourages increased staff engagement, we are not requiring the training to be completed in a specific manner or format. These requirements permit facilities with the flexibility to determine the manner in which staff are trained on evidence-based best practices and protocols to advance the delivery of maternal care and other training topics as identified by the facilities' QAPI program. This flexibility allows facilities to test different approaches to conducting training over time, which could be informed by post-training evaluations or monitoring of outcomes.

High-quality orientation of trainees entering a new health care setting is imperative to support education and patient safety.[658] Therefore, we are revising the staff training requirements and will require staff to complete training when hired. Specifically, at new §§ 482.59(c)(2) and 485.649(c)(2) we are requiring hospitals and CAHs to provide relevant new staff with initial training. We are also requiring the governing body to identify and document what staff must complete the initial training and subsequent biannual training on evidence-based best practices at §§ 482.59(c)(3) and 485.649(c)(3). Research has demonstrated that a practical and well-structured nursing orientation program can have a positive impact on new nurses who are joining health care organizations, including improved competence.[659] [660] Another study demonstrated that effective new employee orientation reduces role ambiguity and role conflict. Role ambiguity is negatively correlated to task performance and role conflict reflects job attitudes.[661] The Joint Commission describes an orientation program, ''as an introductory program and/or activities intended to guide a person in adjusting to new surroundings, employment, policies/procedures, essential job functions, etc.[662] The hospital or CAH will be responsible for determining when and how long a person is considered to be in orientation.

Comment: Several commenters stated that financial, staffing, and infrastructure limitations would make training requirements burdensome for facilities. Commenters recommended modifying the proposed provisions to accommodate the specific needs of each facility and provide resources, technical assistance, and financial support/funding, particularly for hospitals in rural and/or underserved areas, to help facilities effectively implement the provisions. To ensure high-quality training, some commenters recommended specific resources that facilities may use as a guide to implement these requirements. Some examples include the HHS training ''Culturally and Linguistically Appropriate Services (CLAS) in

[655] *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2011.0617*

[656] *https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2019/10/clinical-guidelines-and-standardization-of-practice-to-improve-outcomes.*

[657] *https://www.cms.gov/files/document/qso-23-09-hospital.pdf*

[658] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8760640/.*

[659] *https://www.sciencedirect.com/science/article/pii/S2666142X24000419#bib0028.*

[660] *https://www.sciencedirect.com/science/article/pii/S2352013221000028.*

[661] *https://www.sciencedirect.com/science/article/pii/S0278431920304096.*

[662] *https://www.sciencedirect.com/science/article/pii/S2666142X24000419#bib0028.*

Maternal Health Care [663] and ACOG's ''Guidelines for Perinatal Care, 8th Edition.'' [664]

Response: We understand the commenter's concerns about the potential burden that these training requirements could place on facilities. We therefore are revising the staff training requirements and reduced the frequency to every two years to ease any financial strain this requirement may place on facilities. While facilities will have upfront costs to implement these requirements, the benefits for patient outcomes outweighs the burden. Additionally, hospitals and CAHs have the flexibility to identify which evidence-based best practices and protocols they will train on to improve the delivery of maternal care within their facility. We are not prescribing a specific format the training be conducted in, allowing facilities to carry out the training in a manner that best fits their needs. In addition, we are also allowing for a staggered implementation. Further details on the implementation timeframe can be found in section A.XXI.7 of this final rule with comment period. During this time period, facilities will be able to gather resources and support to be prepared for the effective date.

To further mitigate burden concerns, we refer facilities to several resources facilities that may be utilized to achieve compliance with these requirements (although others may be used). For example, facilities will have support from Quality Improvement Organizations (QIOs), which serve people with Medicare, health care providers, and communities. The QIO Program data-driven initiatives bring stakeholders together at the local, community, and tribal levels to improve care coordination and the quality-of-care transitions and increase patient safety.[665] Perinatal quality collaboratives (PQCs) are State or multistate networks of teams that work to identify health care processes in need of improvement in order to advance the quality of care for mothers and babies.[666] Additionally, the Health Resource and Services Administration (HRSA) funds the Alliance for Innovation on Maternal Health (AIM) to establish patient safety bundles.[667] [668] Perinatal quality collaboratives often support the implementation of maternal safety bundles, which have documented success in driving improvements, particularly with regards to obstetric hemorrhage, severe hypertension in pregnancy, and non-medically indicated Cesarean deliveries.[669] [670] [671] [672]

As commenters outlined, facilities may use the credentialing published in the ''Guidelines for Perinatal Care, 8th Edition'' [673] or the HHS ''Culturally and Linguistically Appropriate Services (CLAS) in Maternal Health Care'' [674] training as a resource. Of note, these CoPs do not require adherence to a specific organization's guidelines or recommendations. We expect that facilities will be able to articulate their standards and the source(s) and to demonstrate that their staff training requirements are based on evidence-based best practices. As previously discussed in sections XXIA.1 and XXI.A.2 of this final rule with comment period, HHS and HRSA have established several initiatives to address the health care workforce shortage; CMS is not mandating a specific staffing standard.

Comment: Multiple commenters discussed existing staff training requirements that may be required through either accreditation standards and/or continuing education requirements. Some commenters recommended that CMS maintain flexibility in the training requirements to accommodate existing training requirements from national accreditation and credentialing bodies and to align with best practices from accreditation agencies (for example, TJC) which require a biannual training cycle. Other commenters questioned if the staff training requirement is in addition to continuing education requirements for clinical staff.

Response: We are aware that the majority of hospitals participate in the Medicare program through deemed status with an accrediting organization [675] and that accrediting organizations may have additional requirements that exceed Medicare CoP requirements as part of their CMS-approved deeming program. If a facility is in compliance with those requirements, this may also facilitate compliance with this requirement. Continuing medical education (CME) from local, State, hospital, specialty society, and accrediting organizations may be used by providers and facilities to meet these new requirements, subject to (1) facility's choice of ''evidence-based best practices and protocols to improve the delivery of maternal care within the facility and (2) facility QAPI findings. For example, a specialty society may require that providers complete CME on maternal hypertension (HTN). If the hospital chooses maternal HTN as a training topic and identifies the same specialty society training, then it would align, and the provider may only have to do one training to meet both requirements. Conversely, if the hospital does not choose maternal HTN or creates its own training/protocol, then the provider would have to complete two trainings in this case.

Comment: A few commenters cautiously supported including REHs in the requirements for OB staff training, to the extent such training fits with the REH's scope of practice. A commenter explained that because these requirements allow for flexibility in designing the training curriculum and selecting appropriate trainers, this requirement should apply to REHs. However, another commenter expressed the concern that the ability to provide training would be diminished for REHs because of lack of experience with OB emergencies.

Response: While we recognize that OB staff training is important for REHs as patients utilizing these services may be some of the most high-risk populations, we are not extending the OB staff training requirement to REHs at this time. While not required, we still encourage REHs to train their staff on evidence-based best practices to improve the delivery of maternal care to their patients, within the scope and complexity of the services offered in their facility, to the extent the REH has the resources/capacity to do so. We acknowledge that some REHs may have already implemented these practices. We expect facilities to utilize organizations or individuals that are properly qualified or credentialed to

[663] *https://thinkculturalhealth.hhs.gov/education/maternal-health-care.*

[664] *https://www.acog.org/store/products/clinical-resources/guidelines-for-perinatal-care.*

[665] *https://www.cms.gov/medicare/quality/quality-improvement-organizations.*

[666] *https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pqc.htm.*

[667] *https://saferbirth.org/about-us/.*

[668] *https://www.ihi.org/insights/what-is-a-bundle.*

[669] Jennifer A. Callaghan-Koru et al. Implementation of the Safe Reduction of Primary Cesarean Births safety bundle during the first year of a statewide collaborative in Maryland. Obstet Gynecol 2019;134:109–19.

[670] Elliott K. Main et al. Reduction of severe maternal morbidity from hemorrhage using a state perinatal quality collaborative. Am J Obstet Gynecol 2017;216(3):298.e1–298.e11.

[671] Patricia Lee King et al. Reducing time to treatment for severe maternal hypertension through statewide quality improvement. Am J Obstet Gynecol 2018;218:S4.

[672] *https://www.cms.gov/files/document/qso-22-05-hospitals.pdf.*

[673] *https://www.acog.org/store/products/clinical-resources/guidelines-for-perinatal-care.*

[674] *https://thinkculturalhealth.hhs.gov/education/maternal-health-care.*

[675] *https://www.jointcommission.org/resources/news-and-multimedia/fact-sheets/facts-about-hospital-accreditation/.*

oversee the training and have demonstrated knowledgeable on the subjects.

Final Rule Action: After consideration of the public comments we received, we are finalizing the staff training requirements with modifications as outlined below.

For hospitals, we are finalizing the following CoPs as proposed:

- Section 482.59(c)(1).
- Section 482.59(c)(1)(i).
- Section 482.49(c)(1)(ii).
- Section 482.49(c)(4).
- Section 482.49(c)(5).

For hospitals, we are finalizing the following CoPs with modifications:

- Section 482.59(c) with a modification to clarify that the effective date of the staff training requirements for hospitals is January 1, 2027 (two years are the effective date of the final rule).
- Section 482.59(c)(2) with a modification to require the hospital to provide relevant staff with initial training.
- Section 482.59(c)(3) with a modification to require the governing body to identify and document which staff must complete an initial training and subsequent biannual training.

For CAHs, we are finalizing the following CoPs as proposed:

- Section 485.649(c).
- Section 485.649(c)(1)(i).
- Section 485.649(c)(1)(ii).
- Section 485.649(c)(4).
- Section 485.649(c)(5).

For CAHs, we are finalizing the following CoPs with modifications:

- Section 485.649(c) with a modification to clarify that the effective date of the staff training requirements for CAHs is January 1, 2027 (two years after the effective date of the final rule).
- Section 485.649(c)(2) with a modification to require the CAH to provide relevant staff with initial training.
- Section 485.649(c)(3) with a modification to require the governing body to identify and document which staff must complete an initial training and subsequent biannual training.

4. Quality Assessment and Performance Improvement (QAPI) Program (§ 482.21; § 485.641)

We proposed revisions to the existing QAPI standards (§ 482.21; § 485.641) for hospitals and CAHs that offer obstetrical services.[676] First, we proposed that a hospital or CAH that offers OB services would be required to use its QAPI program to assess and improve health outcomes and disparities among OB patients on an ongoing basis (§ 482.21(b); § 485.641(e)(2)). Specifically, the facility at a minimum must: (1) analyze data and quality indicators collected for the QAPI program by diverse subpopulations as identified by the facility among OB patients; (2) measure, analyze, and track data, measures, and quality indicators on patient outcomes and disparities in processes of care, services and operations, and outcomes among OB patients; (3) analyze and prioritize patient health outcomes and disparities, develop and implement actions to improve patient health outcomes and disparities, measure results, and track performance to ensure improvements are sustained when disparities exist among OB patients; and (4) conduct at least one performance improvement project focused on improving health outcomes and disparities among the hospital's population(s) of OB patients annually.

Next, under a new standard for Maternal Health QAPI activities for hospitals (§ 482.21(e)(1)) and CAHs (§ 485.641(d)(4)(i)), we proposed to require that for hospitals and CAHs that offer OB services, leadership must be engaged in the facility's QAPI activities. For purposes of this provision, leadership is defined as facility leadership, obstetrical services leadership, or their designate(s).

We further proposed that if a MMRC is available at the State or local jurisdiction in which the facility was located, hospitals (at § 482.21(e)(2)) and CAHs (at § 485.641(d)(4)(ii)) that offer OB services must have a process for incorporating MMRC data and recommendations into the facility's QAPI program.

Finally, we solicited public comments and evidence related to these proposals, including how these proposals would impact maternal health and safety, how facilities currently use their QAPI programs to address maternal health, best practices for data analysis and stratification in QAPI programs, best practices for sharing QAPI findings with impacted communities, and whether these proposed requirements should be applicable to REHs.

We received several comments on these proposals. We address those comments and our responses below:

Comment: Many commenters supported encouraging the use of QAPI programs to collect data, evaluate disparities, and address gaps in maternal health care to improve equity and outcomes for OB patients. Specifically, several commenters supported the QAPI revisions for OB patients related to data analysis, describing such QAPI work as important for improving maternal health. Several commenters stated that targeted data collection and analysis by diverse subpopulations is important for identifying disparities and enabling data-driven interventions. A few commenters also appreciated the CMS' permitting flexibility for hospitals to use the data analysis methodology most appropriate for their patient population.

However, other commenters expressed concern regarding the potential burden of these standards in terms of staff, technology, and data expertise, which could cause more hospitals to eliminate OB services and contribute to worse access to OB care and higher risks of maternal and infant morbidity and mortality, especially in rural and underserved communities. Multiple commenters recommended a phased implementation of the requirements to ensure facilities can successfully meet the new standards. Multiple commenters recommended that CMS offer resources (including financial) and technical assistance to support implementation, especially in rural facilities.

Response: We appreciate all input received on this topic. We agree that data analysis by diverse subgroup can drive improvements in maternal health and reduce associated disparities. As discussed in the CY 2025 OPPS/ASC proposed rule preamble, this new standard builds on other CMS quality improvement and data analysis initiatives, such as the ''Birthing-Friendly'' hospital designation and complements existing work by State Perinatal Quality Collaboratives.[677] Such initiatives can reduce the burden on facilities in meeting these revised requirements. Facilities may also choose to partner with QIOs as well as leverage integrated health system resources (as described in 42 CFR 482.21(f)) in order to reduce any burden of compliance. In addition to the resources cited in the CY 2025 OPPS/ASC proposed rule, CMS will develop guidance for facilities to support compliance with these new standards. We note that financial assistance or issues pertaining to payment policy are beyond the scope of

[676] For purposes of the proposal, CMS considers a facility to ''offer obstetrical services'' when the facility ''[holds itself] out to the public (by name, posted signs, advertising, or other means) as a place that provides care for obstetrical medical conditions.'' This is similar to how emergency departments are defined in EMTALA (42 CFR 489.24(b), ''Dedicated emergency department'', paragraph (2)).

[677] *https://www.cdc.gov/maternal-infant-health/pqc/index.html.*

the CoPs. CMS will also allow for a phased in implementation timeline for these QAPI standards as further discussed in section XXI.A.7 of this final rule with comment period.

Comment: Multiple commenters noted concern for duplication and overlapping Federal quality efforts related to maternal health and these new CoPs. One commenter stated that the existing QAPI CoP requirements are comprehensive, making any new QAPI requirements unnecessary and duplicative.

Instead of the CoPs, several commenters suggested CMS use other policy levers, such as existing quality reporting and performance improvement programs, to incentivize improvements in maternal health care. Another commenter noted that hospitals are already involved in multiple OB quality efforts, including already having a QAPI program in their OB department, pursuing the ''Birthing-Friendly'' designation, and adopting maternal health focused quality measures. Additionally, a few commenters noted hospitals are already working to comply with CMS IQR program's new ''Hospital Commitment to Health Equity'' measure,[678] and that other programs exist to report data related to cesarean rates stratified by race and ethnicity. One commenter expressed concern that multiple projects addressing stratification may lead to confusing or duplicative requirements, which could increase burden on safety net hospitals which are already resource limited. Another commenter stated that the HHS Perinatal Improvement Collaborative is an existing example of using data to drive clinical quality improvement and advance health equity.

Commenters also flagged that the Federal Government is currently implementing new policies for the collection and use of race and ethnicity data. A few commenters recommended postponing requirements on the collection, reporting, and use of race and ethnicity data until OMB's revised race and ethnicity data collection standards are fully implemented. These commenters recommended focusing instead on other activities, such as implementation of HHS's Action Plan on Race and Ethnicity Data in preparation for the revised data collection standards.[679]

Overall, these commenters recommended that CMS support providers in these existing quality initiatives, as well as State Perinatal Quality Collaboratives, that foster the sharing of innovations and best practices, rather than pursue new CoPs. Multiple commenters recommended allowing hospitals flexibility to determine their own priorities for data collection, tracking, and analysis rather than new CoPs. A few commenters suggested that CMS provide incentives to facilities that demonstrate participation in evidence-based initiatives to improve maternal and infant health.

Response: CMS has developed a robust number of quality initiatives to spur improvements in maternal health, including the ''Birthing-Friendly'' designation [680] and hospital IQR measures [681] related to maternal health. We appreciate commenters highlighting CMS' ongoing efforts related to quality metrics and maternal health. CMS considers the new QAPI standards for OB services to be complementary to these quality initiatives, rather than duplicative. CMS is not seeking to create new burden nor have facilities repeat existing work, but rather ensure facilities' participation in quality initiatives in order to improve maternal morbidity and mortality while preserving flexibility for facilities in how they choose to go about doing so. Facilities may choose to develop their own quality initiatives/projects or join other local/state/Federal maternal health quality efforts as part of their QAPI program. As discussed in the CY 2025 OPPS/ASC proposed rule preamble, facilities may use data from State Perinatal Quality Collaboratives, CMS IQR maternal health quality measures, or other Federal or State maternal health quality initiatives in order to meet these new QAPI standards at reduced burden. CMS has also provided facilities with the flexibility to choose which maternal health topics and data analysis methods to use in meeting these standards so that their QAPI programs may be tailored to their unique patient populations.

Comment: Commenters also questioned whether new QAPI standards for OB services could cause unintended consequences due to low data quality and/or lack of data expertise. Specifically, a few commenters expressed concerns that analyses based on data which has not been validated may cause health care systems and hospitals to expend resources to identify trends or establish policies that fail to address the root cause of poor maternal health outcomes and inequities. A few commenters cautioned that misclassification or aggregation of data across diverse populations can mask disparities or inflate trends, leading to faulty conclusions, and that failing to account for systemic biases in data collection or analysis can perpetuate existing inequities. Another commenter expressed concern that many hospitals do not have staff sufficiently skilled in analyzing complex datasets to understand the relationship of SDOH data to clinical outcomes.

Response: As discussed in the preamble, hospitals are encouraged to utilize the data analysis methods that best fits their patient population and data analysis resources, and to utilize best practices in conducting their QAPI work. Partnering with QIOs, joining existing local/state/Federal quality efforts, and leveraging integrated health system resources can all be potential options for allowing facilities to comply with these new standards and access data analysis expertise and staff support, while being mindful of burden.

Comment: While several commenters appreciated CMS' permitting flexibility for hospitals to use the data analysis methodology most appropriate for their patient population, other commenters recommended that CMS consider the needs of providers with limited data collection resources or capabilities (staff, technology, data). Specifically, a few commenters stated that it is difficult to conduct statistically valid analyses of subpopulations due to the small number of deliveries in many rural hospitals, and that these data challenges complicate the efforts of smaller hospitals to assess and address disparities. Several commenters were concerned that smaller healthcare facilities may face privacy concerns due to the small size of certain subgroups. Additionally, another commenter recommended CMS ensure EHR vendors can support the required subpopulation analyses prior to adopting these requirements.

Response: CMS is committed to ensuring that all mothers, regardless of facility size or size of their patient demographic group within a particular facility, have access to high quality care. CMS is not requiring specific data analysis nor stratification methods. Rather, hospitals are encouraged to utilize the data analysis method that best fits their patient population and resources and to utilize best practices in conducting their QAPI work. Facilities

[678] *https://www.cms.gov/newsroom/fact-sheets/fy-2023-hospital-inpatient-prospective-payment-system-ipps-and-long-term-care-hospital-prospective.*

[679] *https://www.govinfo.gov/content/pkg/FR-2024-03-29/pdf/2024-06469.pdf.*

[680] *https://data.cms.gov/provider-data/birthing-friendly-hospitals-and-health-systems.*

[681] *https://www.cms.gov/newsroom/fact-sheets/fy-2023-hospital-inpatient-prospective-payment-system-ipps-and-long-term-care-hospital-prospective.*

also have the flexibility to define diverse populations and set the time period for their analyses that best supports robust QAPI evaluations and patient privacy. The proposal does not require that facilities utilize EHRs to conduct their QAPI work, though CMS recognizes that electronic systems can greatly aid this work. We encourage facilities to adopt the analysis method that best suits their available resources, and leverage partnerships with QIOs, existing local/state/Federal quality efforts, and integrated health system resources in order to reduce burden and mitigate data challenges.

Comment: CMS received mixed comments regarding the effectiveness of quality improvement projects to address the maternal health crisis. Several commenters noted that targeted data collection and analysis by diverse subpopulations is important for identifying disparities and enabling data-driven interventions. In contrast, one commenter stated that CMS has not provided evidence that the proposed data analysis requirements are likely to improve maternal health outcomes. Another commenter stated that some hospitals have been working to improve maternal health outcomes without relying on regulatory requirements and have found that disparities persist. These commenters suggest that CMS consider policies addressing non-clinical factors (meaning the social determinants of health (SDOH), such as transportation access, housing quality, and insurance coverage), which have a significant impact on maternal mortality and morbidity, rather than establish new CoPs. On the other hand, several other commenters recommended CMS address the root causes of the maternal health crisis by requiring facilities to prioritize identifying and addressing unmet social needs in their QAPI programs.

Response: CMS recognizes the profound impact of the SDOH on maternal health outcomes. As discussed in the preamble, research indicates data stratification and analyses can allow facilities to identify when disparities occur and develop tailored interventions. Facilities have the flexibility to design their QAPI efforts to address SDOH, clinical factors, or both based on the needs of their patients and facility resources. While the proposal does not require facilities to do so, CMS believes facilities can play a critical role in connecting patients to resources that can address SDOH and improve outcomes. We encourage facilities to partner with existing community resources to assist patients with SDOH needs.

Comment: CMS received multiple comments regarding concerns from rural providers regarding the QAPI requirements. Specifically, several commenters urged CMS to exclude REHs and CAHs from the new QAPI requirements due to concerns regarding additional burden and compliance challenges faced by rural and low-volume providers compared to larger/urban facilities. A commenter recommended providing technical assistance to support these rural providers in effectively implementing QI initiatives, including integrating quality measurement with data reporting within their EHRs.

Response: CMS is committed to ensuring high quality OB care for all mothers regardless of geographic location, but is also sensitive to the burden concerns of rural providers. As will be discussed in section XXI.A.7 of this final rule with comment period, CMS will allow for a phased in implementation timeline for these QAPI standards in order to reduce burden. We will also issue subregulatory guidance regarding how surveyors will assess compliance with these requirements after publication of the final rule. We encourage facilities to utilize the data analysis method that best suits their available resources and leverage partnerships with QIOs, existing local/state/Federal quality efforts, and integrated health system resources in order to reduce burden and mitigate data challenges. While the proposal does not require that facilities use EHRs in their QAPI work, providers interested in doing so may wish to review the following resources from the Office of the National Coordinator for Health Information Technology (ONC) resources among others:

- ONC. ''Clinical Quality and Safety.'' *https://www.healthit.gov/topic/clinical-quality-and-safety*.
- ONC. ''Quality Improvement Briefs.'' *https://www.healthit.gov/resource/quality-improvement-briefs*.
- ONC. ''Continuous Quality Improvement.'' *https://www.healthit.gov/faq/what-continuous-quality-improvement*.

ONC. ''Section 8: Quality and Patient Safety.'' Health IT Playbook. *https://www.healthit.gov/playbook/quality-and-patient-safety/*.

Comment: We received several comments regarding the proposal to require facilities to conduct at least one maternal health performance improvement project (PIPs) annually. A few commenters supported the proposal, noting its potential to spur improvements in maternal morbidity and mortality. However other commenters stated that such projects may take longer than one year to implement and evaluate, and suggested CMS allow PIPs over a longer period (such as two or three years). A commenter supported allowing providers to choose PIPs that align with State or Federal quality initiatives and are specific to the needs of their facility or community but expressed concern that providers that do not participate in statewide maternal health initiatives may struggle to meet the new requirements. Two commenters suggested CMS allow hospitals to fulfill the goal of the PIP requirement through their participation in statewide quality improvement initiatives, such as the Perinatal Quality Collaboratives and the AIM patient safety bundles.

Response: We agree that PIPs can take longer than one year to fully implement and evaluate. We did not propose to require that facilities conduct a new/different maternal PIP each year. Rather facilities must be actively performing at least one PIP on maternal health a year, but this can be the same PIP over multiple years. As discussed in the preamble, facilities may choose to join existing local/state/Federal quality initiatives and utilize resources such as Perinatal Quality Collaboratives and the AIM patient safety bundles in order to comply with this requirement and reduce burden.

Comment: CMS received mixed comments regarding the proposal to require OB leadership to engage in QAPI. Several commenters stated that QAPI activities would be more successful with buy-in from facility leadership, which would ensure alignment with organizational goals and allocation of necessary resources. One commenter stated that the proposal is redundant because existing CoPs already outline who is responsible and accountable for ensuring the implementation of QAPI activities. One commenter recommended delaying the requirement to ensure leadership is engaged in QAPI activities by 12 months to allow time to train OB providers in quality improvement methods.

Response: We agree with commenters that leadership engagement is often a key ingredient for successful QAPI efforts. While the existing CoPs do set certain expectations for QAPI oversight, they do not specifically require OB leadership involvement as these requirements do. We believe this level of detail is needed in order to address the maternal health crisis. As discussed in section XXI.A.7 of this final rule with comment period, we will allow for a phased in implementation timeline for

these QAPI standards in order to reduce burden.

Comment: Many commenters supported the incorporation of MMRC data into facilities' QAPI programs. Commenters noted that MMRC data can inform hospital policies and patient safety practices and improve disparities. A commenter highlighted that the California Maternal Quality Care Collaborative (CMQCC) [682] already engages in these activities and is achieving success in targeting complications which disproportionately affect Black patients to drive better perinatal outcomes.

A few commenters did not support the proposal. One commenter said the proposal would be unnecessarily burdensome, particularly for rural hospitals with low volumes of births. Another noted lack of support for the proposal given that maternal deaths are rare, especially those that occur within the hospital. These commenters recommended allowing hospitals to focus on internal morbidity data instead of statewide data.

Several commenters also expressed concern regarding MMRC data itself, specifically that these data may not be relevant to all hospitals (particularly rural hospitals), that recommendations from MMRCs may be inconsistent across States, and that data collection is slow. These commenters recommended allowing flexibility. In particular, these commenters suggested allowing collaborations with other hospitals on performance improvement projects to satisfy the requirements, instead of relying on MMRCs.

Response: As discussed in the CY 2025 OPPS/ASC proposed rule preamble, evidence shows that data from MMRCs has been central in driving improvements in maternal morbidity and mortality across the country. While CMS is sensitive to concerns from rural providers, CMS disagrees that exclusion or modification of this MMRC proposal for rural providers is appropriate. CMS notes that State MMRCs often assess maternal deaths by region and/or by rurality. In this way, MMRC data can be relevant and specific to rural areas. Additionally, MMRC recommendations are written to allow facilities flexibility in their implementation rather than a one-size-fits-all approach, which allows rural facilities to adapt MMRC recommendations to their circumstances. Lastly, CMS notes that rural areas are not the only areas with limited resources or OB access. Urban hospitals, especially those in certain historically underserved communities, may also experience these challenges. CMS agrees that collaboration on QAPI work across different facilities and entities can enhance results and reduce burden. The proposal permits facilities to engage in such collaboration but does not require it. In particular, facilities may wish to join ongoing existing State Perinatal Quality Collaboratives, partner with QIOs, and/or leverage integrated health system resources (as described in 42 CFR 482.21(f)) in order to reduce any burden of compliance.

Comment: One commenter recommended that Tribal MMRCs be included alongside State and local MMRCs. This commenter noted that though Tribal MMRCs are not currently operating, their inclusion in the proposal could support their development. The commenter further asked that facilities be required to report data to any relevant Tribal MMRCs as requested by the Tribal MMRC.

Response: We appreciate this comment. To clarify, the current proposal does not include any requirement for facilities to report data to MMRCs (in deference to existing State laws on this subject).[683] We will not amend the proposal at this time related to data reporting, however we will amend the requirement on utilizing data from MMRCs to recognize Tribal MMRCs.

Comment: One commenter stated that requirements in the proposal are too vague and could be subject to disparate interpretations by CMS surveyors, suggesting CMS engage in provider listening sessions to add more specificity to the requirements before finalizing them.

Response: We will be issuing interpretive guidance following this final rule in order to assist facilities in complying with these new CoP standards.

Comment: Several commenters suggested CMS add specific additional topics and detail to the QAPI proposals. One commenter suggested a focus on pre-natal counseling and through post-partum follow-up as areas for the greatest potential to impact quality and safety. Another commenter recommended that CMS require stratification of maternal sepsis and neonatal infection as critical patient safety outcomes. This commenter stated that rates of sepsis during pregnancy are higher for Black patients, Asian/Pacific Islander patients, and Native American patients and stated that understanding maternal sepsis data, including time to initiation of appropriate therapy, through stratified data could inform performance improvement strategies. Another commenter stated that improving evidence-based best practices for C-section births could reduce surgical site infections, which are an area with potential care disparities due to lack of access to proven care, especially for patients with obesity. Another commenter recommended that QAPI work include mental health and substance use disorder metrics and require that QAPI data be made publicly available.

Response: We appreciate commenters sharing their expertise and highlighting key maternal health topics that facilities may wish to address in QAPI work. The proposal does not require facilities to address specific maternal health topics for quality improvement. Instead, facilities are free to choose the topic that best aligns with their patient populations and resources. Given that the current proposal did not include any requirement for facilities to report their maternal QAPI data nor make such data publicly available,[684] we are not revising the requirement at this time related to data reporting.

Comment: Several commenters recommended that CMS address a major cause of the maternal health crisis by requiring facilities to prioritize identifying and addressing unmet mental health and substance use disorders among OB patients. A commenter suggested that facilities collect data on maternal mental health and substance use disorder (SUD) specific metrics to evaluate the effectiveness of evidence-based practices, such as postpartum depression screening, follow-up, and initiation and engagement of SUD treatment. A few commenters further suggested that hospitals be required to collect, report, and incorporate data on rates of drug testing of pregnant people, medical justification for drug testing, demographic makeup of those who are drug tested, and health outcomes of both mother and fetus. A few commenters suggested that facilities further engage with stakeholders with lived experience in mental health and substance use disorder to determine which data and quality indicators are collected.

Response: We appreciate commenters sharing their expertise. CMS recognizes mental health and SUD as a critical area for maternal health. While the proposal does not require facilities to address specific maternal health topics for quality improvement, facilities that

[682] *https://www.cmqcc.org/.*

[683] *https://www.cdc.gov/maternal-mortality/php/mmrc/index.html.*

[684] *https://www.cdc.gov/maternal-mortality/php/mmrc/index.html.*

wish to work on maternal health, SUD, and behavioral health within their QAPI programs may wish to review the following resources among others:

- SAMHSA. ''Taskforce on Maternal Mental Health.'' *https://www.samhsa.gov/about-us/advisory-councils/acws/task-force-maternal-mental-health*.
- SAMHSA. ''Advisory: Evidence-Based, Whole Person Care of Pregnant People Who Have Opioid Use Disorder.'' *https://store.samhsa.gov/product/advisory-evidence-based-whole-person-care-pregnant-people-who-have-opioid-use-disorder*.
- Alliance for Innovation on Maternal Health. ''Perinatal Mental Health Conditions.'' *https://saferbirth.org/psbs/perinatal-mental-health-conditions*.
- Alliance for Innovation on Maternal Health. ''Maternal Mental Health.'' *https://saferbirth.org/psbs/archive-maternal-mental-health/*.
- Alliance for Innovation on Maternal Health. ''Care for Pregnant and Postpartum People with Substance Use Disorder.'' *https://saferbirth.org/psbs/care-for-pregnant-and-postpartum-people-with-substance-use-disorder/*.

SAMHSA also has provided funding opportunities for a variety of maternal behavioral health initiatives.[685] [686] [687]

Comment: For CMS' questions on best practices for QAPI data analysis and stratification by diverse subgroup and as well as which data stratifications/subgroups/categories are key to ensuring the health and safety of all pregnant, birthing, and postpartum patients, we received several responses. One commenter recommended that CMS incorporate and share best practices to promote accuracy in demographic data collection, such as the ability for patients to self-identify, and to support privacy protections in the collection and reporting of aggregated demographic data. One commenter recommended accounting for patient preferences regarding sharing demographic data when adopting data collection requirements.

A commenter noted that current stratification practices vary according to site and are often impacted by resource constraints. Several commenters recommended CMS identify a minimum set of standardized data elements that impact maternal health outcomes, such as race, ethnicity, disability status, language, age, sexual orientation and gender identity (SOGI), geographic location (including rural versus urban; distance traveled), socioeconomic status (such as income level), immigration status, zip code, payor, gender identity, among other SDOH factors. A few commenters requested additional guidance to support SDOH Z-codes. Another commenter added that CMS should work with stakeholders to identify these common data elements. A few commenters recommended that CMS work with organizations that have already created comprehensive data processes to effectively design data collection practices that hospitals can use to meet nationally recognized standards. Specifically, one commenter further recommended collaboration with the private sector to adopt meaningful measures of maternal health outcomes and disparities such as demographic factors. One commenter suggested that CMS could identify disparities early by promoting the uniform collection of demographic data and consistent stratification of metrics by using the updated OMB Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity.

In terms of best practices for QAPI work, one commenter stated that multidisciplinary collaboration is necessary for effective QAPI processes, including the review of maternal health outcomes. This commenter recommended ensuring that QAPI meetings are led by physician and nurse leadership in collaboration with a range of other disciplines and services throughout the hospital system. Another commenter recommended including practicing OB–GYNs, other OB unit providers, non-medical staff, and patients in QAPI activities to ensure initiatives are practical, address working conditions, and minimize burden.

Response: We thank the commenters for their expertise and feedback on this comment solicitation. Following finalization of this rule, we will issue subregulatory guidance regarding how compliance with this requirement will be assessed. CMS is committed to providing technical assistance to support hospitals in coming into compliance with these requirements, including data analysis by diverse subpopulation. While CMS is requiring that ''obstetrical services leadership'' be involved in facility QAPI work (at §§ 482.21(e)(1) and 485.641(d)(4)(i)), facilities have flexibility regarding additional staff involvement in QAPI work. We agree with commenters that multidisciplinary collaboration is often critical to the success of QAPI activities. Payment policies (such as Z codes) are outside the scope of the CoPs, but we will share this feedback with the appropriate component within CMS.

Comment: Related to CMS' question on best practices for sharing QAPI findings with impacted communities, we received several responses. A commenter stated that community engagement is important to ensuring initiatives are leading to improvements in the community's actual needs. One commenter recommended using patient advisory councils to ensure patient involvement in QAPI initiatives.

A few commenters recommended sharing results of QAPI initiatives with the medical and scientific community, with other providers, and with the public that they serve. Other commenters recommended using existing communication channels, including Patient and Family Advisory Councils, websites, newsletters, community forums, and media outlets (including newspapers and television) to share these data. A few commenters recommended that the Federal Government collect these data and make them publicly available at a single central location.

A few commenters stated that engaging community members, especially in under-resourced communities, can be challenging and recommended establishing technical assistance to help hospitals with this engagement. One commenter stated that technical assistance could include strategies such as addressing power and knowledge differentials, providing materials accessible to lay audiences, incorporating community members from the outset, and compensating community members for their contributions.

Response: We thank the commenters for their input and will consider this feedback in possible future rulemaking. CMS encourages facilities to collaborate with communities to ensure the facility's QAPI work meets patients' needs, and to share QAPI outcomes with communities as applicable.

Comment: Related to CMS' question whether these proposed requirements should be applicable to REHs, we received several responses. A few commenters stated that all hospitals, including REHs, should meet consistent health and safety standards and suggested that CMS find ways to support REHs in providing quality care, including for QAPI. A commenter stated that requiring all levels of care, including REHs, to have baseline requirements regarding OB care delivery is critical to reducing disparities. A few

[685] *https://www.samhsa.gov/newsroom/press-announcements/20240708/biden-harris-administration-announces-funding-opportunities-enhancing-women-behavioral-health.*

[686] *https://www.samhsa.gov/grants/grant-announcements/sm-24-013.*

[687] *https://www.samhsa.gov/newsroom/press-announcements/20230126/grant-opportunities-preventing-substance-misuse-treating-sud-pregnant-postpartum-women.*

commenters suggested providing phase-in timelines as well as financial and technical support for REHs.

However, many commenters were opposed to applying these QAPI proposals to REHs. Several commenters remarked that several of the proposals are not applicable to REHs, and that coming into compliance would be overly burdensome. Several commenters stated that REHs have their own payment methodology and CoPs and should not be required to comply with CoPs meant for other hospital types. Some commenters expressed concern that requiring REHs to comply with these proposals would result in additional closures. A commenter stated that REHs should not be required to have a QAPI due to the resources required.

Response: We thank the commenters for their input. In light of the concerns raised, we will not extend these QAPI standards to REHs at this time.

Final Policy Decision: After consideration of the public comments we received, we are finalizing the proposals, without modification for hospitals and CAHs. CMS is not extending the new QAPI standards to REHs at this time.

5. Emergency Services Readiness (§ 482.55; § 485.618)

We proposed a new standard entitled ''Emergency Services Readiness'' within the existing Emergency Services CoP for hospitals (§ 482.55) and CAHs (§ 485.618) to set clear expectations as well as improve facility readiness in caring for emergency services patients, including pregnant, birthing, and postpartum patients. Notably, these requirements would apply to all hospitals and CAHs offering emergency services,[688] whether or not a hospital/CAH offers an additional specialty service line (such as OB services). This is done with the intention of ensuring baseline health, safety, and training standards for the care of patients with emergency conditions.

First for hospitals (§ 482.55(c)) and CAHs (§ 485.618(e)) that offer emergency services, we proposed that these facilities would be required to have adequate provisions and protocols to meet the emergency needs of patients in accordance with the complexity and scope of services offered. For protocols, hospitals (§ 482.55(c)(1)) and CAHs (§ 485.618(e)(1)) must have protocols consistent with nationally recognized and evidence-based guidelines for the care of patients with emergency conditions. While these CoPs would not require adherence to a specific organization's guideline or recommendations, we expect that facilities would be able to articulate their standards and the source(s) and to demonstrate that their standards are based on evidence and nationally recognized sources.

For hospitals (§ 482.55(c)(3)) and CAHs (§ 485.618(e)(2)) that offer emergency services, applicable emergency services personnel, as determined by the facility, must be trained on these protocols and provisions annually. Once staff are identified, hospitals and CAHs must document that applicable staff have successfully completed such facility-identified training and demonstrate staff knowledge on these topics.

For hospitals that offer emergency services, we further proposed at § 482.55(c)(2) that provisions include equipment, supplies, and medication used in treating emergency cases. Such provisions must be kept at the hospital and be readily available for treating emergency cases. The available provisions must include: (1) drugs, blood and blood products, and biologicals commonly used in life-saving procedures; (2) equipment and supplies commonly used in life-saving procedures; and (3) a call-in-system for each patient in each emergency services treatment area. These supply requirements are similar to existing CAHs (at § 485.618(b) and (c)) and REHs (at § 485.516(c)(2)) supply standards for emergency services, as well as the surgical services CoP supply requirements (§ 482.51(b)(3)). We did not propose any new emergency services equipment, supplies, or medication requirements for CAHs or REHs.

Finally, we solicited public comments and requested evidence related to these proposals, including how these proposals would impact patient (including maternal) health and safety, and whether these proposed requirements should be applicable to REHs.

We received several comments on these proposals. We address those comments and our responses below:

Comment: We received mixed comments on the proposal overall. Several commenters supported adopting requirements that address care in non-obstetric settings, such as emergency departments (EDs). One commenter stated that they felt that existing courses (such as Advanced Cardiovascular Life Support, Advanced Trauma Life Support, and Pediatric Advanced Life Support) are insufficient emergency training, noting that newly graduated NPs and PAs may be working in rural hospitals and CAHs with no or extremely limited emergency training, including in management of OB emergencies. This commenter supported additional training in OB emergencies for all rural hospital and CAH emergency services providers. One commenter stated high quality OB care in the ED is especially important in areas that are resource limited and do not have access to OB care. Another commenter added that training emergency clinical staff on obstetrical and gynecological emergencies would enhance patient safety in rural hospitals and CAHs because emergency providers often provide care in these settings due to a lack of OB specialists. One commenter further stated that ensuring EDs are equipped to treat OB emergencies can promote access even in areas without OB units. Another commenter noted that these requirements are particularly important as restrictions on reproductive care are exacerbating shortages of OB services in some locations.

In contrast, multiple commenters expressed opposition to the proposal. Several commenters stated that these requirements are duplicative to other CoPs. Specifically, a few commenters stated that emergency services protocols for OB patients are redundant of existing requirements because hospitals manage OB patients according to existing protocols and other relevant Conditions of Participation. Another commenter stated that emergency personnel are already trained in a breadth of diagnoses and recommended allowing hospitals flexibility to identify appropriate training based on their patient populations. Several commenters recommended that CMS implement the regulations carefully to avoid detrimental effects, especially for rural hospitals.

Response: We appreciate commenters' support for the proposal. The proposal aims to ensure the health and safety of all emergency services patients, including obstetrical patients, by requiring hospitals and CAHs to have appropriate emergency protocols and provisions in place. We agree that declines in obstetrical access across the country, including in rural areas, increase the importance of training in obstetrical and gynecological emergencies for emergency clinical staff.

We disagree that the proposal duplicates existing CoPs. There are currently no requirements related to emergency provisions (including for

[688] For purposes of the proposal, CMS considered a facility to ''offer emergency services'' when it met the definition of ''dedicated emergency department'' as defined in EMTALA (42 CFR 489.24(b), ''Dedicated emergency department'').

obstetrical patients) under the existing hospital emergency services CoP. In contrast, CAHs (at § 485.618(b) and (c)) and REHs (at § 485.516(c)(2)) do have supply requirements under their emergency services CoP. The proposal therefore brings hospitals' emergency provisions expectations into alignment with the CAH and REH CoPs on this topic. Similarly for protocols, the existing hospital requirement (42 CFR 482.55(a)(3)) that ''the policies and procedures governing medical care provided in the emergency service or department are established by and are a continuing responsibility of the medical staff'' offers little detail of CMS' expectations for emergency readiness. The CAH emergency services CoP lacks such a provision entirely. For staff training, the hospital emergency services CoP requires that ''there must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility'' (§ 482.55(b)(2)). The CAH standard (§ 485.618(d)) currently requires its personnel to have ''training and experience in emergency care.'' CMS believes clearer expectations surrounding ''qualified/training and experience in emergency care'' and maintenance of qualifications (that is, training) would improve facilities' readiness to care for patients with emergency conditions, enhancing patient health and safety.

The proposal therefore offers clarity regarding CMS' expectations for emergency readiness including protocols, provisions, and training for emergency staff. In response to providers' concerns, especially rural facilities, related to burden, CMS will institute an implementation delay as discussed in section A.XXI.7 of this final rule with comment period.

Comment: A few commenters stated that it is unclear whether the proposed updates were intended to be specific to OB emergencies or apply more broadly.

Response: We appreciate the opportunity to offer further clarity. The proposal is written broadly to ensure hospitals and CAHs meet the needs of all emergency services patients, including, but not limited to, patients with obstetrical emergencies, complications, and immediate post-delivery care needs. Specifically, the proposal requires that hospitals and CAHs develop protocols consistent with nationally recognized and evidence-based guidelines for the care of patients with emergency conditions. We further specify that these protocols must address obstetrical emergencies, complications, and immediate post-delivery care (in accordance with the complexity and scope of services offered at the facility), but the protocol requirement is not limited to these conditions. CMS offers hospitals and CAHs flexibility in determining what other protocols are needed to meet the needs of their specific emergency services patient populations. The same applies for the emergency provisions requirement for hospitals.

Comment: A commenter inquired regarding the scope of CMS' expectations regarding emergency protocols. In particular, this commenter asked if the proposal required facilities to develop protocols for all possible emergency conditions.

Response: We appreciate the opportunity to offer further clarity. We are not requiring that facilities develop a protocol or have provisions for every possible emergency scenario, but facilities should develop protocols and have available provisions to meet the emergency needs of their patients consistent with (1) the complexity and scope of services offered by the facility; and (2) nationally recognized and evidence-based guidelines. The final rule we are adopting specifies that protocols must address obstetrical emergencies, complications, and immediate post-delivery care, but are not limited to these conditions. CMS offers hospitals and CAHs flexibility in determining what other protocols are needed to meet the needs of their specific emergency services patient populations. For example, the American College of Emergency Physicians has issued multiple guidelines for best practices in managing common and critical emergency conditions and has developed a Geriatric Emergency Department Accreditation Program, which provides best practice standards for this at-risk population.[689] [690] For obstetrical emergencies, the Alliance for Innovation on Maternal Health's (AIM; a partnership between HRSA and American College of Obstetricians and Gynecologists (ACOG) and other stakeholders) has developed resources which include example protocols and training resources for responding to obstetrical hemorrhage, severe hypertension, perinatal mental health conditions, sepsis, substance use disorder, and cardiac conditions, among others.[691] ACOG has also developed resources for Obstetric Emergencies in Nonobstetric Settings.[692] Similarly, the HRSA-supported Emergency Medical Services for Children (EMSC) Innovation and Improvement Center has resources for emergency departments seeking to improve ''pediatric readiness.'' [693] We expect hospitals to be able to identify the source of the nationally recognized and evidence-based guidelines utilized in their protocols.

Comment: EMTALA's relationship to the proposal was brought up by multiple commenters. One commenter supported the proposed rule and emphasized the requirement for hospitals with EDs to comply with EMTALA and Federal civil rights laws. In contrast, several commenters stated that these requirements duplicate requirements for hospitals under EMTALA.

Response: EMTALA requirements are separate and distinct from these requirements. As noted elsewhere, CMS expects that all Medicare-participating facilities with emergency departments comply with the EMTALA statute (42 U.S.C. 1395dd) and its implementing regulations (42 CFR 489.24). Specifically, under EMTALA, Medicare-participating hospitals and CAHs with emergency departments must provide individuals presenting to the emergency department with an appropriate medical screening exam and, if an emergency medical condition exists, offer stabilizing treatment or, under certain circumstances, appropriate transfer to receive stabilizing care.

However, EMTALA does not directly address emergency department readiness, which may have exacerbated gaps in access to care, including for obstetrical, geriatric, and pediatric populations.[694] [695] [696] [697] [698] [699] This final rule therefore offers clarity regarding CMS' expectations for emergency readiness for all patients, inclusive of protocols, provisions, and training for emergency staff. The proposed rule preamble included multiple example

[689] *https://www.acep.org/patient-care/clinical-policies.*

[690] *https://www.acep.org/geda.*

[691] *https://saferbirth.org/.*

[692] *https://www.acog.org/programs/obstetric-emergencies-in-nonobstetric-settings.*

[693] *https://emscimprovement.center/domains/pediatric-readiness-project/.*

[694] *https://www.acog.org/news/news-articles/2022/01/commitment-to-action-eliminating-preventable-maternal-mortality.*

[695] *https://rhrc.umn.edu/wp-content/uploads/2021/09/UMN-emOB-Training-Needed_11.12.20_508.pdf.*

[696] *https://www.cdcfoundation.org/sites/default/files/files/ReportfromNineMMRCs.pdf.*

[697] *https://emscimprovement.center/domains/pediatric-readiness-project/.*

[698] *https://publications.aap.org/pediatrics/article/142/5/e20182459/38608/Pediatric-Readiness-in-the-Emergency-Department.*

[699] *https://forms.ihi.org/hubfs/Guide%20to%20Recognition%20for%20GEDA%20Sites_FINAL.pdf.*

resources facilities may utilize to assist in compliance with the proposal.[700] [701] [702] [703] [704]

Comment: We received several questions requesting further guidance on the proposal. One commenter recommended that CMS provide technical resources that would facilitate identification and adoption of nationally recognized and evidence-based guidelines. This commenter also recommended adoption of guidance on the essential provisions required for emergency services or to allow hospitals to tailor their provisions to their specific needs. One commenter recommended that CMS compile a list of resources, including low-cost training resources, that could be used in complying with this regulation. A few commenters recommended allowing hospitals flexibility in selecting which resources and nationally recognized standards to use to meet the requirements, including QAPI and QA activities. Another commenter recommended ensuring that our policies not be prescriptive, which could limit flexibility during a surge beyond typical patient volume.

Response: We are not requiring that facilities adhere to a specific organization's guidelines or recommendations for emergency protocols and provisions. Facilities have flexibility to utilize national medical professional society, accrediting organization, credentialling body, or other national guidelines when determining appropriate protocols and provisions for their emergency services patient populations. We provide examples of such resources in the proposed rule preamble.[705] [706] [707] [708] [709] CMS encourages facilities to further inform their protocols and provisions choices based on the facility's QAPI program as appropriate. We agree that facilities should consider how their protocols may need to be adapted during surge periods. Following publication of this final rule with comment period, we will issue subregulatory guidance on how surveyors will assess compliance with this requirement, which can further assist facilities.

Comment: Several comments requested that CMS provide funding to support compliance with these new requirements. One commenter expressed concern regarding the initial cost to comply with these requirements, especially given the potential consequences for being non-compliant with CoPs. A few commenters recommended providing resources (such as funding and technical assistance).

Response: Funding resources are beyond the scope of the CoPs, but CMS continues to welcome stakeholder feedback on this topic and will share any such feedback with relevant CMS components as applicable. Following finalization of this rule, we will issue subregulatory guidance regarding how compliance with this requirement will be assessed. CMS is committed to providing technical assistance to support hospitals in coming into compliance with these requirements.

Comment: A few commenters supported flexibility for hospitals to define equipment used in lifesaving procedures. A few commenters expressed concern that requiring hospitals to have drugs, blood, blood products, and biologicals commonly used in emergency procedure could create a shortage of drugs and blood supplies.

Response: We are not requiring that facilities have any specific equipment, supplies, nor medication for emergency conditions. Facilities must determine (in accordance with the complexity and scope of services offered) what provisions are necessary to meet the emergency needs of their patients. Facilities may also want to consider what a resilient supply of specific equipment, supplies, and medication would be given their needs. We disagree that these polices would cause a shortage of drugs or blood supplies. In industry stakeholder listening sessions, stakeholders indicated hospitals already routinely have these provisions available. Moreover, CAHs (at § 485.618(b) and (c)) and REHs (at § 485.516(c)(2)) already have equipment, supplies, blood, and medication requirements under their emergency services CoP. The proposal therefore brings hospitals' emergency provisions expectations into alignment with the CAH and REH CoPs on this topic.

Comment: A few commenters requested interpretive guidance on the term ''call-in system.'' A commenter expressed concern that a call-in system would add financial and operational burden to hospitals.

Response: We proposed that each emergency services treatment area must have a call-in-system for each patient. The proposal is similar to the existing surgical services CoP (§ 482.51(b)(3)). By ''call-in system'', we mean a mechanism by which a patient and/or caregiver can alert staff of any emergencies or concerns. Examples may include a call-bell, alarm, or other notification device. Following publication of this final rule with comment period, we will issue subregulatory guidance regarding how compliance with this requirement will be assessed. Given commenters' concern regarding burden, CMS will institute an implementation delay for this requirement as discussed in section A.XXI.7 of this final rule with comment period.

Comment: Several commenters noted the importance of behavioral health emergencies. One commenter recommended that hospitals and CAHs be required to develop evidence-based, person-centered, trauma-informed policies for the identification, treatment, and follow-up care of patients who present with an SUD-related condition, including medications for opioid use disorder and referrals to treatment and support services. The commenter recommended ensuring these protocols include policies to help address health disparities, as well as person-centered and trauma-informed care. Specific to maternal mental health, one commenter stated that evidence shows that mental health conditions (including substance use disorders and suicide) are the leading cause of pregnancy-related deaths. A few commenters recommended that CMS specifically address emergency readiness for OB patients having mental health or substance use emergencies.

Response: We appreciate commenters sharing their expertise and highlighting the importance of behavioral health emergencies, in particular as it relates to maternal health. The proposal does not require facilities to have protocols and provisions specific to behavioral health emergencies. Rather facilities may determine the protocols and provisions that best align with their patient populations. While not required, facilities that wish to work on behavioral health emergency services (including for OB patients) may wish to review the following resources among others:

- American College of Emergency Physicians. ''Psychiatric Patient.'' *https://www.acep.org/patient-care/clinical-policies/Psychiatric-Patient.*
- American Psychiatric Association. ''Clinical Practice Guidelines.'' *https://*

[700] *https://www.acep.org/patient-care/clinical-policies.*

[701] *https://www.acep.org/geda.*

[702] *https://saferbirth.org/.*

[703] *https://www.acog.org/programs/obstetric-emergencies-in-nonobstetric-settings.*

[704] *https://emscimprovement.center/domains/pediatric-readiness-project/.*

[705] *https://www.acep.org/patient-care/clinical-policies.*

[706] *https://www.acep.org/geda.*

[707] *https://saferbirth.org/.*

[708] *https://www.acog.org/programs/obstetric-emergencies-in-nonobstetric-settings.*

[709] *https://emscimprovement.center/domains/pediatric-readiness-project/.*

www.psychiatry.org/psychiatrists/practice/clinical-practice-guidelines.

- Alliance for Innovation on Maternal Health. ''Perinatal Mental Health Conditions.'' *https://saferbirth.org/psbs/perinatal-mental-health-conditions*.
- Alliance for Innovation on Maternal Health. ''Maternal Mental Health.'' *https://saferbirth.org/psbs/archive-maternal-mental-health*.
- Alliance for Innovation on Maternal Health. ''Care for Pregnant and Postpartum People with Substance Use Disorder.'' *https://saferbirth.org/psbs/care-for-pregnant-and-postpartum-people-with-substance-use-disorder*.
- SAMHSA. ''Taskforce on Maternal Mental Health.'' *https://www.samhsa.gov/about-us/advisory-councils/acws/task-force-maternal-mental-health*.
- SAMHSA. ''Advisory: Evidence-Based, Whole Person Care of Pregnant People Who Have Opioid Use Disorder.'' *https://store.samhsa.gov/product/advisory-evidence-based-whole-person-care-pregnant-people-who-have-opioid-use-disorder*.
- SAMHSA. ''Trauma and Violence.'' *https://www.samhsa.gov/trauma-violence*.
- SAMHSA. ''Clinical Guidance for Treating Pregnant and Parenting Women With Opioid Use Disorder and Their Infants.'' *https://store.samhsa.gov/product/clinical-guidance-treating-pregnant-and-parenting-women-opioid-use-disorder-and-their*.
- SAMHSA. ''Improving Cultural Competence.'' *https://store.samhsa.gov/sites/default/files/sma16-4931.pdf*.

Comment: In offering their support for this new CoP, several comments also offered more specific recommendations for training and resources. One commenter specifically recommended addressing the risk of hemorrhage as part of OB emergency care. This commenter recommended ensuring a standard of assessing Quantitative Blood Loss (QBL) as part of early detection of maternal hemorrhage. One commenter recommended topics for training for non-OB emergency staff, including routine screening for risk factors and signs of complications in perinatal patients, stabilizing perinatal patients, and transfer protocols. The commenter noted that Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) has the courses ''OB Triage'' and ''Maternal Fetal Triage Index'' that can educate staff on common perinatal complications and appropriate escalation. A few commenters recommended using the regulations to encourage simulation-based training because this modality allows staff to practice decision-making and teamwork in a controlled environment.

Response: We thank the commenters for their expertise regarding best practices and resources. While the proposal does require facilities to ensure that relevant staff (as identified by the hospital) are trained annually on the emergency services protocols and provisions, facilities are not required to utilize any specific training modality, resources, nor metrics as part of training efforts. Rather facilities may determine the protocols, provisions, and training resources that best align with their specific situation. This is designed to enhance flexibility and reduce provider burden.

Comment: A commenter recommended that CMS adopt a requirement for hospitals to have protocols in place to reduce ED boarding, which the commenter defined as a ''dangerous health system overload that puts patients in a holding pattern as they wait for an inpatient bed or transfer after their initial care.''

Response: We thank the commenter for this input. While ED boarding is beyond the scope the CY 2025 OPPS/ASC proposed rule, we will consider this input for possible future rulemaking.

Comment: We received comments regarding CAHs' standard for ''Coordination with emergency response systems.'' Some commenters expressed concern that these requirements for CAHs would require having a physician available on a 24/7 basis, which would be difficult to accomplish than the current requirement to have a practitioner available 24/7. A few commenters stated that the proposal to have a physician immediately available is more restrictive than a similar requirement for CAHs to have a practitioner available and would be more difficult for CAHs to meet.

Response: For clarity, we are not proposing any new standards or revisions to CAHs' ''Coordination with emergency response systems'' CoP (currently found at 42 CFR 485.618(e)). The text on this topic in this final rule is solely for amendatory purposes (that is, moving the current regulations text down to new 42 CFR 485.618(f)). We are not proposing any new staffing standards within CAHs' emergency services CoP.

Comment: We solicited comment on ways to reduce any burden associated with these proposals. One commenter recommended that the Federal Government create technical assistance programs for rural hospitals. These programs would be housed in the Health Resources and Services Administration (HRSA) and would support facilities with purchasing equipment and providing training and access to tele-consultation.

Response: We thank the commenter for their input. While directly providing financial support for equipment purchases and training is beyond the scope of the CoPs, we have shared this feedback with relevant CMS and HHS components.

Comment: To our question on whether these proposed requirements should apply to REHs, we received mixed responses. A few commenters supported adoption of emergency services readiness requirements for REHs. These commenters stated that many individuals giving birth may initially present to an REH and therefore these facilities should be able to recognize and address emergency situations to stabilize patients prior to transfer. Another commenter supported extending the proposed CoPs to REHs because these facilities should be prepared to provide high-quality care despite workforce and resource challenges, especially for REHs in rural, Black, and Indigenous communities which are most likely to be impacted by maternity ward closures. One commenter recommended that CMS use caution when extending the proposed updates to REHs.

Response: We thank the commenters for their input. In light of the mixed responses, CMS will not extend these new Emergency Services standards to REHs at this time.

Final Policy Decision: After consideration of the diversity of perspectives in public comments received, we are finalizing as proposed for hospitals and CAHs. CMS is not extending these new Emergency Services standards to REHs at this time.

6. Transfer Protocols (§ 482.43)

We proposed revisions to the hospital discharge planning regulations to include requirements for transfer protocols. We proposed at § 482.43(c) to require that hospitals have written policies and procedures for transferring patients under their care. This would be inclusive of hospital inpatients (for example, transfers from the emergency department to inpatient admission, transfers between inpatient units in the same hospital, as well as transfers between inpatient units at different hospitals). This would ensure that patients are transferred to the appropriate level of care promptly and without undue delay, in order to meet their needs. We also proposed to require the hospital to provide training to the relevant staff (as determined by the

facility) regarding the hospital policies and procedures for transferring patients under its care.

We received the following comments in response to this solicitation:

Comment: Some commenters supported the transfer protocols requirement. They stated requiring that hospitals have effective transfer processes was important for ensuring continuity of care, reducing the risks associated with care transitions, as well as ensuring that patients are transferred to the appropriate level of care in a timely manner. Some commenters stated that the transfer protocols, aligned with nationally recognized and evidence-based guidelines, will ensure that all pregnant women will receive timely and effective treatment.

However, some commenters opposed the transfer protocols requirement. A few commenters stated that the proposed requirement was duplicated existing transfer policies within the hospitals. One commenter suggested that CMS include only interhospital transfers (transfers between inpatient units at different hospitals) in the transfer protocols. Some commenters stated that the proposed requirement does not only focus on obstetrical or maternity care and there was insufficient evidence linking transfer protocols to better maternal outcomes. Additionally, a few commenters expressed concerns with the overly prescriptive nature of the proposed requirements, asserting that the proposal would not allow hospitals the flexibility to utilize clinical judgement to determine when and where a patient should be transferred. A few commenters suggested rather than implementing transfer protocols, hospitals should follow the guidelines for the transfers published in the Guidelines for Perinatal Care, 8th Edition. Numerous commenters expressed concerns that this would create additional burden and as a result, hospitals would close.

Response: We thank commenters for their feedback. While this requirement does not just focus on obstetrical patients, we note that effective transfer processes can improve transitions of care, increase a hospital's ability to transfer patients promptly to facilities able to appropriately care for them, as well as protect the health and safety of all patients, including pregnant, birthing, and postpartum women.

We also recognize that some hospitals might already have intrahospital (transfers within the same facility) policies in place, but hospitals that do not have an emergency department or are otherwise not covered by EMTALA, may also have a need to transfer patients to other facilities to receive needed services. Additionally, patients that are admitted as hospital inpatients may require transfer between facilities to meet the needs of the patient (for example, changing clinical condition, need for specialty and/or higher level of care). The transfer protocol requirement is meant to establish and standardize transfer protocol requirements of hospital inpatients (for example, transfers from the emergency department to inpatient admission, transfers between inpatient units in the same hospital, as well as transfers between inpatient units at different hospitals) for all hospitals.

We do not agree that the transfer protocol requirement is overly prescriptive. The regulatory flexibility and framework of the requirement will allow each hospital to establish and/or tailor its own policy parameters for inpatient transfers according to its specific patient population, individual institutional needs and resources, and own medical staff recommendations as long as the policies and procedures established and implemented meet or exceed the requirements finalized in this rule. The requirement also allows the hospital flexibility in selecting which staff are required to complete annual training regarding the hospital policies and procedures for transferring patients under their care. Lastly, to mitigate some of the potential burden, professional organizations (such as the American College of Obstetricians and Gynecologists and American Academy of Pediatrics) have resources available to support hospitals as they develop their transfer protocols. Therefore, we are finalizing that hospitals must have written policies and procedures for transferring patients under its care (inclusive of hospital inpatients) to the appropriate level of care (including to another hospital) as needed to meet the needs of the patient.

Comment: Multiple commenters suggested that staff be trained on transfer protocols annually. One commenter suggested that staff be trained upon hiring and then on an annual basis. This would ensure that staff are following the same procedures regarding patient transfers and are informed of any changes to the transfer policies and procedures.

Response: We agree with the commenters that requiring annual training on transfer protocols is essential. This will promote consistency in transfer processes and ensure that transfers are conducted safely by minimizing errors. We are therefore finalizing that hospitals are required to provide annual training to the relevant staff (as determined by the hospital) regarding the hospital policies and procedures for transferring patients under their care.

Comment: We did not receive any public comments regarding criteria for determining whether a transfer is carried out ''promptly and without delay''. One commenter requested interpretive guidance on the term ''promptly and without delay''. Another commenter stated that there are circumstances outside of a hospital's control that make it impossible to ensure that a transfer is carried out ''promptly and without undue delay''. For example, rural hospitals often have trouble finding other hospitals willing to accept patients. In addition, ambulance availability can delay patients being transferred between facilities. Therefore, this can cause unavoidable delays.

Response: We thank commenters for their feedback We agree that transfers should be carried out as promptly as possible. Although it is not a requirement for the CoP finalized in this rule, CMS expects that hospitals are transferring patients as promptly as possible as staff and resources allow.

Comment: Some commenters expressed support for hospitals creating policies regarding their standards for accepting patients. This would ensure prompt care coordination for transferring patients and emphasize the shared responsibility of both transferring and receiving hospitals to ensure transfers are carried out promptly. However, another commenter expressed concerns that having policies that require hospitals to specify the conditions under which transfers will be accepted or not will diminish the ability of facilities, such as rural hospitals from transferring their patients to the appropriate level of care. For example, if a patient fails to meet all the criteria set forth by the selected recipient facility, that patient would be forced to wait for placement with a hospital whose acceptance criteria permitted transfer; further delaying care. One commenter recommended that CMS provide clarification of the required documentation for policies and procedures related to accepting transfers.

Response: We thank commenters for their feedback. We note that the comments we received may be taken into consideration in potential future rulemaking. To ensure that patients receive the care required for their medical conditions, we encourage hospitals to develop policies and

procedures regarding the acceptance of transfers.

Comment: Multiple commenters supported requiring all hospitals to have a documented partnership with another hospital that both provides OB services, as well as has a Medical Fetal Medicine (MFM) specialist available for consultations in urgent situations, if such service(s) are not already offered directly by the hospital. The partnerships would help hospitals build connections and establish relationships between hospitals and support coordinated care handoffs. Furthermore, such partnerships could reduce burdens for hospitals that do not provide obstetrical services. For example, hospitals would be informed of where appropriate specialists are available, therefore ensuring transfers are appropriately carried out. Multiple comments stated that hospitals having access to a robust telehealth OB network could provide real time support for pregnant patients and neonates, facilitate transfers, as well as prevent unnecessary transfers. Other commenters stated that it would be burdensome to establish and maintain these partnerships. A commenter stated that due to the shortage of Maternal Fetal Medicine (MFM) specialists, adding this requirement would exacerbate workforce challenges and increase staff burnout, which could contribute to a reduction in obstetrical services. Another commenter stated that facilities in rural and underserved areas may find it difficult to find and partner with hospitals with MFM specialists due to their limited availability in the area. To mitigate the burden of developing these partnerships, several commenters recommended technical support, funding, interpretive guidance and resources (for example, ACOG's Levels of Maternal Care), to support hospitals' efforts to build relationships within a region.

Response: We thank commenters for their feedback. We note that the comments we received may be taken into consideration in potential future rulemaking. We encourage hospitals to develop collaborative partnerships with other hospitals to improve transitions of care that will support better patient outcomes.

Comment: One commenter recommended that transfer protocols requirement be applied to REHs and CAHs.

Response: REHs provide outpatient services, emergency services, and observation care. They do not provide any acute inpatient hospital services, other than post-hospital extended care services provided in a distinct part unit licensed as a skilled nursing facility (SNF). The transfer protocols in this final rule are inclusive of hospital inpatients (for example, transfers from the emergency department to inpatient admission, transfers between inpatient units in the same hospital, as well as transfers between inpatient units at different hospitals). Furthermore, existing CoPs for CAHs and REHs include requirements related to the transfer of patients in the event that the facility is unable to furnish needed services for a patient or the patient requires a higher level of care. For example, the CAH CoPs at § 485.616(a) require CAHs that are members of a rural health network to have an agreement in place with at least one hospital that is also a member of the network for patient transfer. Additionally, the discharge planning requirements at § 485.642(b) require CAHs to discharge, transfer, or refer the patient, where applicable, with all necessary medical information pertaining to the patient's condition. We require similar actions regarding patient transfers for REHs at § 485.538. Therefore, the transfer protocols would not be necessary for REHs and CAHs, as similar requirements are already in place.

Comment: One commenter recommended that CMS require hospitals to include transfers from community settings to such hospitals in their transfer policies. They stated that, in some cases, community providers have encountered difficulties when transferring patients due to hospitals refusing to accept patients' medical records. Another commenter suggested that CMS considered policies that would facilitate better collaboration between hospitals and birthing facilities. They stated that birthing facilities face challenges when transferring pregnant or postpartum individuals and newborns to hospitals, including limited payment for stabilizing and transferring the patients. Furthermore, this would ensure safe and seamless transition for pregnant and postpartum patients. Another commenter stated that hospitals should focus on referral programs that leverage community resources to offer comprehensive care and address non-medical factors.

Response: While requiring hospitals to include transfers from community settings to the hospital in their transfer protocols is outside the scope of this rule, we encourage hospitals to foster relationships with local organizations in the community, including birthing facilities. By working together, hospitals, community organizations, and birthing facilities can share resources, enhance access to essential services, and improve maternal care.

Comment: One commenter requested that CMS include a list of resources in its interpretive guidance, that facilities can use when developing their transfer protocol policies and procedures. The commenter recommended Society of Maternal Fetal Medicine (SMFM)'s maternal transport briefing form and checklist.

Response: We thank the commenter for their recommendation. We agree there are a variety of resources to support hospitals in developing transfer protocol policies and procedures. For example, accreditation organizations (such as the Joint Commission) and professional organizations (such as the American College of Obstetricians and Gynecologists and Society for Maternal-Fetal Medicine) have such resources available. In addition, CMS will release interpretive guidance following the publication of the final rule.

Comment: A commenter requested that CMS fund statewide transportation programs in rural States where they are not currently available. This would enable patients from rural hospitals to be transported to a facility offering a higher level of care.

Response: We thank the commenter for their recommendation. However, funding for a statewide transportation program is outside the scope of this final rule with comment period.

Comment: A commenter expressed concern that the transfer protocols could overlap or conflict with existing transfer and stabilization policies under EMTALA.

Response: As noted above, EMTALA regulations are separate and distinct from these proposed CoPs. EMTALA (42 CFR 489.24) requires Medicare-participating hospitals with emergency departments to provide individuals presenting to the emergency department with an appropriate medical screening exam and stabilizing treatment if an emergency medical condition is found or under certain circumstances, appropriately transfer such individuals to receive stabilizing care. However, EMTALA does not address the transfer of hospital inpatients to a higher level of care. The proposed CoP require hospitals to develop policies and procedures for transferring patients under their care. The transfer protocols are inclusive of hospital inpatients (for example, transfers from the emergency department to inpatient ward, transfers between inpatient units in the same hospital, as well as transfers between inpatient units at different hospitals).

Final Rule Action: After consideration of the comments, we are finalizing our proposal for transfer protocols with the following modification: Acute care hospitals are required to provide annual training to the relevant staff (as determined by the facility) regarding the hospital policies and procedures for transferring patients under its care. These requirements do not apply to CAHs and REHs.

7. Implementation Timeframe

In the CY 2025 OPPS/ASC proposed rule, we did not propose to delay the implementation of the new and revised CoP requirements. However, we received many comments and recommendations with respect to the effective date and the date of implementation of the requirements in hospitals and CAHs.

Comment: Given that the final requirements will be effective 60 days after publication of the final rule, many commenters expressed concerns that this period would not allow facilities enough time to meet the new and revised CoP requirements. Some commenters stated that many of the provisions would require possible extensive changes (for example, hiring additional staff, and purchasing additional equipment and supplies) to ensure full compliance. Commenters also expressed concern that requiring hospitals, especially small, rural hospitals, to comply with these requirements will result in unintended consequences, such as the closure of labor and delivery units. This would only exacerbate the existing maternal health care access challenges.

Some commenters recommended a period of discretionary enforcement to allow hospitals time to come into compliance. One commenter recommended postponing the implementation of the new CoPs until CMS had a better understanding of the potential impact of the proposed policies on providers and organizations. While some commenters recommended that we delay implementation until interpretive guidance was available to facilities, other commenters recommended that we delay implementation of the requirements for CAHs and other facilities with low-birth volumes.

Some commenters suggested that we implement a phase-in timeframe for the requirements as to not impose burden on the facilities or obstetrical workforce. However, various implementation timeframes were suggested. A few commenters suggested that we implement a phase-in timeframe of 1 year to 2 years. A couple of commenters recommended a phase-in timeframe of 4 years. Other commenters suggested that we implement different phase-in timeframes for hospitals and CAHs.

Response: We believe the new and revised OB services CoPs will help ensure that all pregnant, birthing, and postpartum women receive consistent, high quality maternal health care, regardless of their geographic location. However, we acknowledge that these proposed requirements would require a robust review of existing programs and would necessitate changes to ensure full compliance with the new and revised obstetrical CoP requirements. To reduce some of the burden of complying with these requirements, and to avoid any unintended consequences, we are finalizing an implementation approach in phases, that allows additional time for hospitals and CAHs to comply with the requirements of this rule.

Final Rule Action: After consideration of the public comments, we are finalizing a phased-in implementation for hospitals and CAHs in 3 phases, over a 2-year period. Specifically,

- Phase 1 would require facilities to comply with the following requirements 6 months following the effective date of the final rule:
  - *Emergency services readiness for hospitals (§ 482.55) and CAHs (§ 485.618)*
  - *Transfer protocols for hospitals only (§ 482.43)*
- Phase 2 would require facilities to comply with the following requirements 1 year following the effective date of the final rule:
  - *Organization, staffing, and delivery of services for hospitals ((§ 482.59(a) and (b)) and CAHs (§ 485. 649(a) and (b))*
- Phase 3 would require facilities to comply with the following requirements 2 years following the effective date of the final rule:
  - *OB staff training in hospitals (§ 482.59(c)) and CAHs (§ 485.649(c))*
  - *QAPI program for OB services in hospitals (§ 482.21) and CAHs (§ 485.641)*

We note that the final regulations are effective 60 days following publication of this final rule with comment period in the **Federal Register**. The implementation date for the specific requirements is listed in Table 174.

TABLE 174: IMPLEMENTATION TIMEFRAME FOR HOSPITALS AND CAHS

Regulatory Section(s)	Implementation Date
Emergency Services Readiness for Hospitals (§482.55) and CAHs (§ 485.618) *Transfer Protocols for Hospitals (§482.43)*	6 months following the effective date of the final rule
Organization, Staffing, and Delivery of Services for Hospitals ((§482.59(a) and (b)) and CAHs (§485.649(a) and (b))	1 year following the effective date of the final rule
Training for OB Staff in Hospitals (§482.59(c)) and CAHs (§485.649(c)) *QAPI Program for OB Services in Hospitals (§ 482.21) and CAHs (§ 485.641)*	2 years following the effective date of the final rule

XXII. Modification to the Hybrid Hospital-Wide All-Cause Readmission and Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measures in the Hospital Inpatient Quality Reporting Program

A. Background

We refer readers to the following final rules for detailed discussions of the history of the Hospital Inpatient Quality Reporting (IQR) Program, including statutory history, and for the measures we have previously adopted for the Hospital IQR Program measure set:

- The FY 2010 Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System (IPPS/LTCH PPS) final rule (74 FR 43860 through 43861);
- The FY 2011 IPPS/LTCH PPS final rule (75 FR 50180 through 50181);
- The FY 2012 IPPS/LTCH PPS final rule (76 FR 51605 through 61653);
- The FY 2013 IPPS/LTCH PPS final rule (77 FR 53503 through 53555);
- The FY 2014 IPPS/LTCH PPS final rule (78 FR 50775 through 50837);
- The FY 2015 IPPS/LTCH PPS final rule (79 FR 50217 through 50249);
- The FY 2016 IPPS/LTCH PPS final rule (80 FR 49660 through 49692);
- The FY 2017 IPPS/LTCH PPS final rule (81 FR 57148 through 57150);
- The FY 2018 IPPS/LTCH PPS final rule (82 FR 38326 through 38328 and 38348);
- The FY 2019 IPPS/LTCH PPS final rule (83 FR 41538 through 41609);
- The FY 2020 IPPS/LTCH PPS final rule (84 FR 42448 through 42509);
- The FY 2021 IPPS/LTCH PPS final rule (85 FR 58926 through 58959);
- The FY 2022 IPPS/LTCH PPS final rule (86 FR 45360 through 45426);
- The FY 2023 IPPS/LTCH PPS final rule (87 FR 49190 through 49310);
- The FY 2024 IPPS/LTCH PPS final rule (88 FR 59144 through 59203); and
- The FY 2025 IPPS/LTCH PPS final rule published on August 28, 2024 (89 FR 69515 through 69577).

We also refer readers to 42 CFR 412.140 for Hospital IQR Program regulations.

B. Updates to the Form, Time, and Manner Requirements for the Hybrid Hospital-Wide All-Cause Readmission (HWR) and Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (HWM) Measures for the FY 2026 and the FY 2027 Payment Determinations

1. Background of the Hybrid HWR and Hybrid HWM Measures in the Hospital IQR Program

The Hospital IQR Program previously adopted two hybrid measures: (1) the Hybrid Hospital-Wide Readmission (HWR) measure; and (2) the Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (HWM) measure. Hybrid measures use more than one data source for measure calculation; specifically for the Hybrid HWR and Hybrid HWM measures, they use core clinical data elements (CCDEs), linking variables, and claims data (80 FR 49698). CCDEs are a set of clinical variables derived from electronic health records (EHRs) that can be used to risk adjust hospital outcome measures (80 FR 49699). Linking variables are administrative data that can be used to link or merge the CCDEs and administrative claims data for measure calculation (80 FR 49703). These measures are designed to enhance risk adjustment of administrative claims-based outcome measures by utilizing patient clinical data captured in EHRs (80 FR 49698).

We initially solicited public comment on the potential future adoption of hybrid measures into the Hospital IQR Program in the FY 2016 IPPS/LTCH PPS final rule adoption (80 FR 49698 through 49704). In subsequent years, we adopted both the Hybrid HWR measure and the Hybrid HWM measure with initial voluntary reporting periods. A discussion of the measure history for both measures follows.

The Hybrid HWR was the first hybrid measure introduced into the Hospital IQR Program. The Hybrid HWR measure is designed to capture all unplanned readmissions that arise from acute clinical events requiring urgent rehospitalization within 30 days of discharge. The measure was adopted in a stepwise fashion starting with voluntary reporting periods. In the FY 2018 IPPS/LTCH PPS final rule, we finalized 6 months of voluntary reporting for the CY 2018 reporting period (82 FR 38350 through 38355). In the FY 2020 IPPS/LTCH PPS final rule, we finalized 2 additional years of voluntary reporting, followed by mandatory reporting impacting the FY 2026 payment determination (84 FR 42465 through 42479). Then, in the FY 2024 IPPS/LTCH PPS final rule, we modified the Hybrid HWR measure cohort to include both Medicare fee-for-service (FFS) patients and Medicare Advantage (MA) patients 65 years and older for the FY 2027 payment determination and for subsequent years (88 FR 59161 through 59168).

The Hybrid HWM measure was the second hybrid measure to be adopted into the Hospital IQR Program. The Hybrid HWM measure is an outcome measure that captures the hospital-level, risk-standardized mortality rate (RSMR) of unplanned, all-cause mortality within 30 days of hospital admission for any eligible condition. Like the Hybrid HWR measure, we adopted the Hybrid HWM measure in a stepwise fashion, starting with a period of voluntary reporting. We initially adopted the Hybrid HWM measure in the FY 2022 IPPS/LTCH PPS final rule and finalized one voluntary reporting period followed by mandatory reporting impacting the FY 2026 payment determination (86 FR 45365 through 45374). Then in the FY 2024 IPPS/LTCH PPS final rule, we modified the Hybrid HWM measure cohort to include both Medicare fee-for-service (FFS) patients and Medicare Advantage (MA) patients 65 to 94 years old for the FY 2027 payment determination and for subsequent years (88 FR 59161 through 59168).

As previously noted, these hybrid measures use data from claims in combination with CCDEs and linking variables pulled from hospital EHRs. We previously finalized that hospitals must submit linking variables on 95 percent of hospital discharges (84 FR 42470; 86 FR 45371). The previously finalized linking variables are: (1) CMS Certification Number; (2) Health and Insurance Claims Number or Medicare Beneficiary Identifier; (3) Date of Birth; (4) Sex; (5) Admission date; and (6) Discharge date (84 FR 42469; 86 FR 45371). The previously finalized CCDEs are vital signs and laboratory results (84 FR 42469; 86 FR 45371). We also previously finalized that hospitals would be required to report CCDEs on 90 percent of discharges in a given reporting period (84 FR 42469; 86 FR 45371). These submission requirements were finalized beginning with mandatory reporting for the FY 2026 payment determination (84 FR 42469 through 42470; 86 FR 45371). We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42465 through 42479) and FY 2022 IPPS/LTCH PPS final rule (86 FR 45365 through 45374) for more information regarding data sources, measure calculation, and risk adjustment requirements. We also refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42506 through 42508), the FY 2021 IPPS/LTCH PPS final rule (85 FR 58941), the CY 2021 PFS final rule (85 FR 84472), and the FY 2022 IPPS/LTCH PPS final rule (86 FR 45421) for our previously adopted policies regarding certification, file format, and data submission requirements for hybrid measures in the Hospital IQR Program. For both hybrid measures, we previously finalized that hospitals must submit data for the mandatory reporting period impacting the FY 2026 payment

determination, based on performance data from July 1, 2023, through June 30, 2024, by October 1, 2024 (86 FR 45370). We finalized that data collected during the voluntary reporting periods would not be publicly reported (84 FR 42470; 86 FR 45371). We also finalized that we would begin public reporting of both hybrid measures' results, beginning with data collected from the July 1, 2023, through June 30, 2024, reporting period, impacting the FY 2026 payment determination (84 FR 42470 through 42471; 86 FR 45371).

2. Extension of Voluntary Reporting of CCDE and Linking Variable Data for the Hybrid HWR and Hybrid HWM Measures

Based on hospital performance during the most recent voluntary reporting period, it appeared that hospitals are unprepared for mandatory reporting of the Hybrid HWR and Hybrid HWM measures. As a part of measure maintenance, we routinely monitor hospital performance on the Hospital IQR Program's measures. We have been closely monitoring the results of voluntary reporting for both hybrid measures, including most recently the results of the second voluntary period for Hybrid HWR and the first voluntary period for Hybrid HWM. During these periods, approximately one-third of IPPS hospitals participated. The data indicated that three-fourths of the participating hospitals would not have met the reporting thresholds for the CCDEs and linking variables if the reporting requirement had been mandatory, and accordingly, would have been subject to a one quarter reduction to their annual payment update under the Hospital IQR Program for the given fiscal year.

The hospitals that participated in the voluntary reporting were mostly large, non-rural, non-critical access, and non-safety net. Based on our experience with implementing new types of digital measures, we understand that small and rural hospitals, as well as hospitals with fewer financial resources, may need additional time and flexibility to successfully implement new measure reporting requirements relative to larger, non-rural hospitals (82 FR 38357). We therefore believe the reporting failure rate may have been even higher if all IPPS hospitals participated.

In addition, we received feedback from hospitals (via email and help desk questions) raising various issues with reporting including issues related to CCDE collection timing and clinical workflow, issues with the types of units required for CCDE values, and achievability of the data submission requirement thresholds. We continued to investigate whether any of these issues or any other issues may be making it difficult for hospitals to meet CCDE and linking variable thresholds (that is, of 90 percent and 95 percent, respectively, of hospital discharges) and continued to analyze the root cause of these challenges.

We appreciate that, in light of the information discussed above, hospitals participating in the Hospital IQR Program may need additional time to remediate the issues and develop experience with reporting of CCDEs and linking variables before being subject to the associated program payment adjustments for noncompliance. In the CY 2025 OPPS/ASC proposed rule, we therefore proposed that for the FY 2026 payment determination (based on performance data from July 1, 2023, through June 30, 2024), the submission of CCDEs and linking variables would remain voluntary (89 FR 59502). We proposed that for the FY 2027 payment determination and subsequent years, the submission of CCDEs and linking variables would then become mandatory.

We explained in the CY 2025 OPPS/ASC proposed rule, that under our proposal, a hospital's annual payment determination for FY 2026 would not be affected by the voluntary reporting of CCDEs and linking variables, although we would still evaluate and assess the claims data portion of these measures (89 FR 59502). We proposed that the Hybrid HWR and Hybrid HWM measures would be publicly reported based on claims data for the FY 2026 Hospital IQR Program. We explained that the proposal would allow the Hospital IQR Program to publicly display hospital information on these important clinical areas and provide patients with visibility into hospital performance, while providing hospitals with more time to improve reporting on CCDEs and linking variables. Under the proposal, hospitals would continue to receive confidential hospital-specific reports in the Spring as a preview of public reporting. We noted that the hospital-specific reports would reflect the CCDEs and linking variables, should hospitals choose to submit them. We also stated in the proposed rule that we would continue to evaluate potential changes to the reporting requirements related to CCDEs and linking variables.

We invited public comment on our proposal.

Comment: Many commenters supported the proposal to extend voluntary reporting of the CCDEs and linking variables for the Hybrid HWR and Hybrid HWM measures, for the performance period of July 1, 2023, through June 30, 2024, impacting the FY 2026 payment determination for the Hospital IQR Program due to reporting challenges.

Response: We thank the commenters for their support.

Comment: Some commenters supported the proposed extended voluntary reporting for the performance period of July 1, 2023, through June 30, 2024, impacting the FY 2026 payment determination, but requested that voluntary reporting be extended further for both measures. The commenters' reasons for requesting additional years of voluntary reporting were due to challenges they identified with the current measure reporting requirements. Some of the challenges identified were:

- Many commenters noted issues specifically with capturing the weight value within the 24-hour timeframe as specified by the measure. Commenters noted challenges with this timeframe due to changes in patient status from observation to inpatient, data inconsistencies with patient transfers between facilities, labs being collected during pre-op appointments prior to the 24-hour timeframe for surgical patients, and prolonged emergency department stays. A few commenters noted while CMS has approved further revisions to the measure logic including updates to the timing of taking a patient's weight, these updates do not take effect until reporting that impacts the FY 2027 payment determination due to the existing eCQM Annual Update process. These commenters therefore noted that voluntary reporting should be extended until the FY 2027 payment determination when changes to the timing requirements for capturing the weight value will be implemented;
- Many commenters also noted challenges with the reporting of some of the CCDE required laboratory results. These challenges include difficulties related to the timing of when labs were drawn, including labs drawn outside of the 24-hour period currently specified by the measures, noting that this 24-hour requirement also encourages unnecessary duplication of lab tests. Many commenters also stated that some of the required laboratory results appear as ''missing'' because they were unnecessary to draw for the patient;
- Many commenters expressed concern regarding the lack of a standard unit of measurement for required CCDE data elements, specifically platelet values. A few commenters noted that units of measurement commonly used for platelets were counted as ''missing'' in their performance reports. A few commenters suggested additional

guidance is needed on whether the result for a non-standard unit can be converted;

- A few commenters stated that they received data submission errors related to linking variables, such as sex and date of birth;
- A few commenters stated that they need additional time to develop processes to improve collection of Health Insurance Claims Number or Medicare Beneficiary Identifier (HICN/MBI) for Medicare Advantage patients, which is one of the required linking variables for both measures;
- Several commenters representing specialty hospitals requested that the measures be refined to include a minimum relevant population threshold exemption for other patient populations such as surgical, hospice, psychiatric, and orthopedic patients; and
- Many commenters expressed the need for a longer voluntary reporting period to address clinical workflow and improve data collection processes by working with their hospitals' vendors before requiring reporting on all elements of these hybrid measures. A few commenters noted that small and rural hospitals require more time and flexibility to successfully implement new measure reporting requirements. Another commenter stated that hospitals need time to adjust time and date of admission status, as they found issues with misalignment between the CMS claims data and their EHR vendor. A few commenters expressed that variations in EHR systems present challenges in meeting measure thresholds. A commenter stated that these hybrid measures have been especially challenging during times of limited resources following the COVID–19 public health emergency.

Response: We thank the commenters for their feedback regarding the need for additional time before mandatory reporting of CCDEs and linking variables. Based on this feedback, in addition to finalizing our proposal to extend voluntary reporting of the CCDEs and linking variables for the Hybrid HWR and Hybrid HWM measures, for the performance period of July 1, 2023, through June 30, 2024, impacting the FY 2026 payment determination for the Hospital IQR Program, we will also finalize an additional year of voluntary reporting of the CCDEs and linking variables for these measures, for the performance period of July 1, 2024, through June 30, 2025, impacting the FY 2027 payment determination.

Specific to comments about the current timing requirements for CCDEs, in the eCQM Annual Update that will be posted in Spring 2025, we will extend the anchor timestamp requirement for CCDEs from the first CCDE beginning 24 hours before to 24 hours after the start of the inpatient admission for laboratory results and 24 hours before to 2 hours after the start of the inpatient admission for vital signs (except weight), to the first CCDE resulted after the start of the hospital encounter. This change may increase hospital success in reaching Hospital IQR Program threshold requirements, while maintaining the intent of the measure to collect the earliest laboratory test results and vital signs upon hospital arrival. The Spring 2025 Annual Update impacts the July 1, 2026, through June 30, 2027, performance period which is associated with the FY 2029 payment determination.

Specific to commenter concerns that platelets counted as ''missing'' in performance reports, we note that beginning with July 1, 2023, through June 20, 2024, performance period data, which is associated with the FY 2026 payment determination, platelet laboratory test values with the unit of Femtoliter (fL) will be accepted. The current specifications request hospitals to submit CCDE in Unified Code for Units of Measure (UCUM) units. To reduce hospital burden, any unit may be submitted by hospitals, as we convert to standard units during data cleaning. When the reported unit is not able to be converted to the requested UCUM units, the value will be set to missing and the median value reported for that CCDE will be imputed. In analyzing the data from the voluntary periods, we observed a large proportion of platelet values that were marked as missing. Within the platelet values reported as missing, a large portion of submitted values were unusable in measure calculation due to a unit, Femtoliter (fL), that cannot be converted to the standard unit (10*3/uL) without additional lab values from hospitals. This means that reported fL values were set to missing and the submission did not count towards hospitals' 90 percent reporting threshold for CCDEs. In reviewing these results, we confirmed that we are able to convert the values and/or apply a data imputation method to utilize values for platelets using data that are submitted in Femtoliters.

Regarding concerns about submitting sex and date of birth linking variables, we note that those linking variables are no longer required for submission.

Regarding the request for a population threshold exemption, in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49304), we stated that we do not believe that threshold exemptions are necessary for hybrid measures because the measures utilize the Initial Patient Population (IPP) and CMS confirms the measure cohort to determine whether a hospital has met the denominator criteria. However, we will continue to review hospital performance and consider ways to address the needs of specialty hospitals with a small number of relevant patients.

Comment: Many commenters described challenges meeting the 90 percent thresholds for CCDEs and the 95 percent thresholds for linking variables, and recommended reducing the required percentages. A few commenters recommended lowering the threshold of reporting laboratory results (included in the CCDEs) to no more than 80 or 85 percent for the first mandatory reporting period.

Response: We understand that some hospitals experienced difficulties with the submission requirements for CCDEs and linking variables for these measures during the voluntary reporting periods. We thank commenters for providing details of those challenges. We will continue to monitor hospital performance of these measures and intend to propose to lower the reporting thresholds in the upcoming FY 2026 IPPS/LTCH PPS proposed rule.

Comment: One commenter recommended that CMS create a specific hybrid measure Extraordinary Circumstances Exception (ECE) consideration based on the use of Certified Electronic Health Record Technology (CEHRT). The commenter stated that electronic Clinical Quality Measures (eCQMs) and hybrid measures are the only two collection types in the Hospital IQR Program that require the use of CEHRT and that CMS has specific ECE considerations for eCQMs, including issues related to the use of CEHRT. The commenter stated that CMS should have ECE considerations in the same manner as eCQMs when it comes to the use of CEHRT.

Response: We thank the commenter for this suggestion and will take it under consideration.

Comment: A few commenters requested additional clarity within measure specification documents. These commenters stated that the definitions in the specifications are not clear, that the specifications do not clearly describe the percentage thresholds required for measure submission, and that the measure specifications do not clearly describe how the measure results will be calculated. A few commenters requested clarification within the specifications on the surgical specialty cohort of the Hybrid HWR measure and the surgical divisions of the Hybrid HWM measure and sought additional

information regarding what group of surgical patients might be excluded.

Response: We thank the commenters for identifying topics within the measure specifications that could be clearer or where additional guidance would be useful. Regarding concerns that the specifications do not describe the percentage thresholds, we note that we do not typically include programmatic form, time, and manner requirements in the measure specifications.

Regarding measure calculation, for the Hybrid HWR measure, index admissions are assigned to one of five mutually exclusive specialty cohort groups consisting of related conditions or procedures. For each specialty cohort group, the standardized readmission ratio (SRR) is calculated as the ratio of the number of ''predicted'' readmissions to the number of ''expected'' readmissions at a given hospital. This approach is analogous to a ratio of ''observed'' to ''expected'' used in other types of statistical analyses. The specialty cohort SRRs are then pooled for each hospital using a volume-weighted geometric mean to create a hospital-wide combined SRR. The combined SRR is multiplied by the national observed readmission rate to produce the RSRR. Similarly, for the Hybrid HWM measure, index admissions are assigned to one of 15 mutually exclusive service-line divisions consisting of related conditions or procedures. For each service-line division, the standardized mortality ratio (SMR) is calculated as the ratio of the number of ''predicted'' deaths to the number of ''expected'' deaths at a given hospital. This approach is analogous to a ratio of ''observed'' to ''expected'' used in other types of statistical analyses. A hospital-wide composite SMR is then created by pooling the service-line SMRs for each hospital using an inverse variance-weighted mean. To produce the risk-standardized mortality rate (RSMR), the composite SMR is multiplied by the national observed mortality rate.

Additional information regarding measure calculation, including the surgical cohort and surgical divisions, is available in the measures' methodology reports available at *https://www.cms.gov/medicare/quality/initiatives/hospital-quality-initiative/measure-methodology*. We also note that although data submission requirements may differ by cohort or division (*i.e.,* hospitals must submit laboratory test results for at least 90 percent of discharges in non-surgical patients, meaning those not assigned to the surgical specialty cohort of the Hybrid HWR measure or the surgical divisions of the Hybrid HWM measure), no specialty cohort is excluded from the measure. We note that any updated guidance, or any future updates to measure specifications, will be made available at: *https://qualitynet.cms.gov/inpatient/measures/hybrid/methodology*.

Comment: Many commenters stated that they experienced issues with the quality and timing of the feedback reports provided by CMS. Many commenters expressed concern regarding the timing in receiving Hospital-Specific Reports (HSRs), stating that it prevented hospitals from being able to make improvements and correct data before the submission period closes. A few commenters stated that the HSRs were difficult to interpret. Several commenters expressed concern that CCDE and linking variable requirement threshold results reported in the voluntary reporting HSRs did not accurately reflect the true results due to calculations including surgical cohort patients, Medicare fee-for-service beneficiaries under the age of 65, and Medicare Advantage beneficiaries. One commenter noted that because the linking variables, vital signs, and laboratory test results are summated for all patients included in the initial population of the measure, patients that are excluded from the measure calculation are still being included in the summary Mandatory Reporting Data Submission Requirements table. The commenter stated that this makes it difficult to calculate whether their facility is meeting submission threshold requirements, as it is difficult to determine the specialty cohort the patient is in when they are excluded.

Response: We thank the commenters for sharing their experiences during the most recent voluntary reporting period and appreciate the helpful feedback and suggestions regarding ways to improve the feedback process for reporting of the Hybrid HWM and Hybrid HWR measures. Regarding timing of HSRs, Hospital IQR Program HSRs are usually released in the spring, approximately 8 months after the end of the hybrid data submission deadline. This reflects the length of time needed for the production process (*i.e.,* extracting and processing the data, updating the calculation code, running results, and updating and populating HSRs). We recognize that this year, the HSRs were not delivered until June 28, 2024, which was later than intended. We plan to release the HSRs in the spring next year. Regarding interpretation of the reports, we provided a HSR User Guide for the 2024 Voluntary Reporting to assist hospitals with interpreting the confidential HSR reports, available at: *https://qualitynet.cms.gov/inpatient/measures/hybrid/reports*, and the QualityNet Q&A tool [710] is also available for assistance if there are questions in interpreting HSRs.

Regarding concerns that patients that are excluded from the measure calculation were included in the voluntary reporting HSRs, Medicare FFS beneficiaries under the age of 65 were erroneously included in the threshold calculations in the 2023 voluntary reporting HSRs, but the 2024 voluntary reporting HSRs appropriately limited the age ranges. In the 2024 voluntary reporting HSRs, surgical cohort patients were erroneously included in the laboratory values thresholds, which should be based on the non-surgical patients only. The HSRs provided information that allowed hospitals to filter and remove these patients to derive their true laboratory values threshold result.

Regarding commenter concerns that the calculation of the inpatient population was incorrect due to inclusion of Medicare Advantage beneficiaries in the measure cohort, we are not aware of any hybrid HSRs including Medicare Advantage beneficiaries or data. However, we note that Medicare Advantage beneficiaries will be included in calculations for measure cohorts with the discharge data from July 1, 2024, through June 30, 2025 (88 FR 59161 through 59165 and 88 FR 59165 through 59168). We will review the commenter's concerns and review the initial patient population included in the next HSR release, which will include Medicare Advantage patients, for any issues.

Comment: Commenters provided many suggestions to improve the submission process. A few commenters recommended having a test submission process like that of eCQMs. One commenter recommended continuous monitoring and a formal feedback mechanism for ongoing improvement. A few commenters recommended CMS provide reports to support validation at the time of submission. Several commenters recommended providing technical assistance and resources to assist hospitals in meeting the thresholds. One commenter recommended best practice sharing and targeted support for small and rural hospitals. One commenter stated the style sheets used to evaluate the Quality Reporting Document Architecture (QRDA) I reports needed to be updated.

[710] Available at: *https://cmsqualitysupport.servicenowservices.com/qnet_qa*.

Additionally, a few commenters noted delayed or missing responses from CMS help desk and JIRA tickets.

Response: Regarding a test submission process, we note that the annual hybrid measures submission period is similar to the annual eCQM submission periods. Once we announce the HQR system is open to accept hybrid measure data, hospitals and/or vendors can test their submission files as often as needed and until the deadline. Once hospitals and/or vendors have validated their files are properly formatted and errors corrected, they can submit their files to ''production.'' Both ''test'' and ''production'' file submissions may be submitted once the portal opens through the submission deadline. We note that CMS does not maintain a QRDA style sheet; however, the HL7 QRDA I and III standards zip files direct users to use the Clinical Document Architecture stylesheet available at: *https://hl7.org/permalink/?CDAStyleSheet*.

We wish to note there are several additional ways for hospitals and EHR vendors to receive technical assistance to support implementation of these measures, which include CCSQ Support Central [711] and ONC JIRA.[712] Additional resources about the hybrid measures, including fact sheets, frequently asked questions, and webinar recordings, are available on our QualityNet website at: *https://qualitynet.cms.gov/inpatient/measures/hybrid/resources*. We will continue to identify opportunities to improve our responsiveness and quality of technical assistance.

Comment: One commenter did not support the proposal to delay mandatory reporting of the CCDEs and linking variables for the Hybrid HWR and Hybrid HWM measures for a year from the previously finalized FY 2026 payment determination. The commenter stated that while they appreciated CMS' analyses from recent voluntary reporting that 75 percent or more of hospitals are projected to not meet the reporting thresholds for key hybrid data elements, the commenter stated that CMS should not allow hospitals to delay mandatory reporting in these important measures due to the hospitals' own actions or inactions. The commenter stated that a reduction of annual payment update is a fair consequence given hospitals have had ample notification of CMS' plans for these measures. The commenter stated that allowing such delays sets a troubling precedent, as it implies that hospitals' actions or inactions during the voluntary reporting period can influence and potentially disrupt the established timeframes set by rulemaking.

Response: We thank the commenter and agree that these measures are important. Hybrid measures are a new mode of data collection for quality measures. They are unique compared to other quality measures in that they use more than one source of data and calculation requires that hospitals submit administrative data elements along with the CCDEs extracted from hospital EHRs. We understand that hospitals have faced a myriad of challenges with this new form of submission, as discussed in the comment summaries, and need additional time to successfully adapt to this method of reporting. Additionally, we will benefit from additional time to analyze the issues hospitals are facing to determine whether further refinements to the measures are warranted to enable reasonable levels of successful reporting for hospitals.

After consideration of the public comments we received, we are finalizing our proposal to continue voluntary reporting of the CCDEs and linking variables for both the Hybrid HWR and Hybrid HWM measures, for the performance period of July 1, 2023, through June 30, 2024, impacting the FY 2026 payment determination for the Hospital IQR Program. We are also finalizing our proposal that the Hybrid HWR and Hybrid HWM measures will be publicly reported based on claims data for the performance period of July 1, 2023, through June 30, 2024, impacting the FY 2026 payment determination.

Additionally, based on public comments regarding the need for additional time, we are further extending voluntary reporting of CCDEs and linking variables for the performance period of July 1, 2024, through June 30, 2025, impacting the FY 2027 payment determination for the Hospital IQR Program, for both the Hybrid HWR and Hybrid HWM measures. The Hybrid HWR and Hybrid HWM measures will be publicly reported using claims data for the performance period of July 1, 2024, through June 30, 2025, impacting the FY 2027 payment determination. We intend to make additional changes to the measures, including lowering the reporting thresholds, and will propose any substantive changes in future rulemaking.

[711] Available at: *https://cmsqualitysupport.servicenowservices.com/ccsq_support_central*.

[712] Available at: *https://oncprojectracking.healthit.gov/olp/*.

XXIII. Individuals Currently or Formerly in the Custody of Penal Authorities

A. Medicare FFS No Legal Obligation To Pay Payment Exclusion and Incarceration (Revisions to 42 CFR 411.4)

1. Background

Section 1862(a)(2) of the Act prohibits Medicare payment under Part A or Part B for any expenses incurred for items or services for which the individual furnished such items or services has no legal obligation to pay, and which no other person (by reason of such individual's membership in a prepayment plan or otherwise) has a legal obligation to provide or pay for, except in the case of Federally qualified health center services. We refer to this payment exclusion as the ''no legal obligation to pay'' payment exclusion. The no legal obligation to pay payment exclusion is codified in regulation at § 411.4. The regulatory exclusion includes a general rule at § 411.4(a) that applies to all services (except as provided in § 411.8(b), which applies to services paid for by a government entity) and a special condition at § 411.4(b) for services furnished to individuals in custody of penal authorities.

In the 1989 final rule establishing the special condition at § 411.4(b) for services furnished to individuals in custody of penal authorities, we explained that the purpose of § 411.4(b) is to clarify how the no legal obligation to pay payment exclusion applies to services furnished to prisoners (see 54 FR 41716, 41723 (Oct. 11, 1989)) (''1989 final rule''). We explained that prisoners generally have the status of public charges and, as such, have no obligation to pay for the medical care they receive. Consequently, under the statutory no legal obligation to pay payment exclusion at section 1862(a)(2) of the Act, Medicare is prohibited for paying for such care. We noted, however, that in certain circumstances prisoners could have a legal obligation to pay for health care items or services they receive, and in such circumstances, Medicare may pay for the items or services.

As finalized in the 1989 final rule, the special rule at § 411.4(b) specifies the conditions that must be satisfied to establish that a prisoner has a legal obligation to pay for health care items or services and, thus, that Medicare may pay for such items or services. Specifically, § 411.4(b) provides that Medicare may pay for services furnished to individuals in the custody of police or other penal authorities or in the

custody of a government agency under a penal statute only if the following conditions are met: (1) State or local law must require individuals in custody to repay the cost of the medical services they receive while in custody; and (2) the State or local government must enforce the requirement to pay by billing all such individuals, whether or not covered by Medicare or any other health insurance, and by pursuing collection of the amounts they owe in the same way and with the same vigor that it pursues the collection of other debts.

In 2007, we added a description of ''custody'' to the special condition at § 411.4(b) for services furnished to individuals in the custody of penal authorities (see 72 FR 47130, 47405 through 47406 (Aug. 22, 2007)) (''2007 final rule''). We noted that CMS would not defer to a particular State or local government's definition or interpretation of what constitutes ''custody.'' Instead, we adopted a definition of ''custody'' that is consistent with how the term has been defined by Federal courts for purposes of the habeas corpus protections of the U.S. Constitution. As finalized, § 411.4(b) provides that individuals who are in custody include, but are not limited to, individuals who are under arrest, incarcerated, imprisoned, escaped from confinement, under supervised release, on medical furlough, required to reside in mental health facilities, required to reside in halfway houses, required to live under home detention, or confined completely or partially in any way under a penal statute or rule. We explained that, under this description, individuals who are on parole, probation, bail, or supervised release may be in custody for purposes of the payment exclusion. We also stressed that individuals who are under supervised release for the purpose of receiving medical services on so-called ''medical furlough,'' and who are required to return to a State or local government facility after the medical services are furnished, are considered to be in custody for purposes of the no legal obligation to pay payment exclusion.

In the 2007 final rule, we responded to several commenters who objected to the breadth of the description of custody that we adopted. The commenters maintained that the policy would place an unreasonable burden on hospitals, because hospitals often have no means of identifying whether an individual is in custody for purposes of § 411.4(b) if the individual is not physically confined in a correctional facility or brought to the hospital by government authorities. Another commenter added that a hospital has no way of knowing whether an individual who is in custody for purposes of § 411.4(b) has a legal obligation to pay for his or her medical care. In response, we stated that hospitals are not required to seek criminal histories or do background checks on all patients being registered. We explained that, if Medicare denies payment because the individual receiving care is in custody of penal authorities, the provider or supplier will be directed to seek payment from the State or local government that has custody of the individual. We concluded that, if the State or local government believes in such circumstances that it is not responsible for the care provided to the individual, it should be prepared to prove to Medicare either that the individual would not be considered to be in custody under Federal habeas corpus law or that the State or local government has no legal obligation to pay for the services because the conditions in § 411.4(b)(1) and (2) are satisfied.

There have been no further revisions to § 411.4 since it was revised in 2007.

2. Summary of the Proposed Provisions

The special condition at § 411.4(b) for services furnished to individuals in custody of penal authorities operates as a rebuttable presumption. The presumption is that individuals who are in custody, as the term is described in § 411.4(b), have no legal obligation to pay for health care items or services they receive while in custody; therefore, Medicare is prohibited from paying for such health care items or services under the statutory no legal obligation to pay payment exclusion. The presumption can be rebutted by a showing that: (1) the State or local government requires individuals in custody to repay the cost of the medical services they receive while in custody; and (2) the State or local government enforces the requirement to pay by billing all such individuals, whether or not covered by Medicare or any other health insurance, and by pursuing collection of the amounts they owe in the same way and with the same vigor that it pursues the collection of other debts.

In the CY 2025 OPPS/ASC proposed rule, we proposed to narrow the description of ''custody'' in § 411.4(b), because, as explained in greater detail below, we no longer believe that certain classes of individuals should be presumed to be in custody for purposes of the no legal obligation to pay payment exclusion. We also proposed to consider certain individuals who are required to reside in halfway houses not to be in custody for purposes of the no legal obligation to pay payment exclusion under specified conditions.

We proposed to redesignate the description of ''custody'' as § 411.4(b)(3), to remove individuals who are on supervised release and home detention from the current description of ''custody,'' and to strike the phrase ''completely or partially in any way under a penal statute or rule.'' Under the proposal, individuals who have been lawfully released from confinement in jail, prison, penitentiary, or similar institution, or released following arrest (that is, the individuals are no longer physically detained by law enforcement or penal authorities) on bail, parole, probation, or home detention would not be presumed to be in custody for purposes of the no legal obligation to pay payment exclusion, even if such individuals have been conditionally released and may be required to return to jail, prison, penitentiary, or similar institution at some later time (for example, due to conviction or failure to satisfy the conditions of their supervised release). However, individuals who are on ''medical furlough'' or similar arrangements (that is, the individuals are under the control of law enforcement or penal authorities and required to return to jail or prison after medical services have been provided) would still be considered in custody for purposes of § 411.4(b)(3). Given the differences in terminology used by various Federal, State, and local government penal authorities to refer to different levels of control and confinement in the criminal justice system, we invited comments on the appropriateness of the terminology in the existing description of ''custody'' in our regulations and whether additional or different terminology should be incorporated in the description of ''custody'' at § 411.4(b)(3). We also invited comment on whether we should explicitly state in regulatory text that individuals on bail, parole, probation, or home confinement are not considered to be in custody for purposes of proposed § 411.4(b).

In the CY 2025 OPPS/ASC proposed rule, we stated that we were proposing to narrow the description of custody in § 411.4(b)(3) for several reasons. First, we believe that individuals who have been released from jail or prison on bail, parole, probation, or home detention, or who have been sentenced to probation or home detention in lieu of incarceration, typically have a legal obligation to pay for the health care items or services they receive. We do not believe that such individuals have

the status of public charges, and we do not believe that Federal, State, or local government law enforcement or penal authorities are typically responsible for providing for the health care of such individuals. We stated that we, therefore, no longer believe that such individuals (and the providers and suppliers who furnish services to them) should have the burden to prove that the special conditions in existing § 411.4(b)(1) and (2) have been satisfied in order to receive payment from Medicare. We sought specific, detailed comments on the circumstances in which individuals who have been released from incarceration on bail, parole, probation, or home detention have a legal obligation to pay for some or all of the health care items or services they receive. We also sought comment on what specific health care items or services, if any, are typically furnished by Federal, State, or local governments at no cost to individuals who have been released from jail or prison on bail, parole, probation, or home detention.

We also proposed to narrow the description of ''custody'' in § 411.4(b) to remove barriers to access to Medicare by individuals who are returning to the community after incarceration. According to advocates for individuals returning to the community from incarceration, confusion about the applicability of the payment exclusion has led individuals released from incarceration to not apply for Medicare, even if they are eligible, or to apply only for Medicaid, because they believe that Medicare will not pay for items or services that they receive under the payment exclusion. Advocates have also maintained that certain providers or suppliers may be hesitant or refuse to treat individuals who are on bail, parole, probation, or home detention because the providers or suppliers believe that Medicare payment is not available for items or services provided to such individuals. As a result, according to advocates such individuals may delay or forgo necessary treatment, including treatment for substance use disorders, upon release from incarceration. We stated that the proposed changes to the description of ''custody'' were intended to clarify that Medicare may pay for health care items and services furnished to an individual while on bail, parole, probation, or home detention, provided the individual has a legal obligation to pay for such items or services, without having to prove that the special conditions in § 411.4(b)(1) have been satisfied. (See section XII.2 of this final rule with comment period for a discussion of proposed modifications to the special enrollment periods (SEP) for formerly incarcerated individuals under §§ 406.27(d) and 407.23(d) that would also increase access to Medicare for individuals returning to the community from incarceration.)

We also explained in the CY 2025 OPPS/ASC proposed rule that our proposal to narrow the description of ''custody'' in § 411.4(b) was intended to bring the Medicare no legal obligation to pay payment exclusion into greater alignment with certain related Social Security and Medicaid provisions. As we noted, CMS relies on data provided by the Social Security Administration to identify individuals who are in custody of penal authorities. However, under Social Security regulations, individuals who are released from incarceration on parole, probation, or home detention are generally not considered to be confined for purposes of a limitation on payment of certain benefits (see section 202(x)(1) of the Social Security Act (42 U.S.C. 402)), and the Social Security data do not track such individuals. Our proposal to narrow the description of ''custody'' was intended to improve the alignment between the no legal obligation to pay regulation at § 411.4(b) and the data that is used to help carry out the rule. In the proposed rule we also noted, however, that there would still be substantive differences between the Social Security definition of ''confinement'' and the proposed description of ''custody'' at § 411.4(b)(3). Most notably, the Social Security Administration suspends benefits if the individual has been convicted of a criminal offense and sentenced to a period of confinement, and based on that conviction remains confined for more than 30 days. In contrast, under our proposed description of ''custody,'' an individual would be considered to be in custody of penal authorities for purposes of the Medicare no legal obligation to pay payment exclusion if the individual is under arrest; confined in jail, prison, penitentiary, or similar institution while awaiting trial (that is, the person has not yet been convicted); or confined in jail, prison, penitentiary, or similar institution following conviction for any period of time, including sentences of less than 30 days. We noted that these differences are a result of Medicare's statutory no legal obligation to pay payment exclusion. Specifically, in the proposed rule, we explained our belief that individuals who are confined to jail while awaiting trial typically do not have a legal obligation to pay for health care items or services. We invited comments on whether such individuals confined to jail while awaiting trial typically pay for health care items or services they receive or have a legal obligation to do so.

Our proposal to narrow the description of ''custody'' in § 411.4(b)(3) was also intended to bring the Medicare no legal obligation to pay payment exclusion into closer alignment with Medicaid. As we explained in the CY 2025 OPPS/ASC proposed rule, under Medicaid regulations, Federal Financial Participation (FFP) is not available for services provided to individuals who are inmates of public institutions (see § 435.1009), and an ''inmate of a public institution is defined generally as ''a person living in a public institution'' (see § 435.1010). According to Medicaid State Health Official Letter (SHO) # 16–007, however, individuals who are on parole, probation, or home confinement are generally not considered to be inmates for purposes of Medicaid (see SHO # 16–007 (RE: To facilitate successful re-entry for individuals transitioning from incarceration to their communities) (April 28, 2016) *available* at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/sho16007_41.pdf*). By no longer including such individuals in the Medicare description of ''custody'' at § 411.4(b)(3), our proposal was intended to improve dually eligible individuals' access to both Medicare and, potentially, Medicaid, including accessing benefits for an already-enrolled individual. As explained in the proposed rule, advocates shared anecdotally that some Medicaid agencies automatically suspend payment for services to an individual whose Medicare benefits are suspended due to a presumption that the individual is in custody. In addition, according to advocates, some individuals who are recently released from jail or prison on bail, parole, probation, or home detention have only enrolled in Medicaid, because they believe, even where they have a legal obligation to pay, that Medicare will not pay for their health care under the no legal obligation to pay payment exclusion. Our proposal to narrow the description of ''custody'' in § 411.4(b)(3) was intended to remove this real or perceived barrier to Medicare access.

We cautioned in the CY 2025 OPPS/ASC proposed rule, and we reiterate and underscore in this final rule with comment period, that the generally applicable no legal obligation to pay payment exclusion at § 411.4(a) continues to apply to services furnished to individuals on bail, parole, probation, or home detention in the same way it applies to any other Medicare

beneficiary who receives an item or service where there is no legal obligation to pay. The no legal obligation to pay payment exclusion in § 411.4(a) is a general rule that is applicable to *all* health care items or services (except Federally qualified health center services and as provided in § 411.8(b)) received by any Medicare beneficiary, regardless of whether the individual is in custody of penal authorities. Nothing in the proposed modification of the special condition at § 411.4(b) and the description of ''custody'' that we are finalizing in this final rule with comment period affects the scope of the general rule at § 411.4(a). Thus, if an individual on bail, parole, probation, or home detention has no legal obligation to pay for a health care item or service, the general rule at § 411.4(a) would continue to prohibit Medicare from paying for such a service, regardless of the scope of the description of ''custody'' in § 411.4(b)(3). For example, if a State or local government requires substance use disorder counseling as a condition of parole, and the State or local government does not charge all parolees for such services, then the parolee has no legal obligation to pay for such service under § 411.4(a); therefore, Medicare is prohibited under § 411.4(a) from paying for the service. In the proposed rule, we invited comments on what types of medically necessary health care items or services, if any, are typically provided at no cost to individuals on parole, probation, or home detention.

In addition to the proposed changes to the description of ''custody,'' we also proposed to reorganize and renumber the regulation at § 411.4(b). Currently, § 411.4(b) includes both a description of ''custody'' and a statement of the conditions that must be satisfied for payment to be made under Medicare for items or services furnished to individuals in custody of penal authorities. We proposed to separately codify the description of ''custody'' and the special conditions for payments. Specifically, at proposed § 411.4(b)(1)(i) through (iii), we proposed to state the conditions that must be satisfied for Medicare to pay for items or services furnished to an individual in custody of penal authorities; we also proposed certain non-substantive edits to the regulatory language adopted from current § 411.4(b). At proposed § 411.4(b)(2), we proposed a definition of ''penal authority'' that would apply generally to § 411.4(b). At § 411.4(b)(3), we proposed a description of ''custody'' that is narrower in scope than the current description.

To align the regulatory text with the statutory no legal obligation to pay payment exclusion at section 1862(a)(2) of the Act, we proposed certain non-substantive edits to § 411.4(a). Specifically, the statute refers to items and services but the current regulation refers only to services. Consistent with the statute, we proposed to refer to both items and services in the regulatory text. We also proposed to add a reference to Federally Qualified Health Center services at § 411.4(a) to align with the statute. Also, the current regulatory text at § 411.4(a)(2) states that no other person or organization has a legal obligation to pay, whereas the statute refers only to a person. Therefore, we proposed to delete ''organization'' from the regulation text because the term ''person'' includes both natural and non-natural persons, and the term ''organization'' is therefore superfluous. We also proposed to align the parenthetical in § 411.4(a)(2) with the statutory parenthetical and to replace the term ''beneficiary'' in § 411.4(a)(1) and (2) with ''individual'' to align with section 1862(a)(2) of the Act.

We also proposed to redesignate the special conditions that are specified in current § 411.4(b)(1) and (2) as § 411.4(b)(1)(i) through (iii). Under the proposal, the rebuttable presumption in § 411.4(b)(1) would apply to all items or services furnished to individuals in custody of penal authorities, regardless of who provides the items or services. We invited comments on whether the scope of the rebuttable presumption in proposed § 411.4.(b)(1) should be limited to items or services furnished by the penal authority or by a third party with which the penal authority has arranged to provide the items or services, noting that, if we limit the scope of the rebuttable presumption in this way, the rebuttable presumption in proposed § 411.4(b)(1) would not apply to items or services furnished to individuals in custody of penal authorities by third parties who do not have an arrangement or contract with the penal authority to provide the items or services. We also invited comments on whether individuals in custody of penal authorities are permitted to arrange for their own health care with third parties who do not have an agreement with the penal authority to provide the items or services. Lastly, we proposed at proposed § 411.4(b)(3)(v) to clarify that an individual who is required to reside in a mental health facility would only be considered to be in custody under the no legal obligation to pay payment exclusion if the individual is required to reside in such a facility under a penal statute or rule.

In the CY 2025 OPPS/ASC proposed rule, we addressed our particular concerns with the application of the no legal obligation to pay payment exclusion to individuals residing in halfway houses. We noted that, according to the National Institute of Justice (NIJ), a research, development, and evaluation agency of the U.S. Department of Justice, the term ''halfway house'' usually refers to temporary housing, provided in a community-based residential facility, which uses around-the-clock supervision and offers services to assist with the transition from incarceration to the community (see *https://crimesolutions.ojp.gov/ratedpractices/90#1-0*). The NIJ notes that, although the degree to which services are provided to residents varies significantly among halfway house programs, the following characteristics are common to most halfway houses: (1) constant supervision and daily contact between staff and returning individuals; (2) a requirement for participants to abide by rules (such as curfews and drug testing); and (3) access to employment, education, life skills training, and additional services as needed (such as substance use disorder treatment and counseling).

As the name suggests, halfway houses occupy a middle ground between complete custodial incarceration and unconditional release, and there appears to be wide variation in the degree of control exercised over halfway house residents in various State, local, and Federal facilities. Given this variability, we solicited comments on whether halfway house residents typically have a legal obligation to pay for health care items and services, and if so, to what extent (that is, do they have a legal obligation to pay for all or most health care items or services, or only certain items or services) and under what conditions. In particular, we solicited detailed comments, with examples as appropriate, focusing specifically on the legal obligation that halfway house residents have to pay for the health care items and services they receive.

To provide greater focus for our comment solicitation on halfway houses, we proposed regulatory text at § 411.4(b)(3)(vi) that is drawn from the Medicaid payment exclusion rule at § 435.1009. As explained in SHO # 16–007, FFP is available for services furnished to Medicaid-eligible individuals living in halfway houses, provided the following conditions are met: (1) residents are not precluded from working outside the facility in

employment available to individuals who are not under justice system supervision; (2) residents can use community resources (libraries, grocery stores, recreation, education, etc.) at will; and (3) residents can seek health care treatment in the broader community to the same or similar extent as other Medicaid enrollees in the state. SHO # 16–007 adds that ''at will'' is consistent with certain house rule restrictions and travel limitations, and stipulates that the State Medicaid agency must ensure that the halfway house meets the requirements enumerated above.

Consistent with Medicaid guidance, we proposed at § 411.4(b)(3)(vi) to consider an individual to be in custody for purposes of the special condition for payment at § 411.4(b) if the individual is required to reside in a halfway house under any of the following conditions: residents are precluded from working outside the facility in employment that is available to individuals who are not under penal authority supervision; residents may not use community resources (for example, libraries, grocery stores, recreation, or educational institutions) at will; or residents may not seek health care items and services in the broader community to the same or similar extent as individuals who are not under penal authority supervision. Like Medicaid, we proposed to interpret ''at will'' to be consistent with certain house rule restrictions and travel limitations. Our proposal to align the Medicare no legal obligation to pay payment exclusion at § 411.4(b) with Medicaid guidance was intended to facilitate access to Medicare for dually eligible individuals returning to the community from incarceration and residing in halfway houses.

Consistent with our discussion regarding bail, parole, probation, and home detention, we noted in the proposed rule, and we reiterate and emphasize in this final rule with comment period, that the general no legal obligation to pay payment exclusion at § 411.4(a) could apply to services furnished to individuals in halfway houses even if those individuals are not considered to be in custody for purposes of § 411.4(b). If an individual and the individual's insurance, if any, has no legal obligation to pay for a health care item or service, then Medicare may not pay for the item or service. In the CY 2025 OPPS/ASC proposed rule, we invited comments on whether individuals who reside in halfway houses under the conditions described in proposed § 411.4(b)(3)(vi) typically do not have a legal obligation to pay for health care items or services, or whether fewer, other, or additional factors compared to the factors described in the proposal would form a more appropriate basis for a presumption that the individual is in custody and has no legal obligation to pay for health care items or services.

In the CY 2025 OPPS/ASC proposed rule, we proposed to define ''penal authority'' at § 411.4(b)(2) as a police department or other law enforcement agency, a government agency operating under a penal statute, or a State, local or Federal jail, prison, penitentiary, or similar institution. We are aware that private contractors in some circumstances may be responsible for operating certain penal institutions or halfway houses, and we sought comment on whether such contractors should explicitly be included in the proposed definition of ''penal authority.'' As we stated in the CY 2025 OPPS/ASC proposed rule, the proposed definition was intended to be broad enough to include all agencies or institutions that might place or hold an individual in custody, as the term is described at proposed § 411.4(b)(3), regardless of whether the individual has been convicted of a crime. We stated in the proposed rule that the term ''penal authority'' does not appear to be commonly used outside of the Medicare context. We invited comments on whether other terminology would be more appropriate or would align more closely with terms commonly used in the criminal justice system. We also invited comments on whether the proposed definition of ''penal authority'' is too broad or narrow for purposes of the no legal obligation to pay payment exclusion.

We received 67 comments on our proposal to narrow the description of ''custody'' in § 411.4(b) and the other proposals described above. Commenters included advocacy organizations for justice involved-individuals, States, local government and law enforcement organizations, providers and suppliers, and provider organizations. With one exception, all of the commenters supported our proposal to narrow the description of ''custody.'' A summary of the comments and our responses follows.

Comment: With one exception, commenters unanimously supported our proposal to narrow the description of ''custody'' in § 411.4(b)(3)(i) by removing individuals who are on supervised release and home detention and striking the phrase ''confined completely or partially in any way under a penal statute or rule'' from the description. The vast majority of commenters agreed that individuals on supervised release, including individuals on bail, parole, probation, or home detention, are typically responsible for their own health care costs, including securing health insurance from an employer or Medicaid. One commenter representing an advocacy organization for justice-involved individuals surveyed its community-based partners in six states and reported that, universally, the people that they serve on pretrial release, probation, and parole do not receive health care from the justice system, prisons, or jails. Another commenter representing various law enforcement and correctional facility associations stated that, in almost all U.S. jurisdictions, individuals living under any form of community supervision are responsible for securing and paying for their own health care. Likewise, a commenter representing a State's community bail fund suggested that people living in the community under any form of supervised release are typically responsible for their own health care costs. A commenter representing hospitals explained that jails do not currently have an obligation to pay for care provided to formerly incarcerated individuals, so the care provided by hospitals to this population often is uncompensated. A commenter representing a State's department of corrections explained that, while people in their State living under supervised release (including bail, community supervision, re-entry centers, and electronic home monitoring) are responsible for their own health care costs, the department of corrections does pay for intensive inpatient substance use disorder treatment for people on community supervision and in partial confinement for a small number of individuals, and it also pays for this inpatient substance use treatment if an individual does not have insurance.

Most commenters suggested that our proposal to narrow the description of ''custody'' would also promote successful reentry and community integration for people in the criminal legal system. For example, a commenter representing a State agency for public counsel services explained that its clients reentering the community who do not qualify for Medicaid often face significant health care costs, needing to either pay out-of-pocket or find other insurance, which may lead individuals to delay or forgo treatment. The commenter further explained that its clients are often unable to access treatment that is required by conditions of probation, parole, and bail, due

simply to lack of access to health insurance, and that this causes violations to occur, which can lead to the individuals being returned to custody. Other commenters representing addiction and mental health advocacy groups noted that an individual is at the highest risk for an overdose during the first 2 weeks following release from incarceration. According to these commenters, equipping individuals with timely access to substance use, mental health, and other health-related services before release would facilitate the transition to care that is necessary to mitigate the risk of recidivism and to prevent death and other avoidable harms. Another commenter representing a team of researchers, physicians, and community health workers noted that there are significant health and racial disparities between individuals with and without a history of incarceration, as well as between those on probation or parole or those who are not. Citing these substantial disparities and barriers to health care access, the commenter suggested that the proposed revisions are a crucial step towards alleviating these inequities and improving healthcare access and health outcomes. The commenter further stated that increasing Medicare access for individuals on probation and parole has the capacity to increase preventive care utilization, improve health outcomes, and enhance racial health and healthcare equity.

Commenters also reported that the proposal to narrow the description of ''custody'' would improve dually eligible individuals' access to both Medicare and, potentially, Medicaid, including accessing benefits for already-enrolled individuals. One commenter provided an example of a dually enrolled individual on probation who was legally responsible for paying for his own medication and enrolled in Part D. According to the commenter, the individual was barred from submitting claims for the medication under Part D because the individual was considered to be in custody under the Medicare no legal obligation to pay payment exclusion, but was also denied coverage for the medication under Medicaid because the individual was enrolled in Part D. Another commenter, representing a nonpartisan research and policy organization, explained that some individuals who are recently released from jail or prison on bail, parole, probation, or home detention have only enrolled in Medicaid because they believe, even where they have a legal obligation to pay, that Medicare will not pay for their health care under the no legal obligation to pay payment exclusion.

Response: Based on our review of the comments, we are persuaded that the overwhelming majority of individuals who are on bail, parole, probation, or home detention have a legal obligation to pay for most or all of the health care items or services that they receive. We therefore no longer believe it is reasonable to presume that such individuals have no legal obligation to pay for their health care. We also agree with the commenters that narrowing the description of ''custody'' in the regulatory no legal obligation to pay payment exclusion will improve access to Medicare, including access by dually eligible individuals, thus facilitating the transition to the community for formerly incarcerated individuals, mitigating the risk of recidivism, and helping to prevent death and other avoidable harms. Therefore, using our authority in sections 1862(a)(2) and 1871 of the Act, we are finalizing our proposal to remove individuals who are on supervised release and home detention and to strike the phrase ''confined completely or partially in any way under a penal statute or rule'' from the description of ''custody'' at final § 411.4(b)(3)(i). As explained in further detail below, we are also finalizing an illustrative list at § 411.4(b)(3)(ii) of individuals who are not considered to be in custody for purposes of the payment exclusion.

Although we are narrowing the description of ''custody'' to no longer include individuals on bail, parole, probation, or home detention (and, as explained below, individuals who are required to reside in halfway houses), we reiterate that the generally applicable no legal obligation to pay payment exclusion at § 411.4(a) would continue to apply to services furnished to such individuals in the same way it applies to any other Medicare beneficiary who receives an item or service where there is no legal obligation to pay. The no legal obligation to pay payment exclusion in § 411.4(a) is a general rule that is applicable to *all* health care items or services (except Federally qualified health center services and as provided in § 411.8(b)) received by any Medicare beneficiary, regardless of whether the individual is in custody of penal authorities. Thus, if a State furnishes an item or service (or arranges for an item or service to be furnished), such as intensive inpatient substance use disorder treatment, to non-Medicare individuals who are on bail, parole, probation, or home detention or who are required to reside in a halfway house, and the individuals and the individuals' insurance (if any) are not pursued for payment with the same vigor that the State pursues the collection of other debts, then Medicare payment may not be made for similar items or services, because the Medicare beneficiaries, like the non-Medicare individuals, have no legal obligation to pay for the items or services.

Comment: One commenter did not support CMS' proposed changes for formerly incarcerated individuals. The commenter stated a concern that, under our proposal, Medicare would no longer pay for community health programs that support and assist individuals returning to the community from incarceration, in an effort to prevent recidivism. The commenter expressed concern that failure to pay for such medical services would cause more harm to communities, straining the healthcare system and leading to costly health care in emergency departments.

Response: We believe that the commenter misunderstood our proposed revisions. By narrowing the description of ''custody'' at § 411.4(b)(3)(i), we were not proposing that we no longer pay for Medicare-covered items or services furnished to these individuals. Rather, we were proposing to narrow the description of ''custody'' in § 411.4(b)(3)(i) because we no longer believe that certain classes of individuals should be presumed to be in custody for purposes of the no legal obligation to pay payment exclusion. We also proposed to narrow the description of ''custody'' to remove barriers to accessing Medicare by individuals who are returning to the community after incarceration. By adopting these revisions to the description of ''custody,'' we believe that we are adequately addressing this commenter's concerns regarding policies that facilitate successful re-entry for individuals transitioning from incarceration to their communities.

Comment: Many commenters encouraged CMS to explicitly state in the regulatory text that individuals on bail, parole, probation, or home confinement are not considered to be in custody. Commenters stated that explicit regulatory text would provide much needed clarity to individuals, providers, and advocates who are navigating these circumstances. One commenter representing an advocacy organization suggested that regulatory language set in the affirmative is easier to understand and will help further align the approaches of Medicare and Medicaid. The commenter also noted that it can be hard for individuals with criminal legal histories to find health care providers, and affirmative

regulatory language can help address that issue by providing reassurance to providers that their services will be reimbursed by Medicare. Additionally, the commenter expressed concern that, without explicitly stating who is not considered to be in custody under the payment exclusion, providers may not attempt to submit claims to Medicare or may not encourage Medicare enrollment for patients under community supervision because it is too complicated or may refuse to provide services to people on community supervision, citing Medicare's payment exclusion as the reason. Another commenter representing a state Medicaid and CHIP office agreed that expressly specifying in regulation when an individual is not considered to be in custody of a penal authority would help achieve consistency and clarity, reduce potential ambiguity, and ensure fair treatment of these individuals.

Response: We are persuaded by the commenters. Therefore, using our authority at sections 1862(a)(2) and 1871 of the Act, at § 411.4(b)(3)(ii), we are including in the regulatory text an illustrative list of individuals who are not considered to be in custody under the no legal obligation to pay payment exclusion, including individuals on bail, parole, probation, and home detention and individuals who are required to reside in halfway houses. We agree that this should help to achieve consistency and clarity, reduce potential ambiguity and uncertainty, and give providers and suppliers reassurance that their services may be reimbursed by Medicare. As finalized, § 411.4(b)(3)(ii) provides that individuals who are not considered to be in custody under the payment exclusion *include, but are not limited to,* those individuals who are released to the community pending trial (including those in pretrial community supervision and those released pursuant to cash bail), on parole, on probation, on home detention or home confinement, or required to live in a halfway house or other community-based transitional facility. The list is intended to be illustrative, not exhaustive. An individual is not deemed to be in custody merely because the terminology used by a particular penal authority to denote that individual's status does not align with the terminology used in final § 411.4(b)(3)(ii). Rather, the description of ''custody'' at § 411.4(b)(3)(i) states the sufficient conditions for determining whether an individual is considered to be in custody for purposes of the no legal obligation to pay payment exclusion. (We note also that, under the qualification ''including, but not limited to'' in final § 411.4(b)(3)(ii), individuals who have no involvement with the criminal justice system or who have been unconditionally released from the custody of penal authorities are also not considered to be in custody under the Medicare payment exclusion rule.) As a reminder, if an individual in any of the circumstances listed in final § 411.4(b)(3)(ii) does not have a legal obligation to pay for a health care item or service, the general rule at § 411.4(a) would continue to prohibit Medicare from paying for such an item or service, regardless of the scope of the description of ''custody'' in § 411.4(b)(3)(i), and regardless of the fact that such individuals are not considered to be in custody under § 411.4(b)(3)(ii).

Comment: Most commenters addressing the breadth or appropriateness of the terminology in our proposed description of ''custody'' suggested that we remove the term ''under arrest.'' Some commenters stated that this term is imprecise and overly broad, and could prevent people who are on bail or pre-trial release and whose services are not covered or provided by a carceral setting from accessing Medicare. Another commenter noted that home detention is sometimes referred to as ''home arrest.'' One commenter explained that there are typically two different periods of confinement following arrest and prior to conviction. According to the commenter, when an individual is arrested, they are often confined on site or in a local police station before they are arraigned. After the individual is arraigned, they may be held in jail awaiting trial in pre-trial detention. The commenter stated that, during the pre-arraignment period, the provision of health care services is typically minimal and any health care items or services furnished are billed to the individual receiving them. In contrast, according to the commenter, individuals who are confined in jail during pre-trial detention typically do not have a legal obligation to pay for their health care. The commenter indicated that, to the extent that the term ''under arrest'' refers to pre-arraignment confinement, it should not be included in the description of ''custody,'' because these individuals typically have a legal obligation to pay for their own health care, whereas, to the extent that the term ''under arrest'' refers to pre-trial detention in jail, the term is not necessary, because the proposed description of ''custody'' already includes individuals incarcerated in jail. Many other comments agreed that the term ''incarcerated in jail'' sufficiently captures the subset of individuals who have been placed under arrest and have no legal obligation to pay for their own health care.

Response: After reviewing the comments, we agree that the phrase ''under arrest'' is imprecise and overly broad, and we are therefore removing the term from the description of ''custody'' at final § 411.4(b)(3)(i). Specifically, based on the information provided by commenters regarding the typical obligation of individuals who are under arrest to have a legal obligation to pay for the health care items or services that they receive before they are arraigned, we do not believe that it is appropriate to presume that such individuals have no legal obligation to pay for their own health care. We are also concerned that the term ''under arrest'' may cause confusion for individuals post-arraignment, because it may be applied in some jurisdictions to individuals that we are explicitly excluding from the description of ''custody,'' including individuals who have been released to the community pending trial and individuals who are on home detention or confinement. Lastly, we agree that, insofar as individuals who are under arrest are incarcerated or physically detained in a jail or similar institution, these individuals would be considered to be in custody under the description of ''custody'' at final § 411.4(b)(3)(i)(A). We reiterate that, if an individual who is under arrest has no legal obligation to pay for a health care item or service, the general rule at § 411.4(a) would continue to prohibit Medicare from paying for such an item or service, regardless of the scope of the description of ''custody'' in § 411.4(b)(3). Given the breadth and imprecision of the term ''under arrest,'' as identified by the commenters, we are similarly not including the term ''under arrest'' in the list of individuals who are presumed not to be in custody at final § 411.4(b)(3)(ii).

Comment: One commenter representing those with lived experience of the criminal justice system asserted that careful consideration should be given to individuals who experience a very short period of incarceration related to a violation of the conditions of their probation or parole. According to the commenter, the sanctions for such violations of probation or parole often fall in a gray area between a defined sentence and a pre-hearing holder. The commenter expressed a concern that individuals who are temporarily incarcerated for violating the conditions

of their probation or parole may be denied Medicare payment for health care items or services for even a short period of time.

Response: An individual who is incarcerated is considered to be in custody of penal authorities under final § 411.4(b)(3)(i)(A), even if the individual is not convicted of a crime and even if the time spent in incarceration is relatively short. While the individual is incarcerated, the special condition at § 411.4(b) applies to health care items or services that the individual receives. We note, however, that once the individual is released to the community from incarceration for the probation or parole violation, the individual would no longer be considered to be in custody under final § 411.4(b)(3), and it would no longer be necessary to overcome the rebuttable presumption at § 411.4(b)(1) for Medicare payment to be made for items or services furnished after the individual is released from incarceration.

Similar principles apply to individuals who are intermittently incarcerated, such as individuals who are required to reside in jail over the weekend but are allowed to live at home during the week. For the time period when an individual is required to be in jail, the individual is considered to be in custody under § 411.4(b)(3)(i), and there is a presumption that the individual has no legal obligation to pay for health care items or services that they receive during this period. On the other hand, the individual is not considered to be in custody under § 411.4(b)(3)(i)(A) for those days in the week when the individual is not required to reside in jail, prison, penitentiary, or similar institution. Assuming the individual would also not be considered to be in custody under § 411.4(b)(3)(i)(B) through (D) (that is, the individual is not temporarily outside of a jail, prison, penitentiary, or similar institution; on medical furlough or similar arrangement; escaped from confinement by a penal authority; or required to reside in a mental health facility under a penal statute or rule), the rebuttable presumption at § 411.4(b) would not apply to health care items or services that the individual receives on those days that the individual is not in jail or prison.

Comment: A few commenters stated that those on ''medical furlough'' should also be removed from the description of ''custody'' at § 411.4(b)(3)(i). One commenter representing a hospital association expressed concern that, without including the furlough class of individuals, hospitals will continue to provide services that remain unreimbursed and generally unbillable. A commenter representing local law enforcement agencies asserted that individuals on medical furlough are responsible for securing and paying for their own health care. Another commenter representing a State department of health asserted that individuals on medical or geriatric parole in its State have the freedom to choose their own medical care and are financially responsible for that care. The commenter expressed a concern that the phrase ''medical furlough or similar arrangements'' could be interpreted broadly to preclude coverage for those on medical and geriatric parole. The commenter also objected to the phrase ''temporarily outside of a jail, prison, penitentiary, or similar institution on medical furlough or similar arrangement'' in the proposed description of ''custody'' because the commenter believed that bail, probation, parole, and home confinement, which we proposed to remove from the description of ''custody,'' are all instances where an individual is ''temporarily outside of a jail, prison, penitentiary, or similar institution.''

Response: After considering the comments received, we do not believe it is appropriate to remove ''medical furlough or similar arrangement'' from the description of custody. The special condition at § 411.4(b) helps prevent improper Medicare payments for items and services furnished to individuals in custody of penal authorities, because such individuals typically have no legal obligation to pay for their own health care. We are concerned that categorically excluding medical furlough from the description of ''custody'' in § 411.4(b)(3) may lead to improper payments, as a penal authority would have an incentive to place Medicare beneficiaries on medical furlough to receive health care items or services that the penal authority furnishes to similarly situated non-Medicare individuals at no cost (that is, the penal authority does not pursue payment from the non-Medicare individuals and the individuals' insurance, if any). To prevent improper payments in such circumstances, we believe it is reasonable to require the penal authority to overcome the rebuttable presumption in § 411.4(b)(1) in order for Medicare payment to be made for health care items or services furnished to an individual on medical furlough. And, as explained in our response to other comments, if a penal authority has established a program or policy permitting medical furloughs or similar arrangements, we do not believe it is unreasonably burdensome for the penal authority to overcome the rebuttable presumption in § 411.4(b)(1).

We note also that we are not sure of the precise meaning of the terms ''medical or geriatric parole'' as used by the second commenter. In our regulations, the term ''medical furlough or similar arrangement'' refers to a situation where an individual is *temporarily* released from incarceration for the purpose of receiving medical services, and is unconditionally *required* to return to the jail or prison after the medical services are furnished. In contrast, the term ''parole,'' as we understand it, typically refers to a permanent release from incarceration, even if the individual has to meet certain conditions to retain their freedom. To the extent that ''medical or geriatric parole'' refers to ''parole'' in the latter sense, then, under final § 411.4(b)(3)(ii)(B), individuals who are released on medical or geriatric parole are not considered to be in custody for purposes of the payment exclusion. We note that the list of individuals who are not considered to be in custody under § 411.4(b)(3)(ii) is illustrative only and is not intended to apply only where penal authorities use specific terminology.

Comment: One commenter suggested that CMS clarify the difference between ''medical furlough'' and the practice of ''compassionate release.'' According to the commenter, ''compassionate release'' occurs where an individual is released from incarceration due to extraordinary circumstances, such as a severe or terminal illness. The commenter added that, because such individuals have completed their sentences, they typically have a legal obligation to pay for their own health care.

Response: As explained in our response to the previous comment, ''medical furlough or similar arrangement'' refers to a temporary release from incarceration for the purposes of obtaining health care with a requirement that the individual return to incarceration after treatment. In contrast, as described by the commenter, individuals who have received compassionate release are considered to have completed their sentences, and they are legally responsible for paying for their own health care. Under the circumstances described by the commenter, we agree that ''compassionate release'' is not an example of ''medical furlough or similar arrangement,'' and individuals who have received compassionate release as described by the commenter are not considered to be in custody under the

no legal obligation to pay payment exclusion. Although we do not believe that it is necessary to state specifically in regulation that individuals who have received compassionate release are not considered to be in custody, we reiterate that the list of individuals who are not considered to be in custody at final § 411.4(b)(3)(ii) is illustrative only, not exhaustive, and not intended to apply only where penal authorities use specific terminology.

Comment: One commenter representing an advocacy organization suggested that, instead of the term ''bail'' in the regulations at § 411.4(b), CMS use the phrase ''released to the community pending trial (including those in pretrial community supervision and those released pursuant to cash bail).'' This commenter expressed concern that, although bail technically refers to the process of pre-trial release, it is often used to only mean cash bail. According to the commenter, many individuals are released to the community prior to trial without cash bail and are responsible for paying for their health care.

Response: After considering the comments, we agree that the term ''bail'' may be too narrow, because it does not necessarily include individuals who have been released from jail prior to trial on their own recognizance. Therefore, we are using the phrase ''released to the community pending trial (including those in pretrial community supervision and those released pursuant to cash bail)'' rather than ''bail'' in final § 411.4(b)(3)(ii)(A).

Comment: The commenters that addressed the issue of individuals who reside in halfway houses supported narrowing the description of ''custody'' to exclude some or all individuals who are required to reside in halfway houses. We did not receive any comments in favor of considering all halfway house residents to be in custody for purposes of the no legal obligation to pay payment exclusion. Commenters reported that individuals who are required to reside in halfway houses are typically responsible for paying for their own health care. One commenter representing various law enforcement and correctional facility associations stated that, in almost all U.S. jurisdictions, individuals living in partial confinement facilities (such as halfway houses and work release facilities) are responsible for securing and paying for their own health care. Another commenter stated that most halfway house residents are responsible for their own health care, even when their freedom of movement is restricted, and gave as an example a person living in a halfway house with restricted freedom of movement setting up a mental health appointment with a therapist in the community as part of their re-entry plan. One commenter representing a State department of corrections stated that halfway house residents in its State are not responsible for their own health care if they are on ''confined'' status, while residents on ''furloughed'' status are legally responsible for the costs of that health care. A commenter representing a different State's department of corrections noted, without using the term ''halfway house,'' that individuals in its State under ''partial confinement'' are responsible for their own health care, with the exception of intensive inpatient substance use disorder treatment, which the State provides to certain individuals without charge. A third commenter representing a different State reported that individuals in its State are not required to live in halfway houses, and that individuals residing in the community under the supervision of the State's department of corrections are responsible for their own medical costs.

Response: We are persuaded by the commenters that individuals who are required to live in halfway houses typically have a legal obligation to pay for all or most of the health care items or services that they receive. Given this, we no longer believe that such individuals should be presumed to be in custody of penal authorities, with no legal obligation to pay for their own healthcare, and we no longer believe that the rebuttable presumption at § 411.4(b)(1) must be overcome in order for Medicare to pay for health care items or services furnished to such individuals. Therefore, using our authority in sections 1862(a)(2) and 1871 of the Act, in this final rule with comment period, we are not including individuals who are required to live in halfway houses in the description of custody at § 411.4(b)(3)(i). The regulation text at final § 411.4(b)(3)(ii)(E) expressly states that individuals who are required to reside in halfway houses or other community-based transitional facilities are not considered to be in custody for purposes of the no legal obligation to pay payment exclusion. We are using the phrase ''community-based transitional facility'' in the regulatory text at final § 411.4(b)(3)(ii) to make it clear that the residence where an individual resides need not be explicitly classified as a ''halfway house'' under State or local law for the exclusion from our description of ''custody'' to apply. We reiterate that § 411.4(b)(3)(ii), as finalized, is an illustrative, not exhaustive, list of individuals who are not considered to be in custody for purposes of the no legal obligation to pay payment exclusion.

With respect to work release programs, we understand that these programs differ from jurisdiction to jurisdiction. In some jurisdictions, individuals in work release programs reside in halfway houses or other community-based transitional facilities and leave the facility for limited time periods to work. Under § 411.4(b)(3)(ii)(E), these individuals are not considered to be in custody for purposes of the payment exclusion, because they reside in a halfway house or similar institution. In other jurisdictions, individuals who participate in work release programs are required to reside in a jail, prison, or similar institution while not working, even if they are permitted to leave the jail, prison, or similar institution to work for limited periods. For purposes of the no legal obligation to pay payment exclusion, these individuals are considered to be in custody under § 411.4(b)(3)(i)(A), even for the time period when they are outside of the jail or prison working, because they reside in, and remain inmates of, a jail, prison, or similar institution. We believe that the penal authority typically retains a legal obligation to pay for the health care of such individuals, even for the period when they are outside of the jail or prison working.

Finally, we note that, although commenters stated that halfway house residents typically have a legal obligation to pay for their own health care, some commenters also reported that, in certain instances, halfway house residents are not responsible for paying for some or all of their health care. We remind parties that, under the general no legal obligation to pay payment exclusion at § 411.4(a), if an individual who is required to live in a halfway house has no legal obligation to pay for a health care item or service, the general rule would continue to prohibit Medicare from paying for such an item or service, regardless of the scope of the description of ''custody'' in § 411.4(b)(3)(i), and regardless of the fact that halfway house residents are not considered to be in custody under final § 411.4(b)(3)(ii)(E).

Comment: Commenters generally supported our proposal to rely on Medicaid guidelines, drawn from SHO # 16–007, to determine if an individual who is required to reside in a halfway house should be considered to be in custody for purposes of the no legal

obligation to pay payment exclusion. Many commenters maintained that, if individuals have freedom of movement, then they should be entitled to have Medicare pay for their care. One commenter urged CMS to focus on freedom of movement and association as the determining factor, as opposed to focusing solely on the three factors drawn from SHO # 16–007 that are intended to demonstrate that an individual has freedom of movement and association (that is, freedom to seek work outside of the facility, use community resources, and procure health care in the community). The commenter expressed a concern that some halfway house residents with relatively high degrees of freedom of movement and association may be inappropriately considered to be in custody under the Medicare no legal obligation to pay payment exclusion if the facility where the individual resides fails to meet one or more of the three enumerated factors. Some commenters reported that, in some instances, halfway house residents may have their movement restricted but still have a legal obligation to pay for the health care items and services that they receive.

Many commenters explained that halfway houses are transitional facilities designed to support re-entry, where individuals typically only reside for a number of weeks. One commenter noted that a halfway house resident's degree of freedom of movement and association often increases over time as the individual advances through incentive-based phases. The commenter maintained that, under the proposed adoption of Medicaid guidelines from SHO # 16–007, on-going evaluation of an individual's degree of freedom of movement and association would be necessary to determine if the individual has the requisite degree of freedom necessary to no longer be considered in custody under the Medicare payment exclusion. The commenter recommended that CMS develop guidelines for individualized assessments of whether a halfway house resident is considered to be in custody, and include in the consideration a resident's access to health care both within and outside of the halfway house facility. Another commenter recommended that CMS focus on the reason for an individual's release to a halfway house—specifically, to facilitate successful reintegration into society—instead of the degree of freedom that the individual enjoys to determine whether the individual is in custody for purposes of the no legal obligation to pay payment exclusion.

Response: The special condition at § 411.4(b) for services furnished to individuals in custody of penal authorities is intended to clarify how the general no legal obligation to pay payment exclusion applies to services furnished to individuals in custody of penal authorities. Thus, the touchstone of our analysis is whether individuals who are required to live in halfway houses typically have a legal obligation to pay for the health care items or services that they receive. As noted in the response to comments above, we are persuaded that individuals who are required to reside in halfway houses typically have a legal obligation to pay for most or all of the health care items or services they receive. Therefore, we no longer believe that such individuals should be presumed to be in custody, with no legal obligation to pay for their own health care, under the Medicare no legal obligation to pay payment exclusion.

Although the Medicaid guidelines in SHO #16–007 offer a more targeted approach to halfway house residents, based on the comments, we are not convinced that the freedom of movement and association standard employed by Medicaid overlaps in all cases with the legal obligation to pay standard that is central to the Medicare payment exclusion. Given the typically short duration of halfway house residency, and the fact that individuals' level of freedom may increase during their residency, we are also concerned that the guidelines in SHO # 16–007 may be difficult to administer in the Medicare context, potentially adding burden and barriers to accessing Medicare payment for health care items and services. Rather than incorporate Medicaid guidelines in SHO #16–007, we are excluding halfway house residents from the description of ''custody'' at § 411.4(b)(3).

Comment: Numerous commenters suggested that we exclude from the rebuttable presumption any items or services furnished by a third party not under arrangement or contract with the penal authority. In response to our comment solicitation regarding whether an individual in custody of a penal authority is permitted to arrange for their own health care with third parties that do not have an arrangement or contract with the penal authority to provide the items or services, one commenter reported that the practice of arranging care with outside third parties varies from jurisdiction to jurisdiction. The commenter stated that, both for security purposes and to streamline staff operations, most jails and prisons use a centralized provider—either contracted or through direct hire—that provides a set of health care services and items. A commenter representing local law enforcement agencies stated that individuals in custody may be permitted to arrange for their own health care with third parties other than the health care entity that normally provides care to the penal authority facilities' residents. This commenter further explained that the incarcerated individual is typically required to pay out of pocket, not only for the health care services but also for the costs to the facility to transport the individual to the visit, including the associated custody staff costs. The commenter supported Medicare paying for the costs of such visits, including the associated transportation costs. One commenter representing a State department of corrections explained that, in the commenter's State, incarcerated individuals can request and access any health care items or services not covered by the State's health plan, but individuals are responsible for all costs related to the medical care, including transport, custody escort, mileage, medications, and any complications or follow up care indicated. The commenter explained that prison staff arrange for and schedule the care. Another commenter requested that we not presume that an individual in the custody of a penal authority who receives items and services from a third party not contracted with a penal authority has no legal obligation to pay for such items and services. This commenter went on to state that, alternatively, if such a presumption does continue to apply in these circumstances, information about how to rebut such a presumption should be amended to include circumstances where a non-contracted third party has provided health care items and services. The commenter also expressed concern that providers may not understand that the burden of rebutting the presumption is on the State or local government, not on the individual.

Several commenters representing mental health care providers requested that the rebuttable presumption not be limited to items or services furnished by the penal authority or by a third party with which the penal authority has arranged to provide the items or services. However, the commenters also suggested that the proposed regulatory description of when an individual is in ''custody'' and the requirements related to how to rebut the presumption that an individual has no legal obligation to pay

for their health care items and services would impose undue challenges to access and administrative burden for providers in confirming if someone is in custody, per the proposed definition. The commenters maintained that, by not finalizing our proposal, providers would be better positioned to serve individuals in what is often a particularly vulnerable and crucial time to access care, and individuals would have greater access to provider organizations, thereby strengthening their choice in the right treatment and care for them.

Response: After carefully considering the comments, we are not limiting the scope of the rebuttable presumption at § 411.4(b)(1) to only those items or services that are furnished by the penal authority or by a third party with which the penal authority has arranged to provide the items or services. The special condition at § 411.4(b) helps prevent improper Medicare payments for items and services furnished to individuals in custody of penal authorities, because such individuals typically have no legal obligation to pay for their own health care. We are concerned that limiting the scope of the rebuttable presumption at § 411.4(b)(1) to only items or services furnished by or on behalf of penal authorities may lead to improper payments, as penal authorities would have an incentive to arrange for Medicare beneficiaries to be treated by third party providers and suppliers, while furnishing similar items or services to similarly situated non-Medicare individuals without pursuing payment from the non-Medicare individual and the individual's insurance, if any.

To prevent improper payments in such situations, we believe it is reasonable and not unduly burdensome to require the penal authority to overcome the rebuttable presumption in § 411.4(b)(1). For example, assume that a penal authority has established a program or policy that permits individuals to receive health care items or services from third party providers or suppliers, and further that the health care items or services in question are not furnished to non-Medicare individuals at no cost (that is, the penal authority charges both Medicare beneficiaries and non-Medicare individuals for the items or services, and pursues payment in full for the items or services from both Medicare beneficiaries and non-Medicare individuals and the individuals' insurance, if any). To the extent that the penal authority is responsible for arranging such care and collecting amounts owed by incarcerated individuals for the health care items or services received, we do not believe it is unreasonably burdensome for the penal authority to overcome the rebuttable presumption in § 411.4(b)(1).

Comment: With respect to the terminology used to describe individuals who are required to reside in mental health facilities, one commenter requested that CMS replace ''under a penal statute or rule'' with ''as a result of violations of the penal code.'' According to the commenter, this terminology aligns with Medicare Part D guidance, which provides that individuals who are confined to mental health facilities as a result of *violations* of the penal code are considered to be incarcerated, while individuals who are confined to such facilities as a result of court orders not related to penal violations are not considered incarcerated.

Response: We decline to make the suggested edit because we believe it would make the description of ''custody'' too narrow for individuals who are required to reside in a mental health facility. In particular, the term ''violation'' suggests that the individual must be convicted of a criminal violation in order to be considered to be in custody under the no legal obligation to pay payment exclusion. In contrast, our description of ''custody'' is intended to capture those individuals who do not have a legal obligation to pay for their health care, which we believe also includes individuals who are required to reside in a mental health facility under a penal statute prior to conviction, while the individual is awaiting trial.

Comment: One commenter supported expanding the definition of ''penal authority'' to include private parties operating correctional facilities of any kind. The commenter stated that expanding the definition would facilitate access to the special enrollment period for individuals returning from incarceration.

Response: We are not persuaded that it is necessary to explicitly include private parties operating correctional facilities in the definition of penal authority at § 4114(b)(2). The definition of ''penal authority,'' as finalized, includes ''a State, local or Federal jail, prison, penitentiary, or similar institution.'' The definition does not specify that the facility must be owned and operated directly by a governmental authority in order to be a ''penal authority.'' Rather, under final § 411.4(b)(2), a jail, prison, or other correctional facility qualifies as a ''penal authority'' regardless of whether it is owned or operated by a governmental entity or by a private entity on behalf of a governmental entity.

Comment: Commenters variously suggested revising the term ''penal authority'' to ''correctional authority,'' ''correctional facility,'' ''carceral facility,'' or ''correctional institution.'' However, most commenters recommended we use the term ''correctional facility,'' which the commenters maintained is commonly used terminology in the criminal justice system, including by Medicaid. One commenter suggested we seek alternatives to the term ''penitentiary.''

Response: After consideration of the public comments we received, we are not persuaded to change the term ''penal authority'' in the regulation text. The definition is intended to be broad enough to include all agencies or institutions that might place or hold an individual in custody, as the term is described at final § 411.4(b)(3)(i), regardless of whether the individual has been convicted of a crime. The terms suggested by commenters are not broad enough to accomplish this. Similarly, to ensure that the definition is sufficiently broad, we are not striking the term ''penitentiary.'' We are aware that the term ''penal authority'' does not appear to be commonly used outside of the Medicare context but nonetheless believe that this is the best term to implement our policies.

After consideration of the public comments we received, we are finalizing our proposal to narrow the description of custody at final § 411.4(b)(3)(i), with one modification: we are striking the term ''under arrest.'' We are also finalizing at § 411.4(b)(3)(ii) an illustrative list of individuals who are not considered to be in custody for purposes of the no legal obligation to pay payment exclusion. In addition, we are not including halfway house residents in the description of ''custody'' in final § 411.4(b)(3)(i), and we are clarifying at § 411.4(b)(3)(ii)(E) that individuals who are required to live in a halfway house or other community-based transitional facility are not considered to be in custody for purposes of the no legal obligation to pay payment exclusion. We are also finalizing our proposed non-substantive edits to § 411.4(a) and our proposal to reorganize and renumber the regulation at § 411.4(b). Lastly, we are finalizing the definition of ''penal authority'' at § 411.4(b)(2) as proposed.

B. Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals

1. Background

The Consolidated Appropriations Act, 2021 (Pub. L. 116–260) provided the authority to establish Medicare Part A and B special enrollment periods (SEP) for individuals due to exceptional conditions. In the final rule titled ''Medicare Program; Implementing Certain Provisions of the Consolidated Appropriations Act, 2021 and Other Revisions to Medicare Enrollment and Eligibility Rules,'' which appeared in the **Federal Register** on November 3, 2022 (87 FR 66454), CMS used this authority to establish an SEP for formerly incarcerated individuals. Individuals who use this SEP are able to enroll in Medicare Premium Part A and Part B and avoid potential gaps in coverage and late enrollment penalties (LEPs). As established in §§ 406.27(d)(1) and 407.23(d)(1), an individual is eligible to enroll in Medicare Parts A and/or B using this SEP so long as they demonstrate that they are eligible for Medicare and failed to enroll or reenroll in Parts A and/or B due to being in custody of penal authorities, and there is a record of release either through discharge documents or data available to the Social Security Administration (SSA). The SEP provisions at §§ 406.27(d) and 407.23(d) incorporate the description of 'in custody of penal authorities' from the payment exclusion parameters already established in § 411.4(b). In the November 2022 final rule, we stated that it was important to align the scope of the SEP with the scope of individuals specified in § 411.4(b) as individuals in custody of penal authorities; alignment with § 411.4(b) provides a measure of assurance that individuals who are no longer subject to the payment exclusion are able to enroll in Medicare (Part B and, if necessary, premium Part A). We also noted that we would continue to assess the impact of alignment of the SEP with the scope of the payment exclusion. (87 FR 66464)

2. Summary of the Proposed Provisions, Public Comments and Responses to Comments

Section 202 of the Act generally provides the basis for SSA to determine an individual's eligibility for old age, survivors, and disability insurance (OASDI) benefits, also known as social security benefits, under Title II of the Act. For most Medicare beneficiaries, entitlement to Medicare Part A is based on entitlement to OASDI benefits under Title II per section 226 of the Act.[713] In addition, the SSA is responsible for determining entitlement to Part A and eligibility for Part B of Medicare. (See Pub. L. 103–296, sec. 105.) Section 202(x) of the Act suspends payment of OASDI benefits to prisoners, certain other inmates of publicly funded institutions, fugitives, probationers, and parolees, including when an individual is confined in a jail, prison, or other penal institution or correctional facility pursuant to conviction of a criminal offense for a period of more than 30 days. We proposed to amend the SEP at §§ 406.27(d)(1) and 407.23(d)(1) to align the SEP triggering event more closely with the bases on which an individual's OASDI benefit is reinstated or initiated rather than on the scope of the Medicare payment exclusion in § 411.4(b). We believe that these proposed amendments would streamline the administrative process for determining an individual eligible for this SEP and align eligibility for this SEP with an individual's obligation and ability to pay for services that would otherwise be covered by Medicare. Furthermore, we believe that the alignment of this SEP with the initiation or reinstatement of OASDI benefits is appropriate, as it allows a population facing many challenges reintegrating into society to enroll or reenroll in Medicare by having premiums deducted from their OASDI benefits, rather than paying out of pocket.

The proposed amendments to § 411.4(b), discussed in section XXIII.A of this final rule with comment period, would narrow the list of settings where an individual is presumed to have no obligation to pay for Medicare-covered items and services—and, thus, Medicare is prohibited from paying for those services—because the individual is in custody of a penal authority. The rebuttable presumption at § 411.4(b) provides the individual an opportunity to indicate to CMS that the other entity did not cover certain items or services and ask that Medicare provide payment, but this option is moot if the individual is not able to enroll in Medicare. (See section XXIII.A of this final rule with comment period for more information about the rebuttable presumption and operation of the payment exclusion.) Under the current version of this SEP, beneficiary advocate groups raised concerns about the possibility for scenarios where an individual is not able to enroll when their items and services could be covered by Medicare, or they are able to enroll (and pay monthly premiums) but Medicare is not able to pay for their services.

In making determinations about the suspension of OASDI benefits due to an individual's incarceration, SSA uses data it collects from jails, prisons, other penal institutions or correctional facilities and certain mental health institutions regarding individuals confined in those and similar institutions for the reasons outlined in section 202(x)(1)(A) of the Act. *See* SSA System of Records Notice: Prisoner Update Processing System 60–0269, at 64 FR 11076 (Mar. 8, 1999) and updated at 72 FR 69723 (Dec. 10, 2007), 78 FR 40542 (Jul. 5, 2013), and 83 FR 54969 (Nov. 1, 2018). However, information about individuals within the full scope of the current provisions at § 411.4(b), including not only individuals who are confined in certain institutions but also individuals who are under arrest but not yet convicted, on medical furlough, or residing in half-way houses may not be as extensively or reliably available. As a result, making eligibility determinations for the SEP for formerly incarcerated individuals as it is currently drafted is operationally difficult. In addition, the current SEP for formerly incarcerated individuals incorporates the rebuttable presumption that is included in § 411.4(b) for situations where an individual (or healthcare provider seeking to bill Medicare for the services) can demonstrate that state or local law requires individuals to repay the cost of medical services while they are in custody and the state or local government entity enforces the requirement to pay by billing all such individuals, whether or not covered by Medicare or any other health insurance, and by pursuing collection of the amounts they owe in the same way and with the same vigor that it pursues the collection of other debts. However, SSA does not have a role in administering the Medicare payment exclusion in § 411.4(b). Therefore, there is a high likelihood of potential inconsistency and administrative burden with tying the implementation of the SEP at §§ 406.27(d)(1) and 407.23(d)(1) to the Medicare payment exclusion under § 411.4(b). Although the proposed changes to § 411.4(b) discussed in section XXIII.A to narrow the scope of the payment exclusion would flow through to §§ 406.27(d) and 407.23(d) without amendment to the SEP parameters, we believe that addressing the rebuttable presumption and potential administration burden is

[713] For more detailed information about entitlement and eligibility for Medicare, please refer to sections 226, 226A, 1818, 1818A, 1836, and 1881A of the Act and 42 CFR parts 406 and 407.

appropriate and will reduce potential confusion.

Further, since the establishment of the SEP in January 2023, we have received feedback that raised concerns about tying SEP eligibility to the Medicare payment definition at § 411.4(b) and how SSA has begun administering the SEP using the data in SSA's systems. We have heard that the SEP eligibility parameters are confusing and potentially prevent or discourage eligible individuals from accessing the SEP. Conversely, situations may arise in which an individual is enrolled in Medicare using the SEP due to SSA data; however, due to the payment exclusion and limited exceptions for these settings, claims for health care may not be paid even if the specific state or local government does not provide health care in this type of setting.

Under our proposal, we intend that SSA would make a determination of an individual's eligibility to enroll using the Medicare SEP at §§ 406.27(d)(1) and 407.23(d)(1) based on the data SSA collects and keeps in its systems for determining OASDI benefit suspensions and any additional documentation provided by individuals to demonstrate that they have been released from incarceration. By more closely aligning the eligibility criteria for the SEP for formerly incarcerated individuals with the data used by SSA in applying the OASDI benefit suspension requirement in section 202(x)(1)(A) of the Act, we intend that the SEP can be more efficiently and accurately administered. With the proposed revisions, the SEP at §§ 406.27(d) and 407.23(d) will provide an opportunity, beginning January 1, 2025, for an individual to enroll in Medicare under the new parameters if the individual was released from incarceration on or after January 1, 2023, failed to enroll in Medicare (Premium Part A or Part B) due to being incarcerated, and is still within the 12-month SEP described in §§ 406.27(d) and 407.23(d).

Overall, we proposed to revise the eligibility requirements at §§ 406.27(d) and 407.23(d), beginning January 1, 2025, to remove the use of a release from the ''custody of penal authorities as described in § 411.4(b)'' and instead tie the eligibility for this SEP to whether an individual is ''released from confinement in a jail, prison, or other penal institution or correctional facility,'' which is phrasing that is more consistent with section 202(x)(1)(A)(i) of the Act. However, we did not propose that a criminal conviction or formal sentencing be required for an individual to have been confined in a jail, prison, or other penal institution or correctional facility because conviction of crime is not required for the payment exclusion in § 411.4(b) to apply. As this differs from the requirements under section 202(x)(1)(A) of the Act, we also solicited comment on what documentation an individual can provide to demonstrate they were confined and released without conviction to determine eligibility for the SEP for formerly incarcerated individuals under §§ 406.27(d) and 407.23(d). Further, individuals who have escaped confinement are not considered to be ''released'' from confinement. Under our proposal, both §§ 406.27(d) and 407.23(d) would use the terms ''incarcerated'' and ''incarceration'' as a general reference for individuals who meet either standard. The proposed change in the eligibility criteria for the SEP for formerly incarcerated individuals would align more closely with the standards SSA uses to determine whether an individual is within the scope of the limitation on payment of OASDI benefits established by section 202(x)(1)(A)(i) of the Act.

In the rulemaking to adopt and finalize §§ 406.27(d) and 407.23(d), we did not fully contemplate the implications of tying the SEP's eligibility criteria to the Medicare no legal obligation to pay payment exclusion (which includes a rebuttable presumption). A rebuttable presumption like the one available under the payment exclusion does not work well in enrollment context because although payment can be determined at the service level, an enrollment is either effectuated or not. It may be that for some services, the presumption that the individual has no legal obligation to pay can be rebutted while for other services it is not rebutted based on the scope of the state or local entity's policies and the individual's (or the healthcare providers) ability to provide sufficient evidence. However, enrollment in Medicare, including the obligation to pay Medicare premiums, would not vary with the specific service. While the proposed changes to § 411.4(b) would narrow the range of settings in which an individual is presumed to be in custody and another entity is responsible for the individual's health care coverage, we believe that the proposed revisions to §§ 406.27(d) and 407.23(d) would best address concerns about access to and confusion with the SEP for individuals who have been released from incarceration.

We proposed several changes to §§ 406.27(d) and 407.23(d) to significantly align the SEP eligibility criteria, beginning January 1, 2025, with the criteria used by SSA to determine whether an individual is incarcerated. Throughout, our proposed changes are largely to replace references to an individual being in custody of penal authorities as described in § 411.4(b) with references to an individual's confinement in a jail, prison, or other penal institution or correctional facility. First, we proposed to amend the introductory text in paragraph (d) of both §§ 406.27 and 407.23 to state the general rule that there is an SEP for Medicare eligible individuals who are no longer incarcerated after January 1, 2023. We use ''incarcerated'' and ''incarceration'' in this introductory language and in paragraph (d)(3), respectively, to include both being in custody of penal authorities as described in § 411.4(b) (and in the proposed revisions to paragraph (d)(1) of each regulation regarding the current scope of the SEP) and being confined as described in our proposed amendments to paragraph (d)(2) of each regulation. Using the term ''incarcerated'' is consistent with how these regulations were originally established and leads to more streamlined and less repetitive regulation text. We invited comments on the proposal, especially its implications for people in halfway houses, to ensure access to the SEP for formerly incarcerated individuals.

Second, we proposed to reorganize paragraphs (d)(1) and (2) to establish the rules for eligibility for and the duration of the SEP for releases from incarceration during the periods between (1) January 1, 2023, through December 31, 2024, and (2) on or after January 1, 2025. We proposed to revise §§ 406.27(d)(1) and 407.23(d)(1) to state the current parameters and duration for the SEP that are applicable to releases after January 1, 2023, and before January 1, 2025. The current eligibility requirements are proposed to be redesignated as paragraph (d)(1)(i) and the current duration of the SEP (from current §§ 406.27(d)(2) and 407.23(d)(2)) are proposed to be redesignated paragraph (d)(1)(ii), with clarifications that the date of release is used as part of the eligibility criteria. At §§ 406.27(d)(2) and 407.23(d)(2) we proposed to establish new parameters and duration for the SEP that would be applicable beginning January 1, 2025. Specifically, we proposed at new §§ 406.27(d)(2)(i) and 407.23(d)(2)(i) that an individual is eligible for the SEP if they are released on or after January 1, 2025, from confinement in a jail, prison, or other penal institution or correctional facility would be eligible for the SEP. The existing parameters

(currently at §§ 406.27(d)(1) and 407.23(d)(1)) that the individual must demonstrate that they are eligible for Medicare and failed to enroll or reenroll due to being incarcerated and there is a record of release either through discharge documents or data available to SSA would continue to be applicable and are therefore included in proposed §§ 406.27(d)(2)(i) and 407.23(d)(2)(i). At new §§ 406.27(d)(2)(ii) and 407.23(d)(2)(ii), we proposed that, beginning January 1, 2025, the SEP starts the day an individual is released from incarceration as determined by SSA and ends the last day of the 12th month after the month in which the individual is released. As noted above, individuals who use this SEP are able to enroll in Medicare Premium Part A and Part B without LEPs and this would continue to be the case whether individual uses this SEP before or after January 1, 2025.

Under the proposal, as originally intended with the SEP, individuals will have a clearer understanding for how to access this enrollment opportunity to ensure they do not have any gaps in coverage or any LEPs as they leave incarceration.

We received a number of public comments on our proposals. Our summaries and responses to the comments we received are discussed below:

Comment: Commenters unanimously supported our proposal to revise the eligibility requirements for the SEP for formerly incarcerated individuals. Commenters voiced appreciation for the changes and noted the health care access and continuity of care challenges facing formerly incarcerated individuals reintegrating into society and stated that CMS' proposal would reduce potential barriers to Medicare enrollment. Overall, commenters are pleased with the progress and dedication shown by CMS.

Response: We thank the commenters for their support.

Comment: CMS requested and received comments on the application of the SEP proposal for individuals residing in halfway houses. Commenters supported the extension of the SEP to individuals residing in halfway houses, noting that these individuals were responsible for paying for their health services and, while charity care may be available, it is often limited. Many commenters encouraged CMS to adopt the Medicaid program's approach to halfway houses, which extends Medicaid eligibility to individuals that have freedom of movement.

Response: We appreciate the overwhelming feedback received on this request. Based on the feedback received, we are revising the proposal to allow for individuals who have been recently released from incarceration or confinement and are residing in halfway houses to be eligible for this SEP. Specifically, we are revising and adopting the regulations at §§ 406.27(d)(2)(i) and 407.23(d)(2)(i) to explicitly state that individuals released from incarceration or confinement and transitioning to residence in halfway houses are not considered incarcerated or in confinement for the purposes of this SEP.

We note that section 202(x) of the Social Security Act prohibits OASDI benefit payments to beneficiaries that are confined. SSA, at GN 02607.001B.1, currently defines beneficiaries who are ''transferred from the facility to a halfway house'' as being confined, and therefore ineligible to receive OASDI benefits. Consequently, anyone utilizing this SEP and residing in a halfway house that falls under SSA's definition of confinement may be responsible for covering their Medicare premiums directly or through some other means such as Medicaid buy-in. We note that if an individual has Medicaid coverage, they will generally not use this SEP since states enroll most dually eligible individuals in Medicare and pay the premiums on their behalf under their state buy-in agreements with CMS. Further, as SSA systems may not identify individuals in halfway houses as no longer in confinement, these individuals will likely need to provide documentation of discharge to SSA proving that they have been released from incarceration to affirm eligibility for this SEP. However, as individuals in halfway houses are likely required to pay for their own healthcare and there are changes in this rule to § 411.4(b) to remove the exclusion of Medicare payment to individuals residing in halfway houses, we believe that it is critical to also extend eligibility to enroll in this SEP to individuals in halfway houses.

Comment: A few commenters recommended that CMS explicitly specify that individuals on parole, probation, under home confinement, or those in pre-trial status be eligible for the SEP.

Response: We appreciate the commenters' suggestion to further specify the categories of individuals eligible for this SEP. However, we believe the rule is inclusive of individuals on parole, probation, or under home confinement and additional categorization is unnecessary. Individuals on parole, probation, or home confinement will be able to demonstrate that they have been released from confinement and, thus, will be eligible for this SEP.

With respect to individuals in a pre-trial status, those individuals will have access to Medicare coverage and will not lose coverage due to a pending trial. Additionally, the current procedure for OASDI benefits provides that individuals in pre-trial status would not lose benefits, and therefore payment of Medicare premiums through their OASDI benefits would go uninterrupted. Therefore, we will not be making changes to extend the SEP to individuals on parole, probation, under home confinement, and those in pre-trial status.

Comment: Many commenters requested that CMS provide an option for incarcerated individuals to enroll via the SEP prior to being released from incarceration, citing concerns with access to continuity of care and gaps of coverage. Several commenters pointed to CMS' Medicaid Reentry Section 1115 Demonstration Opportunity that allows for Medicaid enrollment and coverage prior to release from incarceration as an example.

Response: We appreciate the feedback from commenters and understand the importance of mitigating the risk of gaps of coverage. However, we proposed changes specific to the eligibility requirements for the SEP for formerly incarcerated individuals and other changes to §§ 406.27(d)(2)(ii) and 407.23(d)(2)(ii), and as such, changing the duration of the SEP to allow for enrollment prior to release from confinement is not within the scope of this rulemaking.

We considered enrollment prior to release in previous rulemaking (CMS–4199–F; 87 FR 6643), but believed that our policy of allowing individuals the option of choosing an entitlement date retroactive to the first day of the month of their release from incarceration (not to exceed 6 months) addressed this issue.

In regard to the comment about applying a similar policy as the Medicaid Reentry Section 1115 Demonstration to Medicare, we note that individuals who are in confinement can enroll in Medicare during another available enrollment period, such as the IEP or GEP, and may maintain their enrollment if premium payments continue to be paid.

Comment: A few commenters suggested that CMS revise ''discharge documents'' in proposed §§ 406.27(d)(2)(i) and 407.23(d)(2)(i) to a more inclusive term, which would allow flexibility in the types of documentation accepted.

Response: We thank the commenters for their suggestion and agree that the term can be revised to be more flexible. As a result, we are revising our language at proposed §§ 406.27(d)(2)(i) and 407.23(d)(2)(i) to replace the term ''discharge documents'' with ''documentation of discharge.'' This will allow individuals who may not have specific discharge documents, but have other proof of their discharge, the ability to use the SEP.

Comment: Many commenters supported the proposal to revise the SEP eligibility criteria and requested that CMS ensure that formerly incarcerated individuals who encountered barriers to accessing the current SEP prior to January 1, 2025, have an opportunity to enroll in Medicare coverage under equitable relief grounds or through applying overlapping effective dates of these SEP changes.

Response: We thank the commenter for their support and suggestion. The parameters for equitable relief, which is a mechanism to correct or eliminate inequity to the individual when their Medicare enrollment rights are prejudiced because of the error, misrepresentation, or inaction of the Federal Government, are defined in statute (section 1837(h) of the Social Security Act) and, as such, are out of scope for this regulation. We encourage individuals to contact SSA to determine the options available to them.

Comment: Several commenters expressed support but also requested that CMS increase outreach measures specifically for this SEP. They recommended that CMS collaborate with stakeholders to distribute and engage in targeted outreach to communities with high rates of incarceration and reentry. One commenter also recommended that CMS put forth detailed educational resources for medical providers as well as guidance for states on these new policies. Another commenter requested that CMS coordinate directly with Medicaid to enroll dually eligible individuals.

Response: We thank the commenters for their support and feedback. CMS plans to continue to collaborate with stakeholders to educate and inform the targeted populations. Since this Medicare SEP is relatively new CMS has been working on several initiatives to engage stakeholders and conduct outreach and education on the availability of this new enrollment opportunity. In collaboration with the Medicare Beneficiary Ombudsman, we have conducted multiple presentations to key groups and updated relevant CMS web pages and materials. We will continue to engage partners and coordinate in how best to reach this population.

Comment: A commenter stated that requiring enrollment in person at an SSA office for the SEP can be challenging for individuals experiencing transportation challenges.

Response: This comment does not pertain to the revision of the SEP eligibility criteria and, thus, is out of scope.

3. Technical Corrections

In the November 2022 final rule that established the SEP for formerly incarcerated individuals, we provided at §§ 406.27(d)(3) and 407.23(d)(3) that, generally, entitlement would begin the first day of the month following the month of enrollment. We also provided that an individual had the option to choose a retroactive entitlement date for a period not to exceed 6 months, provided that the individual pays the monthly premiums for the period of coverage. Upon further examination of the regulations, we have identified a number of technical errors in §§ 406.27(d)(3) and 407.23(d)(3) that we are taking this opportunity to propose to correct.

First, the language in § 407.23(d)(3)(ii) states that the individual has the option to request entitlement retroactive to the *date of release* from incarceration and this implies that coverage could start in the middle of the month. Entitlement for Medicare, regardless of the enrollment period being used or whether entitlement is prospective or retrospective, always begins on the first day of a month. As such, we proposed to revise the language above to state that coverage could begin retroactive to the beginning of the month of release from incarceration. We note that the payment exclusion in § 411.4(b) may continue to apply to any items and services furnished during the period between the first of that month and the actual date of release, provided that the individual or other person has no legal obligation to pay for such services as articulated in § 411.4(a).

Second, in §§ 406.27(d)(3)(ii) and 407.23(d)(3)(ii), we erroneously cited § 406.31 when referencing the requirement for individuals to pay monthly premiums for all periods of coverage. We proposed to correct the reference to § 406.31 in § 406.27(d)(3)(ii) with § 406.32(f) and the reference in § 407.23(d)(3)(ii) to § 408.4.

Third, we also stated at § 407.23(d)(3)(ii) that if the individual requests retroactive enrollment and the application is filed within the first 6 months of the SEP, the effective date could be retroactive to the release from incarceration. If the individual requests retroactive enrollment and the application is filed in the last 6 months of the SEP, the coverage effective date could be retroactive to 6 months after the date of release from incarceration. This provision results in the same coverage effective date regardless of when the individual applies during the last 6 months of the SEP, which we do not think is consistent with our policy goal of providing formerly incarcerated individuals the ability to make the healthcare decisions best suited to their needs and provide them the opportunity to avoid or minimize gaps of coverage (87 FR 66463). We believe the best way to remedy this situation is to link the retroactive period of coverage to the date when the individual applies for Medicare coverage, not when they are released from incarceration. As such, we proposed to revise § 407.23(d)(3)(ii) to state that if the individual requests retroactive enrollment and the application is filed in the last 6 months of the SEP, the coverage effective date is retroactive to the 6th month before the month of enrollment. We believe the proposed approach strikes an appropriate balance of reducing gaps in coverage without creating excessive (and potentially costly) retroactive periods of coverage. We also proposed to make similar changes at § 406.27(d)(3)(ii) for the sake of consistency and clarity.

Comment: One commenter recommended that CMS add the phrase ''no earlier than'' before the description of when coverage begins in § 407.23(d)(3)(ii). The commenter stated that the inclusion of the proposed phrasing would further clarify an individual's ability to make the best decision about the length of retroactive coverage they need.

Response: We appreciate the commenter's recommendation and understand the importance of clarifying language so that individuals can make the decision that best suits them. However, circumstances where enrollees have the ability to pick a length of retroactive Medicare coverage would be unprecedented and would provide additional options for this population that is not available for other retroactive Medicare enrollments. Further, it would lead to operational complexity for SSA and potential enrollees to select their retroactive coverage start time for only this SEP, which may generate unnecessary confusion for individuals using this SEP. Therefore, we are declining the commenter's suggestion and will be

adopting this technical amendment as proposed.

After consideration of the public comments we received, and as discussed above, we are adopting our proposals with the following modifications:

- Sections 406.27(d)(2)(i) and 407.23(d)(2)(i) are being revised to explicitly state that individuals released from incarceration or confinement and transitioning to residence in halfway houses are not considered incarcerated or in confinement for the purposes of this SEP.
- Sections 406.27(d)(2)(i) and 407.23(d)(2)(i) are being revised to replace the term ''discharge documents'' with ''documentation of discharge.''

XXIV. Overall Hospital Quality Star Rating Modification To Emphasize the Safety of Care Measure Group: Request for Information (RFI)

A. Summary

In the CY 2025 OPPS/ASC proposed rule (89 FR 59509), we sought public input on potential methodologic modifications regarding the Safety of Care measure group within the Overall Hospital Quality Star Rating published on the provider comparison tool on *Medicare.gov* (*https://www.medicare.gov/care-compare/*). Patient safety constitutes a fundamental component of the CMS National Quality Strategy, representing a sustained commitment to fostering optimal health outcomes and ensuring the safest possible care for all patients.[714] This RFI, hereinafter referred to as ''Overall Star Rating RFI,'' gathered broad public input on increasing the Safety of Care measure group's contribution to the Overall Hospital Quality Star Rating. We also noted our intention to potentially issue additional RFIs or undertake rulemaking on this topic in the future.

B. Background

The Overall Hospital Quality Star Rating provides a summary of certain existing hospital quality information on *Medicare.gov* based on publicly available quality measure results reported through CMS' hospital quality measurement programs, by assigning hospitals between one and five stars, a way that is simple and easy for patients to understand (85 FR 86193). The Overall Hospital Quality Star Rating methodology was developed and is maintained according to the guiding principles of scientific validity, maximizing inclusion of hospitals and measure information, accounting for heterogeneity of available measures and hospital reporting, accommodating changes in the underlying measures, aligning with CMS hospital quality measure programs to the extent feasible, transparency of the methodology, and responsiveness to input from interested parties. The Overall Hospital Quality Star Rating was first introduced and reported on our Hospital Compare website in July 2016 (now reported on *Medicare.gov*) and has been refreshed multiple times, with the most current refresh in July 2024.[715]

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86193), we codified the Overall Hospital Quality Star Rating methodology, including several methodology refinements, intended to improve the simplicity and predictability of measure emphasis within the methodology over time, and comparability of ratings among hospitals. We also finalized the inclusion of Veterans Health Administration (VHA) hospitals and Critical Access Hospitals (CAHs) in the Overall Hospital Quality Star Rating. In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72233), we provided additional information on the previously finalized policy to incorporate VHA hospitals and finalized a proposal to amend 42 CFR 412.190 to revise how we would refresh the Overall Hospital Quality Star Rating annually.

C. Current Overall Hospital Quality Star Rating Methodology

Measures reported on the provider comparison tool on *Medicare.gov* (*https://www.medicare.gov/care-compare/*) that meet the criteria for inclusion in the Overall Hospital Quality Star Rating are organized into five conceptually coherent measure groups: Safety of Care, Mortality, Readmission, and Patient Experience (all of which include outcome measures), and Timely and Effective Care (which includes a selection of process measures).

The current Overall Hospital Quality Star Rating methodology includes seven general steps. First, the direction of all included measures that indicate better performance with a lower score are reversed to uniformly indicate that a higher score indicates better performance for all the measures, and all measure scores are standardized to a single, common scale to account for differences in measure score units. Second, measures are arranged into measure groups. Each measure group contains a number of publicly reported measures to produce a robust measure group score, which are reflective of differences in hospital quality. Third, the measure group scores are calculated as a simple average of measure scores. Measure group scores are then standardized to a common scale making varying scores comparable. Fourth, the hospital summary score is calculated as a weighted average of measure group scores. Specifically, each measure group score is multiplied by the assigned weight for that group. The weighted measure group scores are then summated to generate the hospital summary score. If a hospital has no measure scores in a group (for example, by not achieving sufficient sample size in any of the measures), the weight is redistributed proportionally across the remaining groups. Fifth, minimum reporting thresholds are applied. To receive a Star Rating, hospitals must report at least three measures in at least three measure groups, one of which must be either the Mortality or Safety of Care measure groups. Sixth, peer grouping is applied. Hospitals are grouped into one of three peer groups based on the number of measure groups for which they report at least three measures: a three-measure peer group, a four-measure peer group, and a five-measure peer group. Seventh, a clustering algorithm is applied within each peer group to assign hospital summary scores to star ratings so that one star is the lowest and five stars is the highest.

For additional details regarding the methodology, we refer readers to § 412.190(d) and the Overall Hospital Quality Star Rating Methodology Reports, available at *https://qualitynet.cms.gov/inpatient/public-reporting/overall-ratings/resources*.

D. Safety of Care in Star Ratings

A foundational commitment of providing healthcare services is to ensure safety, as embedded in the centuries-old Hippocratic Oath, ''First, do no harm.'' Yet, the landmark reports ''To Err is Human'' and ''Crossing the Quality Chasm'' surfaced major deficits in healthcare quality and safety.[716] [717] These reports resulted in widespread awareness of the alarming prevalence of patient harm and, over the past two decades, healthcare facilities implemented various interventions and

[714] *https://www.cms.gov/files/document/cms-national-quality-strategy-handout.pdf.*

[715] Placeholder for 2024 Stars QUS.

[716] Institute of Medicine (US) Committee on Quality of Health Care in America, Kohn, L.T., Corrigan, J.M., & Donaldson, M.S. (Eds.). (2000). To Err is Human: Building a Safer Health System. National Academies Press (US).

[717] Institute of Medicine (US) Committee on Quality of Health Care in America. (2001). Crossing the Quality Chasm: A New Health System for the 21st Century. National Academies Press (US).

strategies to improve patient safety, with some documented successes.[718] Furthermore, the COVID–19 public health emergency (PHE) strained the healthcare system substantially, introducing new safety risks and negatively impacting patient safety in the normal delivery of care.[719] [720]

Safety gaps and further risks in healthcare delivery were illuminated as a result of the COVID–19 PHE, revealing a lack of resiliency in the healthcare system.[721] [722] [723] Therefore, we are increasing efforts to emphasize the importance of patient safety for both patients and healthcare workers. To accomplish these goals, the Federal Government is taking a multi-pronged inter-Agency approach to improve safety. The Agency for Healthcare Research and Quality (AHRQ) on behalf of the Department of Health & Human Services (HHS) established the National Action Alliance to Advance Patient and Workforce Safety as a public-private collaboration to improve both patient and workforce safety and move towards zero harm in healthcare.[724] In September 2023, the President's Council of Advisors on Science and Technology (PCAST) published the ''Report to the President: A Transformational Effort on Patient Safety,'' with a call to action to renew ''our nation's commitment to improving patient safety.'' [725] The report put forth a recommendation as part of the call to action to ''establish and maintain federal leadership for the improvement of patient safety as a national priority.'' We also acknowledged a noticeable decline in patient safety measure scores during the COVID–19 PHE which reinforces the emphasis on patient safety established in several CMS initiatives, including the National Quality Strategy and Universal Foundation.[726] [727] Additionally, hospitals report data on healthcare-associated infection (HAI) measures through a number of CMS quality programs, including the Hospital-Acquired Condition (HAC) Reduction and Hospital Value-Based Purchasing Programs. These programs are designed to improve patient quality of care and safety, as well as reduce complications and mortality, by rewarding hospitals that achieve high scores on measures, including HAI measures, and penalizing those that do not meet or exceed established performance standards.[728] However, it is possible in the current Overall Star Rating methodology for a hospital to score very low in the Safety of Care measure group yet still receive a high Star Rating due to their high performance in other measure groups. Therefore, in the CY 2025 OPPS/ASC proposed rule (89 FR 59510), we noted that we seek to explore potential adjustments to the Overall Hospital Quality Star Ratings methodology that would more greatly emphasize the measures within the Safety of Care measure group, in alignment with other CMS and HHS efforts to improve patient safety across all programs.

There are currently eight measures in the Safety of Care measure group, including six HAI measures (HAI–1 through HAI–6), one Complications measure after total hip or total knee replacement (Hip/Knee), and one composite adverse event measure (Patient Safety and Adverse Events Composite (PSI–90)). While this group of measures has been the same since the inception of the Overall Hospital Quality Star Rating, the specific safety measures included may be subject to change in the future. Measures reported on the provider comparison tool on *Medicare.gov* (*https://www.medicare.gov/care-compare/*) undergo a rigorous development process which includes extensive measure testing, vetting by interested parties, evaluation by the Consensus-based Entity (which convenes the Partnership for Quality Measurement), and undergoing rulemaking for inclusion in CMS programs and public reporting. As such, the Overall Hospital Quality Star Rating methodology uses the measures as required under the CMS programs, with measure scores as reported on *Medicare.gov* at the time of the Overall Hospital Quality Star Rating calculation. Thus, any measures that are removed or suspended from one of the CMS hospital quality measure programs and not published on *Medicare.gov* would no longer be included. Similarly, any measures that are added to the CMS programs and displayed on *Medicare.gov* may be included in the Overall Hospital Quality Star Rating; for example, upcoming measures such as the Severe Obstetric Complication (87 FR 48780), Failure-to-Rescue (89 FR 35934), Hospital Harm-Severe Hypoglycemia (89 FR 35934), and Hospital Harm-Opioid-related Adverse Events (87 FR 48780) measures may be considered for inclusion in the Safety of Care measure group. The assessment presented here is based only on the current group of eight measures as listed above, but the Overall Hospital Quality Star Rating methodology is designed with the flexibility to accommodate such changes in the future.

The current methodology places the highest emphasis on the Safety of Care and Mortality measure groups. First, the measure group weights currently utilized in the Overall Hospital Quality Star Rating methodology are based on CMS policy and interested party feedback. Currently, the Safety of Care, Mortality, Readmission, and Patient Experience measure groups are each weighted 22 percent while the Timely and Effective Care measure group is weighted 12 percent (Table 177). Interested parties generally agreed that outcome measures should have more weight since they represent strong indicators of quality and are most important to patients in making healthcare decisions. Interested parties and stakeholders broadly considered the current weightings to be acceptable.

The Safety of Care and Mortality groups are further emphasized in the reporting threshold to receive a Star Rating: hospitals must report at least three measures in each of at least three measure groups, one of which must specifically be Safety of Care or

[718] Agency for Healthcare Research and Quality. (February 2021). National Healthcare Quality and Disparities Report chartbook on patient safety. Rockville, MD. Available at: *https://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/nhqrdr/chartbooks/patientsafety/2019qdr-patient-safety-chartbook.pdf*.

[719] Lastinger LM, Alvarez CR, Kofman A, Konnor RY, Kuhar DT, Nkwata A, Patel PR, Pattabiraman V, Xu SY, Dudeck MA. Continued increases in the incidence of healthcare-associated infection (HAI) during the second year of the coronavirus disease 2019 (COVID–19) pandemic. Infect Control Hosp Epidemiol. 2023 Jun;44(6):997–1001. doi: 10.1017/ice.2022.116. Epub 2022 May 20. PMID: 35591782; PMCID: PMC9237489.

[720] Patel, PR, Weiner-Lastinger, LM, Dudeck, MA, et al. Impact of COVID–19 pandemic on central-line–associated bloodstream infections during the early months of 2020, National Healthcare Safety Network. Infect Control Hosp Epidemiol 2021. doi: 10.1017/ice.2021.108.

[721] Agency for Healthcare Research and Quality. (2021). AHRQ PSNet Annual Perspective: Impact of the COVID–19 Pandemic on Patient Safety. *https://psnet.ahrq.gov/perspective/ahrq-psnet-annual-perspective-impact-covid-19-pandemic-patient-safety*.

[722] Fleisher, L.A., Schreiber, M.D., Cardo, D., and Srinivasan, M.D. (2022). Health care safety during the pandemic and beyond—building a system that ensures resilience. N Engl J Med, 386: 609–611. *https://www.nejm.org/doi/full/10.1056/NEJMp2118285*.

[723] Implications of the COVID–19 pandemic for patient safety: a rapid review. Geneva: World Health Organization; 2022. Licence: CC BY–NC–SA 3.0 IGO.

[724] AHRQ. (2023). National Action Alliance To Advance Patient and Workforce Safety. *https://www.ahrq.gov/cpi/about/otherwebsites/action-alliance.html*.

[725] *https://www.whitehouse.gov/wp-content/uploads/2023/09/PCAST_Patient-Safety-Report_Sept2023.pdf*.

[726] Fleisher, L.A., Schreiber, M., Cardo, D., Srinivasan, A. (2022). Health Care Safety during the Pandemic and Beyond—Building a System That Ensures Resilience. *The New England Journal of Medicine,* 386(7): 609–611. DOI: 10.1056/NEJMp2118285.

[727] *https://www.cms.gov/aligning-quality-measures-across-cms-universal-foundation*.

[728] *https://www.cms.gov/blog/first-do-no-harm*.

Mortality (85 FR 86228). This decision was partially informed by interested party feedback on the relative importance of patient safety and prevention of mortality.

Given the current ongoing efforts to advance patient safety, we investigated options to even further emphasize the patient safety measures in the Overall Hospital Quality Star Rating, above and beyond the emphasis of the current methodology.

We conducted an internal analysis utilizing data from the July 2023 refresh of the Overall Hospital Quality Star Rating to determine correlations between the Safety of Care measure group and performance in the Overall Hospital Quality Star Rating. There were 3,076 hospitals that met the criteria to receive a Star Rating. Among the 3,076 rated hospitals, 2,995 (97 percent) had at least one Safety of Care measure and therefore received a Safety of Care group score, while 2,615 (85 percent) had at least three Safety of Care measures. Our analysis showed a strong relationship between the Safety of Care measure group and the Star Rating. Hospitals that did well in Safety of Care tended to also do well on the Star Rating; however, there were a few hospitals that performed in the bottom quartile (lowest performing 25 percent) of the Safety of Care measure group that still received a 5-star rating. Of the 3,076 hospitals that received a Star Rating, 658 hospitals with at least three Safety of Care measures scored in the lowest quartile of the Safety of Care measure group and 19 hospitals received a 5-star rating, representing 0.6 percent of all rated hospitals (Table 175). An additional 94 hospitals fell into the lowest quartile of Safety of Care when the analysis was based on hospitals that reported just one or two Safety of Care measures. In general, these hospitals attained 5-star ratings despite poor Safety of Care performance by achieving high performance scores across the other measure groups.

TABLE 175: SAFETY PERFORMANCE OF HOSPITALS BY STAR RATING (3+ SAFETY MEASURES)

	Safety Score Range	N	1 Star	2 Stars	3 Stars	4 Stars	5 Stars
Lowest Quartile	-5.60, -0.38	658	128	230	184	97	**19**
All Hospitals	-5.60, 2.12	2615	216	575	733	680	**411**

We assessed reporting of individual Safety of Care measures and performance in the Safety of Care measure group by various hospital characteristics. We observed significant variation in the number of Safety of Care measures reported across different types of hospitals, typically with fewer measures for hospitals that have generally lower volume and so are less likely to reach sufficient case volume for individual measurements. Specifically: non-teaching hospitals, safety net hospitals,[729] critical access hospitals, smaller (< 100 beds) hospitals, rural hospitals, and hospitals not qualifying for Medicare Disproportionate Share Hospital (DSH) payments were likely to report fewer Safety of Care measures compared to teaching, non-safety net, non-critical access, hospitals with 100+ beds, urban, and DSH-qualifying hospitals (Table 176). There was a broad distribution in performance scores across hospital types; however, certain hospital characteristics appeared to be associated with performance on the Safety of Care measure group. For example, smaller hospitals were more likely to fall toward the extremes of the performance score distribution while larger hospitals fell more toward the center, and safety net hospitals tended to fall into lower quartiles than non-safety net hospitals (Table 176).

[729] Safety net hospitals are defined as those committed to caring for populations without stable access to care, specifically public hospitals or private hospitals with a Medicaid caseload greater than one standard deviation above their respective state's mean private hospital Medicaid caseload. *https://www.cms.gov/newsroom/fact-sheets/data-brief-evaluation-national-distributions-overall-hospital-quality-star-ratings#_ftn3.*

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TABLE 176: SAFETY PERFORMANCE OF HOSPITALS BY HOSPITAL CHARACTERISTICS

		Number of Hospitals Reporting Safety of Care Measures				Distribution of Safety of Care Measure Group Scores			
	N	1 measure	2	3	4+ measures	Q1 Safety	Q2	Q3	Q4
All Hospitals with Safety Score & Star Rating	**2995**	153 (5.1%)	227 (7.6%)	316 (10.6%)	2299 (76.8%)	752 (25.1%)	757 (25.3%)	816 (27.2%)	670 (22.4%)
Specialty status									
Specialty	**941**	22 (2.3%)	38 (4.0%)	64 (6.8%)	817 (86.8%)	235 (25.0%)	240 (25.5%)	263 (27.9%)	203 (21.6%)
Non-Specialty	**1932**	120 (6.2%)	174 (9.0%)	232 (12.0%)	1406 (72.8%)	477 (24.7%)	490 (25.4%)	529 (27.4%)	436 (22.6%)
Teaching Status									
Non-Teaching	**1739**	135 (7.8%)	194 (11.2%)	267 (15.4%)	1143 (65.7%)	462 (26.6%)	402 (23.1%)	453 (26.0%)	422 (24.3%)
Teaching	**1148**	8 (0.7%)	20 (1.7%)	34 (3.0%)	1086 (94.6%)	255 (22.2%)	329 (28.7%)	343 (29.9%)	221 (19.3%)
Safety net Status									
Non-safety net	**2281**	100 (4.4%)	142 (6.2%)	224 (9.8%)	1815 (79.6%)	516 (22.6%)	576 (25.3%)	663 (29.1%)	526 (23.1%)
Safety net	**586**	42 (7.2%)	70 (11.9%)	71 (12.1%)	403 (68.8%)	194 (33.1%)	154 (26.3%)	129 (22.0%)	109 (18.6%)
Critical Access									
Non-Critical Access	**2804**	58 (2.1%)	157 (5.6%)	291 (10.4%)	2298 (82.0%)	692 (24.7%)	729 (26.0%)	791 (28.2%)	592 (21.1%)
Critical Access	**191**	95 (49.7%)	70 (36.6%)	25 (13.1%)	1 (0.5%)	60 (31.4%)	28 (14.7%)	25 (13.1%)	78 (40.8%)
Bed Size									
< 100 beds	**951**	140 (14.7%)	201 (21.1%)	262 (27.5%)	348 (36.6%)	277 (29.1%)	210 (22.1%)	197 (20.7%)	267 (28.1%)
100+ beds	**1922**	2 (0.1%)	11 (0.6%)	34 (1.8%)	1875 (97.6%)	435 (22.6%)	520 (27.1%)	595 (31.0%)	372 (19.4%)
Geographic Location									
Urban	**1924**	25 (1.3%)	43 (2.2%)	120 (6.2%)	1736 (90.2%)	433 (22.5%)	487 (25.3%)	582 (30.2%)	422 (21.9%)

		Number of Hospitals Reporting Safety of Care Measures				Distribution of Safety of Care Measure Group Scores			
	N	1 measure	2	3	4+ measures	Q1 Safety	Q2	Q3	Q4
Rural	**949**	117 (12.3%)	169 (17.8%)	176 (18.5%)	487 (51.3%)	279 (29.4%)	243 (25.6%)	210 (22.1%)	217 (22.9%)
Disproportionate Share Hospital Status*									
DSH-eligible (DSH_cost >0)	**2399**	41 (1.7%)	128 (5.3%)	213 (8.9%)	2017 (84.1%)	611 (25.5%)	639 (26.6%)	677 (28.2%)	472 (19.7%)
DSH_cost: 1st Quintile	***479***	*10 (2.1%)*	*30 (6.3%)*	*45 (9.4%)*	*394 (82.3%)*	*101 (21.1%)*	*117 (24.4%)*	*148 (30.9%)*	*113 (23.6%)*
DSH_cost:2nd Quintile	***489***	*10 (2.0%)*	*24 (4.9%)*	*49 (10.0%)*	*406 (83.0%)*	*112 (22.9%)*	*142 (29.0%)*	*144 (29.4%)*	*91 (18.6%)*
DSH_cost:3rd Quintile	***408***	*16 (3.9%)*	*55 (13.5%)*	*83 (20.3%)*	*254 (62.3%)*	*124 (30.4%)*	*101 (24.8%)*	*96 (23.5%)*	*87 (21.3%)*
DSH_cost:4th Quintile	***511***	*2 (0.4%)*	*8 (1.6%)*	*19 (3.7%)*	*482 (94.3%)*	*136 (26.6%)*	*128 (25.0%)*	*163 (31.9%)*	*84 (16.4%)*
DSH_cost:5th Quintile	***512***	*3 (0.6%)*	*11 (2.1%)*	*17 (3.3%)*	*481 (93.9%)*	*138 (27.0%)*	*151 (29.5%)*	*126 (24.6%)*	*97 (18.9%)*
Non-DSH (DSH_COST =0)	**474**	101 (21.3%)	84 (17.7%)	83 (17.5%)	206 (43.5%)	101 (21.3%)	91 (19.2%)	115 (24.3%)	167 (35.2%)

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E. Potential Future Options to Greater Emphasize Patient Safety in the Overall Hospital Quality Star Rating

As part of the national commitment to improving patient safety, we sought feedback on whether hospitals that performed in the bottom quartile (lowest-performing 25 percent) in the Safety of Care measure group should be eligible to receive the highest 5-star rating. In the CY 2025 OPPS/ASC proposed rule, we noted that we are considering modifying the Overall Hospital Quality Star Rating methodology, specifically the Safety of Care measure group, to reinforce our dedication to emphasize patient safety across CMS. In this section, we discuss three options identified to modify the Overall Hospital Quality Star Rating methodology.

1. Reweighting the Safety of Care Measure Group

We conducted an internal analysis to explore the impact of modifying the weighting system for measure groups in the Overall Hospital Quality Star Rating utilizing data from the July 2023 refresh. Specifically, we explored increasing the weight assigned to the Safety of Care measure group from the current 22 percent to 30 percent while proportionally reducing the weights assigned to the other measure groups to examine the isolated effect of reweighting while otherwise adhering to the current methodology. The exact weighting values noted in the Overall Star Rating RFI are not prescriptive and could be adjusted based on interested party feedback to be more easily interpretable (for example, to 30 percent, 20 percent, and 10 percent), however, the results reported reflect this preliminary reweighting scenario that preserves proportionality between the remaining groups. Current and potential new weights for each measure group are detailed in Table 177.

TABLE 177: OVERALL STAR RATINGS WEIGHTING BY GROUP

Group	Star Ratings Weight (w_d)	Potential New Weight
Safety of Care	22%	30%
Mortality	22%	19.7%
Readmission	22%	19.7%
Patient Experience	22%	19.7%
Timely and Effective Care	12%	10.8%

Our analysis showed that by modifying the weight of the Safety of Care measure group to 30 percent, out of 3,076 hospitals, 213 hospitals would receive a higher Star Rating than when using the current weighting, while 233 hospitals would receive a lower Star Rating. Specifically, among the 752 rated hospitals in the lowest quartile of the Safety of Care measure group, 16 hospitals would achieve a higher Star Rating, while 133 hospitals would receive a lower Star Rating; only 3 of the 752 hospitals would receive a 5-star rating. Implementing this option would reduce the number of hospitals that perform poorly in Safety of Care yet still obtain the highest 5-star rating. However, reweighting the Safety of Care measure group would slightly reduce the influence of other measure groups on the Overall Hospital Quality Star Rating.

2. Policy-Based 1-Star Reduction for Poor Performance on Safety of Care

In the CY 2024 OPPS/ASC proposed rule (89 FR 59514), we explained that we are considering a post hoc policy-based adjustment that would reduce the Star Rating of any hospital in the lowest quartile of Safety of Care (based on at least three measure scores) by one star. Using 2023 Overall Hospital Quality Star Ratings data, applying a one-star reduction for all hospitals in the lowest quartile of Safety of Care with at least three safety measures would result in 530 hospitals, out of 3,076 hospitals, receiving a lower Star Rating. This option would emphasize safety through a new standard for all hospitals regardless of their Star Rating. Since the minimum Star Rating is one star, hospitals already getting one star would not get a further star reduction and therefore would effectively be exempt from this policy-based adjustment. Additionally, some hospitals that perform excellently in all other measure groups except the Safety of Care measure group would still receive a one-star reduction.

3. Reweighting the Safety of Care Measure Group Combined With a Policy-Based Star Rating Cap

In the CY 2024 OPPS/ASC proposed rule (89 FR 59514), we noted that we are also considering increasing the weight of the Safety of Care measure group to 30 percent (and proportionally reducing the weights assigned to the other measure groups, as described in Table 177) while also applying a policy that would limit hospitals in the lowest quartile of Safety of Care (based on at least three measure scores) to a maximum of four stars out of five. Using 2023 Overall Hospital Quality Star Ratings data, implementing a cap of four stars in the lowest quartile of Safety of Care with at least three safety measures combined with the reweighting for all hospitals would result in 235 hospitals, out of 3,076 hospitals, receiving a lower Star Rating and the reduction by 1 star for two hospitals in the lowest quartile of Safety of Care that would otherwise still receive a 5-star rating if only the reweighting solution was applied. This option provides a more targeted solution to the issue of hospitals performing poorly in Safety of Care receiving a 5-star rating and applies equally to all hospitals, reserving the 5-star rating for hospitals achieving a minimum threshold in Safety of Care.

We also explored alternative options for emphasizing patient safety, such as applying only the 4-star rating maximum or combining reweighting of the Safety of Care measure group with a policy-based 1-star reduction, however, these options did not effectively reach our goal of emphasizing patient safety. In our analysis, applying a 4-star rating maximum to hospitals in the lowest quartile of Safety of Care with at least three safety measures would have less impact, resulting in only 19 out of 3,076 hospitals receiving a lower Star Rating from five stars to four stars. Conversely, applying a combination of reweighting the Safety of Care measure group with a 1-star reduction may be considered an 'over-correction', resulting in 635 out of 3,076 hospitals receiving a lower Star Rating with the greatest impact on hospitals already receiving two, three, or four stars in the current methodology.

Feedback solicited during fall 2023 from interested parties, including patients, patient advocates, technical experts, and clinicians, supported the increasing emphasis on Safety of Care in the Overall Hospital Quality Star Rating methodology.[730] However, there was varying feedback from interested parties on the methods to do so, with concerns including a decreased emphasis on the other measure groups, particularly Mortality, and the adequacy of the Safety of Care group measures as currently established to truly represent the experience of patient safety at a hospital.

F. Solicitation of Public Comment

We sought comments on potential modifications to the Safety of Care measure group in the Overall Hospital Quality Star Rating methodology. We requested input from interested parties on the following options: (1) reweighting the Safety of Care measure group; (2) applying a policy-based adjustment that reduces the Star Rating of any hospital in the lowest quartile of Safety of Care (based on at least three measures in the group) by one star; (3) reweighting the Safety of Care measure group combined with a policy-based 4-star rating maximum on Star Rating of any hospital in the lowest quartile of Safety of Care (based on at least three measures in the group). Specifically, we requested comment on the following questions:

- Do you support reweighting the Overall Hospital Quality Star Rating measure groups to give greater weight to Safety of Care as described in option 1? Do you agree with the potential new weights for each measure group (as shown in Table 177)?

[730] *https://mmshub.cms.gov/sites/default/files/Star-Ratings-TEP-Summary-Report-Oct23.pdf.*

• Do you support reducing the Star Rating for hospitals with a low Safety of Care score as described in option 2? Do you agree with the potential policy to apply a 1-star reduction to all hospitals in the lowest quartile of Safety of Care?

• Do you support a combination of reweighting the Safety of Care measure group with a 4-star maximum on Star Rating as described in option 3?

• Do you have feedback or preference towards an approach of both up-scoring high performers and down-scoring poor performers as in options 1 and 3, or an approach of just down-scoring poor performers as in option 2?

• What are other methodological approaches that could be used to emphasize the Safety of Care measure group?

• With respect to the potential changes to the Overall Hospital Quality Star Rating methodology, are there any special considerations for small, rural or safety net hospitals (including Critical Access hospitals)?

Any modification to the Overall Hospital Quality Star Rating methodology would be addressed through future notice-and-comment rulemaking.

We received the following comments on this topic.

Comments on option 1, reweighting the Overall Hospital Quality Star Rating measure groups to give greater weight to Safety of Care are:

Several commenters supported the reweighting of the Safety of Care measure group, adding more emphasis on patient safety. One commenter supported the reweighting of the Safety of Care measure group and encouraged CMS to weigh it equally with the Mortality measure group. Another commenter also supported the reweighting of the Safety of Care measure group as it would allow the recalibration of this measure group, it would establish updated threshold benchmarks, and would better represent quality of care.

A few commenters expressed concern that increasing the weight of the Safety of Care measure group would de-emphasize the importance of other measure groups, particularly Patient Experience, Readmission, or Mortality. A commenter stated that equal weighting of the Mortality and Safety of Care measure groups aligns with the HVBP weighting and suggested using alternative weighting for the Safety of Care measure group could send conflicting signals.

A few commenters expressed concern that not all hospitals report on the same measures within the Safety of Care measure group. A commenter stated that hospitals that do not provide surgical services would not have the opportunity to report on certain measures within the measure group therefore, their score would rely solely on a few of the HAI's. The commenter stated increasing the weight of the Safety of Care measure group could reduce comparability between hospitals and produce less reliable ratings. Another commenter expressed concern that CMS did not take into consideration the consequences to hospitals that do not have data to report on the required number of safety measures.

Comments on option 2, reducing the Star Rating for hospitals with a low Safety of Care score with the potential policy to apply a 1-star reduction to all hospitals in the lowest quartile of Safety of Care are:

A commenter supported the removal of one star for low Safety of Care scores, and suggested hospitals with Safety of Care ratings in the lowest percentile be capped at no more than 4-stars. Another commenter agreed with the approach but believed hospitals with a 4-star rating still hold merit and only taking away one star does not significantly downgrade the ratings. Another commenter supported option 2, but suggested CMS add the new Patient Safety Structural Measure and assess if the current measures in the Safety of Care measure group truly captures the hospital's safety culture.

A few commenters stated that lowering the Star Rating by one star was unfair and overly punitive as well as oversimplified and would lead to hospitals receiving a double penalty. A few commenters noted that reducing the hospitals' Star Rating by one star would have negative impacts to the Star Rating distribution nationwide. Commenters noted that decreasing the Star Rating of hospitals performing poorly in the Safety of Care measure group by one star would not allow accurate comparison across hospitals and would not accurately reflect performance improvement, as there would always be a lowest quartile category, and CMS already penalizes for poor performance on safety measures in other programs. A commenter pointed to an in-house study which suggested this option would increase 1-star hospitals but not have any effect on 5-star hospitals. They noted this could create confusion for consumers and possibly cause reputational concerns for hospitals, especially if a once 5-star hospital was publicly reported as 4-stars. Commenters believed this approach would not take individual hospital nuances into account. A commenter suggested removing one star for poor performers would undermine the Star Rating, as a 4-star hospital that performed well across all measure groups would be compared with a 4-star hospital that did not perform well on the Safety of Care measure group.

Comments on option 3, reweighting the Safety of Care measure group and capping poor performers within the measure group at 4-stars are:

Several commenters supported this option. Commenters supported this option and noted that it is misleading to consumers if a hospital performing in the lowest quartile of this measure group could achieve 5-stars. Commenters believed that reweighting the Safety of Care measure group combined with a policy-based Star Rating cap would incentivize hospitals to invest in safety. A commenter suggested adding more patient safety measures but urged CMS to allow hospitals to test and validate any new measures before capping Star Ratings if this option is proposed. A commenter suggested increased performance and focus on patient safety would ultimately result in performance improvements in other measure groups such as Mortality and Readmissions.

A few commenters felt the reweighting of the Safety of Care measure group along with capping the Star Rating would have negligible impacts and would do a disservice to consumers when choosing a hospital as the Safety of Care measure group may not be as important to the consumer as other categories. A commenter believed this would cause confusion to consumers, as they may not understand why a hospital did not receive a 5-star rating.

We received the following comments on an approach of both up-scoring high performers and down-scoring poor performers as in options 1 and 3, or an approach of just down-scoring poor performers as in option 2:

A few commenters shared varying concerns with respect to an approach of both up-scoring high performers and down-scoring poor performers as in options 1 (reweighting the Safety of Care Measure Group) and option 3 (reweighting the Safety of Care measure group combined with a policy-based Star Rating cap), or an approach of just down-scoring poor performers as in option 2 (policy-based 1-Star reduction for poor performance on Safety of Care). One commenter expressed concern with an automatic ''up-score'' or ''down-score'' approach based on composite measure groupings noting that this approach would likely mislead consumers. Another commenter recommended a maximum of two stars

where there is poor performance in the Safety of Care measure group noting that subpar performance in safety should commensurately and inherently be reflected in a subpar Star Rating.

We received the following comments on special considerations for small, rural or safety net hospitals:

Several commenters were concerned with the impact on smaller hospitals, since at least three measures are required to score the Safety of Care measure group. A few commenters recommended CMS segment small, rural, and safety net hospitals, highlighting that smaller hospitals may report on fewer of the Safety of Care measures due to smaller populations, which could negatively impact their Star Rating. One commenter suggested adding additional safety measures relevant to rural hospitals to more accurately reflect patient safety performance and provide better comparisons among similar facilities.

We received the following comments on the composition of the Safety of Care measure group itself:

Several commenters shared concerns on the use of composite measures in the Safety of Care measure group, specifically PSI–90. One commenter suggested that the PSI–90 be split into individual measures and reweighted for patient safety focus; another commenter suggested removing PSI–90 and replacing it with other, non-composite PSI measures, such as Pressure Ulcer Rate (PSI–03), Iatrogenic Pneumothorax Rate (PSI–06), and Perioperative Hemorrhage and Hematoma Rate (PSI–09), which would allow more targeted and actionable information. A commenter stated the HAI measures should stand alone outside of the composite as their results get lost in the composite results and does not allow for easy comparison of like measures across hospitals. A commenter mentioned that the Safety of Care measure group has the most skewed measures among the five groups in the Overall Hospital Star Ratings and suggested a thorough review of the factors causing skewness in both patient safety and all other measures; another commenter recommended novel approaches to using broader safety measures that are not heavily affected by rare events. A commenter questioned whether the current Safety of Care measure group captures the safety culture of hospitals and was disappointed that CMS was only considering updating the methodology rather than assuring the safety culture of hospitals was taken into consideration; other commenters recommended ensuring all quality measures in the Safety of Care measure group accurately reflect patient and workforce safety.

We received the following comments on alternative methodological approaches that could be used to emphasize the Safety of Care measure group:

A few commenters were concerned that focusing on the Safety of Care measure group would result in excess penalties for hospitals doing well in other measure groups and would not reflect performance improvements in the Safety of Care measure group. One commenter recommended maintaining the current methodology and adding a special flag for hospitals in the lowest quartile for Safety performance, and a different flag for hospitals without a Safety score to highlight important information. Other commenters recommended equal weighting of the outcome-based Mortality, Readmission, and Safety of Care measure groups; incorporating social determinants of health as risk adjustment; and grouping hospitals on volume thresholds and surgical complexities rather the number of measure groups with at least three reported measures. A commenter suggested CMS explore placing more emphasis on patient safety in other programs, such as the Hospital-Acquired Condition Reduction Program (HACRP) and the Hospital Value-Based Purchasing (VBP) Program and was concerned that frequent changes to measures and methodologies could make it difficult for consumers to interpret Star Rating results.

We received the following general comments and recommendations for the Overall Hospital Quality Star Rating modification:

A commenter suggested adding comparison data, including percentile ranges to help identify and prioritize improvement efforts across the entire Star Rating program; another commenter recommended offering ratings by measure groups to give consumers more transparency about a provider's performance in specific areas. Other commenters recommended uniform application of a Star Rating cap across all measure groups, so poor performance in any measure group precludes hospitals from getting a 5-star rating; implementation of a simpler weighting system where the Safety of Care measure group is weighted at 30 percentage, Mortality, Readmission, and Patient Experience measure groups at 20 percentage each, and the Timely and Effective measure group at 10 percentage; delaying the proposal to modify the Overall Hospital Quality Star Rating and re-evaluating its options when more recent, non-COVID data are available; and reconsidering the methodology for determining peer groups.

Response: We thank commenters for their input and acknowledge their concerns and recommendations. We believe efforts to manage the issue of hospitals receiving a high Star Rating while performing in the lowest quartile of the Safety of Care measure group is critical to achieving our vision of emphasizing patient safety across CMS programs. We will take commenters' feedback into consideration as appropriate, in future potential rulemaking related to changes to the Overall Hospital Quality Star Rating.

XXV. Files Available to the Public Via the Internet

The Addenda to the OPPS/ASC proposed rules and final rules with comment period are published and available via the internet on the CMS website. In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59154), for CY 2019, we changed the format of the OPPS Addenda A, B, and C by adding a column titled ''Copayment Capped at the Inpatient Deductible of $1,364.00'' where we flag, through use of an asterisk, those items and services with a copayment that is equal to or greater than the inpatient hospital deductible amount for any given year (the copayment amount for a procedure performed in a year cannot exceed the amount of the inpatient hospital deductible established under section 1813(b) of the Act for that year). In the CY 2022 OPPS/ASC final rule with comment period (85 FR 86266), we updated the format of the OPPS Addenda A, B, and C by adding a column titled ''Drug Pass-Through Expiration during Calendar Year'' where we flagged, through the use of an asterisk, each drug for which pass-through payment was expiring during the calendar year on a date other than December 31. For CY 2025 and subsequent years, we proposed to retain these columns that are updated to reflect the drug codes for which pass-through payment is expiring in the applicable year.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72250) for CY 2023, we changed the format of the OPPS Addenda A, B, and C by adding a column titled ''Drug Pass-Through Expiration during Calendar Year'' to include devices, so that the column reads: ''Drug and Device Pass-Through Expiration during Calendar Year'' where we flagged, through the use of an asterisk, each drug and device for which pass-through payment was expiring

during the calendar year on a date other than December 31.

For CY 2024, we deleted the column titled ''Copayment Capped at the Inpatient Deductible'' and instead added a new column for ''Adjusted Beneficiary Copayment'' to identify any copayment adjustment due to either the inpatient deductible amount copayment cap or the inflation-adjusted copayment of a Part B rebatable drug per section 1833(t)(8)(F) and section 1833(i)(9) of the Act, as added by section 11101 of the Inflation Reduction Act (IRA). We also added another column for notes. The ''Note'' column contains multiple messages including, but not limited to, inflation-adjusted copayment of a Part B rebatable drug, the copayment for a code capped at the inpatient deductible, or 8 percent of the reference product add-on applied for a biosimilar.

In addition, for CY 2024, we updated the format of the OPPS Addenda A, B, and C by adding another column for ''IRA Coinsurance Percentage'' to identify the percentage for the inflation-adjusted copayment of a Part B rebatable drug per section 1833(t)(8)(F) and section 1833(i)(9) of the Act, as added by section 11101 of the Inflation Reduction Act (IRA).

For CY 2025 and subsequent years we proposed to keep the same format for the addenda A, B, and C, and we did not propose any additional changes for CY 2025.

We did not receive any public comments related to the format of the OPPS Addenda A, B, and C and are adopting the addenda format as proposed.

To view the Addenda to this final rule with comment period pertaining to CY 2025 payments under the OPPS, we refer readers to the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*; select ''CMS–1809–FC'' from the list of regulations. All OPPS Addenda to this final rule with comment period are contained in the zipped folder titled ''2025 NFRM OPPS Addenda'' in the related links section at the bottom of the page. To view the Addenda to this final rule with comment period pertaining to CY 2025 payments under the ASC payment system, we refer readers to the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-regulations-and-notices*; select ''CMS–1809–FC'' from the list of regulations. The ASC Addenda to this final rule with comment period are contained in a zipped folder titled ''2025 NFRM Addendum AA, BB, DD1, DD2, EE, and FF'' in the related links section at the bottom of the page.

XXVI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. ICRs for the Hospital Outpatient Quality Reporting (OQR) Program

a. Background

In section XV of this final rule with comment period, we discuss the requirements for the Hospital OQR Program. The Hospital OQR Program is generally aligned with the CMS quality reporting program for hospital inpatient services known as the Hospital Inpatient Quality Reporting (IQR) Program. We refer readers to the CY 2024 OPPS/ASC final rule with comment period (88 FR 82131 through 82140) for detailed discussions of the previously finalized Hospital OQR Program ICRs which are currently approved under OMB control number 0938–1109 (expiration date February 28, 2025).

In this final rule with comment period, we are adopting four web-based measures as proposed that would impact previously approved burden estimates: (1) the Hospital Commitment to Health Equity (HCHE) measure, beginning with the CY 2025 reporting period/CY 2027 payment determination; (2) the Screening for Social Drivers of Health (SDOH) measure, beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; (3) the Screen Positive Rate for SDOH measure, beginning with voluntary reporting for the CY 2025 reporting period and mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; and (4) the Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance Measure (Information Transfer PRO–PM), beginning with voluntary reporting for the CY 2026 reporting period and mandatory reporting beginning with the CY 2027 reporting period/CY 2029 payment determination.

We are also finalizing changes to the Hospital OQR Program that will not impact the previously approved burden estimates. We are removing two claims-based measures beginning with the CY 2025 reporting period/CY 2027 payment determination: (1) Magnetic Resonance Imaging (MRI) Lumbar Spine for Low Back Pain measure; and (2) Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery measure. We are further modifying the public reporting of data for the Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients (Median Time for Discharged ED Patients)—Psychiatric/Mental Health Patients stratification so that it may be published on the Compare tool hosted by HHS, available at: *https://www.medicare.gov/care-compare/*, or its successor website(s), in addition to the Provider Data Catalog downloadable files, available at: *data.cms.gov/provider-data/*, beginning in CY 2025. Lastly, we are requiring electronic health record (EHR) technology to be certified to all electronic clinical quality measures (eCQMs) available to report beginning with the CY 2025 reporting period/CY 2027 payment determination.

In the CY 2024 OPPS/ASC final rule with comment period, we calculated reporting burden estimates for the Hospital OQR Program by utilizing the Bureau of Labor Statistics (BLS) mean hourly wage rate for Medical Records Specialists (88 FR 82132). Specifically, we used the ''general medical and surgical hospitals'' industry to estimate the mean wage, as this categorization aligns the closest with the Hospital OQR Program care setting compared to other industries, such as ''office of physicians'' or ''nursing care facilities.'' The most recent data from BLS' May 2023 National Occupational Employment and Wage Estimates reflects a mean hourly wage of $27.69 per hour for medical records specialists

working in ''general medical and surgical hospitals'' (SOC 29–2072).[731] We calculated the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage, consistent with previous years. This is a rough adjustment, both because fringe benefits and overhead costs vary significantly by employer and methods of estimating these costs vary widely in the literature. Nonetheless, we believe that doubling the hourly wage rate ($27.69 × 2 = $55.38) to estimate total cost is a reasonably accurate estimation method. Accordingly, unless otherwise specified, we calculate cost burden to hospitals using a wage plus benefits estimate of $55.38 per hour throughout the discussion in this section of this rule for the Hospital OQR Program.

In the CY 2024 OPPS/ASC final rule with comment period, our burden estimates were based on an assumption that approximately 3,350 hospital outpatient departments (HOPDs) would report data to the Hospital OQR Program (88 FR 82132). For this final rule with comment period, based on the most recent available data from the CY 2024 Hospital OQR Program payment determination, we estimate that 3,200 HOPDs will report data to the Hospital OQR Program for the CY 2025 reporting period/2027 payment determination.

b. Information Collection Burden Estimate for the Adoption of the Hospital Commitment to Health Equity Measure Beginning With the CY 2025 Reporting Period/CY 2027 Payment Determination

As discussed in section XIV.B.1 of this final rule with comment period, we are adopting the web-based HCHE measure beginning with the CY 2025 reporting period/CY 2027 payment determination. For this measure, HOPDs will be required to report once annually on attestations of ''yes'' or ''no'' to a set of five domains related to organizational efforts towards health equity, using a CMS-designated information system, as described in section XIV.B.1.b of this final rule with comment period.

We estimate the reporting burden associated with this measure to be, on average across all 3,200 HOPDs, no more than 10 minutes per HOPD per year, as we believe the burden for HOPDs to report this measure will be very similar to the burden for hospital inpatient departments to report the same measure once annually under the Hospital IQR Program. We refer readers to the currently approved burden estimate for the HCHE measure in the Hospital IQR Program under OMB control number 0938–1022 (expiration date January 31, 2026) and as discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49385).

Using an estimate of 10 minutes (or 0.167 hours) per HOPD per year, we estimate that this measure adoption will result in a total annual burden increase of 533 hours (0.167 hours × 3,200 HOPDs) at a cost of $29,518 (533 hours × $55.38/hr) across program-eligible HOPDs.

We received no comments on our burden estimates.

c. Information Collection Burden Estimate for the Adoption of the Screening for Social Drivers of Health (SDOH) Measure Beginning With Voluntary Reporting for the CY 2025 Reporting Period Followed by Mandatory Reporting Beginning With the CY 2026 Reporting Period/CY 2028 Payment Determination

In section XIV.B.2 of this final rule with comment period, we are adopting the web-based Screening for SDOH measure beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. For this measure, HOPDs will be required to report whether they screened patients for five health-related social need (HRSN) domains, as described in section XIV.B.2.a of this final rule with comment period.

HOPDs will be able to collect data for the measure using a self-selected screening tool. We expect that most HOPDs will likely collect data through a screening tool incorporated into their EHR or other patient intake process, such as those we describe as examples in section XIV.B.2.e of this final rule with comment period. We estimate the information collection burden related to conducting patient screening associated with this measure to be two minutes (0.033 hours) per patient. This is based on the currently approved burden estimate for the Hospital IQR Program under OMB control number 0938–1022 for the same measure with patient screening for the same HRSN domains and the same frequency of data reporting, as discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49385 through 49386).

In the CY 2025 OPPS/ASC proposed rule, we estimated 498,843,518 patients would be screened annually when the measure becomes mandatory (89 FR 59517). In this final rule, we have revised our methodology to account for multiple HOPD visits per patient and the corresponding reduction in screenings per reporting period. To provide an estimate of patient volume for the purposes of calculating the information collection burden associated with this measure, we utilized data derived from the American Hospital Association which estimates 2,399 outpatient visits per 1,000 population in CY 2022[732] and multiplied this by the estimated total U.S. population in CY 2022[733] to estimate the total number of outpatient visits across the hospitals surveyed. We estimate that each year there are approximately 799,556,849 hospital outpatient visits ((2,399 hospital outpatient visits per 1,000 population in CY 2022[734]) × 333,287,557 total U.S. population in 2022). We then estimate a total of 412,651,290 HOPD patient visits potentially resulting in a patient needing to be screened when the measure becomes mandatory by multiplying the total 799,556,849 (hospital outpatient visits by a ratio of 3,200 HOPDs to the total of 6,200 hospitals surveyed[735] (799,556,849 hospital outpatient visits × 51.61 percent (3,200 HOPDs ÷ 6,200 hospitals surveyed)). We anticipate that the estimate of 412,651,290 is likely an overestimate due to the policy we are finalizing which allows for the use of screening information collected from other settings in the same reporting period, such as the hospital inpatient setting, and the expectation that some patients may have more than one outpatient visit in a reporting period at the same facility, and therefore, their information would have already been collected. To help mitigate the potentially significant impact to our estimates of repeat visits where re-screening would be unnecessary, such as in a follow-up visit, routine treatments, or multiple emergency department encounters, we divided the total number of HOPD patient visits by two. As a result, we estimate a total of

[731] U.S. Bureau of Labor Statistics. Occupational Outlook Handbook, Medical Records Specialists. Accessed April 29, 2024. Available at: *https://www.bls.gov/oes/current/oes292072.htm.*

[732] Kaiser Family Foundation, Hospital Outpatient Visits per 1,000 Population by Ownership Type. Available at *http://www.kff.org/other/state-indicator/outpatient-visits-by-ownership/?currentTimeframe=&0sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.*

[733] Growth in U.S. Population Shows Early Indication of Recovery Amid COVID–19 Pandemic, December 22, 2022. Available at *https://www.census.gov/newsroom/press-releases/2022/2022-population-estimates.html.*

[734] American Hospital Association, Fast Facts on U.S. Hospitals. Available at *https://www.aha.org/statistics/fast-facts-us-hospitals.*

[735] American Hospital Association—Data and Insights, AHA Annual Survey Database™. Available at *https://www.ahadata.com/aha-annual-survey-database.*

206,325,645 HOPD patient visits (412,651,290 ÷ 2) per reporting period when the measure becomes mandatory. We intend to assess actual reported volumes of visits for future estimates. As submission rates among hospitals may vary, we conservatively estimate that for voluntary reporting for the CY 2025 reporting period, 50 percent of HOPDs will screen 50 percent of patients, and beginning with the first mandatory reporting period, 100 percent of HOPDs will screen 100 percent of patients.

We determine the cost for patients (or their representative) undertaking administrative and other tasks, such as filling out a survey or intake form, using a post-tax wage of $24.49/hr based on the report ''Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices,'' which identifies the approach for valuing time when individuals undertake activities on their own time.[736] To derive the costs for patients (or their representatives), a measurement of the usual weekly earnings of wage and salary workers of $1,139 is divided by 40 hours to calculate an hourly pre-tax wage rate of $28.48/hr.[737] This rate is adjusted downwards by an estimate of the effective tax rate for median income households of about 14 percent calculated by comparing pre-and post-tax income,[738] resulting in the post-tax hourly wage rate of $24.49/hr. Unlike our state and private sector wage adjustments, we are not adjusting patient wages for fringe benefits and other indirect costs since the individuals' activities, if any, will occur outside the scope of their employment.

Measure data aggregated to the hospital level as a numerator and a denominator will be submitted via the HQR system annually. Similar to the currently approved burden estimate for web-based measures reported via the HQR system for the Hospital OQR Program under OMB control number 0938–1109, we estimate a burden of 10 minutes per HOPD to report the measure data. Therefore, we estimate that each HOPD will spend 10 minutes (0.167 hours) annually to report the Screening for SDOH measure data to CMS.

For the CY 2025 voluntary reporting period, we estimate a total burden increase for patients of 1,719,380 hours (206,325,645 patients × 50 percent response rate × 50 percent of HOPDs × 0.033 hours per patient) at a cost of $42,107,616 (1,719,380 hours × $24.49/hr). Beginning with the CY 2026 mandatory reporting period, we estimate an annual total burden increase for patients of 6,877,522 hours (206,325,645 patients × 0.033 hours per patient) at a cost of $168,430,514 (6,877,522 hours × $24.49/hr).

For the CY 2025 voluntary reporting period, we estimate a total collection and reporting burden increase for program-eligible HOPDs of 267 hours (3,200 HOPDs × 50 percent of HOPDs × 0.167 hours per HOPDs) at a cost of $14,786 (267 hours × $55.38/hr). Beginning with the CY 2026 mandatory reporting period, we estimate a total collection and reporting burden increase for program-eligible HOPDs of 533 hours (3,200 HOPDs × 0.167 hours per HOPD) at a cost of $29,518 (533 hours × $55.38/hr).

We received no comments on our burden estimates in the proposed rule.

d. Information Collection Burden Estimate for the Adoption of the Screen Positive Rate for Social Drivers of Health (SDOH) Measure Beginning With Voluntary Reporting for the CY 2025 Reporting Period Followed by Mandatory Reporting Beginning With the CY 2026 Reporting Period/CY 2028 Payment Determination

In section XIV.B.3 of this final rule with comment period, we are adopting the Screen Positive Rate for SDOH measure beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. We refer readers to the currently approved burden estimate for the Screen Positive Rate for SDOH measure in the Hospital IQR Program under OMB control number 0938–1022 for the same measure and the same frequency of data reporting, as discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49386). As discussed in section XIV.B.3.g of this final rule with comment period, if a hospital participates in both the Hospital OQR and Hospital IQR Programs, the hospital will need to submit data on this measure separately under each program. As such, we are estimating the burden separately under each program.

For this measure, HOPDs will be required to report on the number of patients who screened positive for one or more of the five domains (reported as five separate rates to reflect each of the five HRSN domains) divided by the total number of patients screened. We previously included the collection burden associated with screening patients in our discussion of the Screening for SDOH measure. Thus, for the Screen Positive Rate for SDOH measure, we estimate only the additional burden for HOPD reporting via the HQR system since patients will not need to provide, and HOPDs will not need to collect, any additional information for this measure. We continue to estimate that, for voluntary reporting for the CY 2025 reporting period, 50 percent of HOPDs will submit data, and beginning with the first mandatory reporting period, 100 percent of HOPDs will submit data.

Measure data aggregated to the hospital level as a numerator and a denominator will be submitted via the HQR system annually. Similar to the currently approved burden estimate for web-based measures reported via the HQR system for the Hospital OQR Program under OMB control number 0938–1109, we estimate a burden of 10 minutes per HOPD to report the measure data. Therefore, we estimate that each HOPD will spend 10 minutes (0.167 hours) annually to report the Screen Positive Rate for SDOH measure data to CMS.

For the CY 2025 voluntary reporting period, we estimate a total collection and reporting burden increase of 267 hours (0.167 hours × 3,200 HOPDs × 50 percent of HOPDs) at a cost of $14,786 (267 hours × $55.38), and beginning with the CY 2026 reporting period, we estimate a total annual collection and reporting burden increase for hospitals of 533 hours (0.167 hours × 3,200 HOPDs) at a cost of $29,518 (533 hours × $55.38/hr) across all program-eligible HOPDs.

We received no comments on our burden estimates.

[736] Office of the Assistant Secretary for Planning and Evaluation, Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices, September 17, 2017. Available at *https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework.*

[737] Bureau of Labor and Statistics, Usual Weekly Earnings of Wage and Salary Workers, First Quarter 2024. Available at *https://www.bls.gov/news.release/pdf/wkyeng.pdf.* Accessed April 16, 2024.

[738] U.S. Census Bureau, End of Pandemic-Era Expanded Federal Tax Programs Results in Lower Income, Higher Poverty, September 12, 2023. Available at *https://www.census.gov/library/stories/2023/09/median-household-income.html.* Accessed April 16, 2024.

e. Information Collection Burden Estimate for the Adoption of the Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance Measure (Information Transfer PRO–PM), Beginning With Voluntary Reporting for the CY 2026 Reporting Period and Mandatory Reporting Beginning With the CY 2027 Reporting Period/CY 2029 Payment Determination

In section XV.C.1.b of this final rule with comment period, we are adopting the Information Transfer PRO–PM beginning with voluntary reporting for the CY 2026 reporting period and mandatory reporting beginning with the CY 2027 reporting period/CY 2029 payment determination. The Information Transfer PRO–PM will use PRO data regarding recovery instructions, collected by HOPDs through a nine-item survey instrument administered to patients post-operatively. The modes of PRO data collection can include completion of the post-operative surveys electronically.

In the CY 2025 OPPS/ASC proposed rule, we estimated 498,843,518 patients would be screened annually when the measure becomes mandatory (89 FR 59518). In this final rule with comment period, we have revised our methodology to account for multiple HOPD visits per patient and the corresponding reduction in screenings per reporting period. To provide an estimate of patient volume for the purposes of calculating the information collection burden associated with this measure, we utilized data derived from the American Hospital Association related to hospital outpatient visits to estimate that each year there are roughly 799,556,849 hospital outpatient visits ((2,399 hospital outpatient visits per 1,000 population in CY 2022 [739]) × 333,287,557 total U.S population in 2022 [740]). We then estimate a total of 412,651,290 HOPD patient visits potentially resulting in a patient needing to be screened when the measure becomes mandatory by multiplying the total 799,556,849 hospital outpatient visits by a ratio of 3,200 HOPDs to the total of 6,200 hospitals surveyed [741] (799,556,849 hospital outpatient visits × 51.61 percent (3,200 HOPDs ÷ 6,200 hospitals surveyed)). However, as not all hospital outpatient visits are related to surgeries and procedures, and there are often multiple visits such as pre- and post-op visits associated with those that are, we estimate that 137,550,430 hospital outpatient visits (412,651,290 hospital outpatient visits ÷ 3 surgery or procedure-specific visits) would more realistically qualify for the cohort of this measure. We anticipate that this may be an overestimate and intend to assess actual reported volumes of visits for future estimates. As submission rates among hospitals may vary, we conservatively estimate that for voluntary reporting for the CY 2025 reporting period, 50 percent of HOPDs will survey 50 percent of patients, and beginning with the first mandatory reporting period, 100 percent of HOPDs will survey 100 percent of patients. While we are also allowing HOPDs to report a sample of at least 300 completed patient surveys, we are requiring all patients to be surveyed for this measure when mandatory reporting begins.

In the CY 2025 OPPS/ASC proposed rule, we estimated each patient would require an average of six minutes to complete the survey (89 FR 59518). In this final rule with comment period, we are revising our estimate to five minutes (0.083 hours) per patient based on more recent information.[742] As described in section XXIV.B.c of this final rule with comment period, for purposes of calculating patient burden, we determine the cost for patients (or their representatives) undertaking administrative and other tasks, such as filling out a survey or intake form, using a post-tax wage of $24.49/hr based on the report ''Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices,'' which identifies the approach for valuing time when individuals undertake activities on their own time.[743] Unlike our state and private sector wage adjustments, we are not adjusting patient wages for fringe benefits and other indirect costs since the individuals' activities, if any, will occur outside the scope of their employment.

Measure data will be submitted via the HQR system annually. Similar to the currently approved burden estimate for web-based measures reported via the HQR system for the Hospital OQR Program under OMB control number 0938–1109, we estimate a burden of 10 minutes per HOPD to report the measure data. Therefore, we estimate that each HOPD will spend 10 minutes (0.167 hours) annually to report the Information Transfer PRO–PM data to CMS.

For the CY 2025 voluntary reporting period, we estimate a total burden for patients of 2,865,634 hours (137,550,430 patients × 50 percent response rate × 50 percent of HOPDs × 0.083 hours per patient surveyed) at a cost of $70,179,377 (2,865,634 hours × $24.49/hr). Beginning with the CY 2026 mandatory reporting period, we estimate an annual total burden for patients of 11,462,536 hours (137,550,430 patients × 0.083 hours per patient) at a cost of $280,717,507 (11,462,536 hours × $24.49/hr).

For the CY 2025 voluntary reporting period, we estimate a total collection and reporting burden for program-eligible HOPDs of 267 hours (3,200 HOPDs × 50 percent of HOPDs × 0.167 hours per HOPDs) at a cost of $14,786 (267 hours × $55.38/hr). Beginning with the CY 2026 mandatory reporting period, we estimate a total collection and reporting burden for program-eligible HOPDs of 533 hours (3,200 HOPDs × 0.167 hours per HOPD) at a cost of $29,518 (533 hours × $55.38/hr).

We received no comments on our burden estimates in the CY OPPS/ASC proposed rule.

f. Information Collection Burden for the Removal of Two Claims-Based Measures

In sections XV.C.2.a and XV.C.2.b of this final rule with comment period, we are removing two claims-based measures beginning with the CY 2025 reporting period/CY 2027 payment determination: (1) MRI Lumbar Spine for Low Back Pain measure; and (2) Cardiac Imaging for Preoperative Risk

[739] Kaiser Family Foundation, Hospital Outpatient Visits per 1,000 Population by Ownership Type. Available at *http://www.kff.org/other/state-indicator/outpatient-visits-by-ownership/?currentTimeframe=0&sortModel=%7B%22colId%22%22Location%22%22sort%22:%22asc%22%7D.*

[740] Growth in U.S. Population Shows Early Indication of Recovery Amid COVID–19 Pandemic, December 22, 2022. Available at *https://www.census.gov/newsroom/press-releases/2022/2022-population-estimates.html.*

[741] American Hospital Association—Data and Insights, AHA Annual Survey Database™. Available at *https://www.ahadata.com/aha-annual-survey-database.*

[742] Yale New Haven Health Services Corporation—Center for Outcomes Research & Evaluation, Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance Measure (PRO–PM) Version 1.0 Methodology Report, April 2024. Available at *https://www.cms.gov/medicare/quality/initiatives/hospital-quality-initiative/measure-methodology.*

[743] Office of the Assistant Secretary for Planning an Evaluation, Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices, September 17, 2017. Available at *https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework.*

Assessment for Non-Cardiac, Low-Risk Surgery measure. Because these measures are calculated using Medicare fee-for-service (FFS) claims that are already reported to the Medicare program for payment purposes, removing these measures will not result in a change in burden associated with OMB control number 0938–1109.

We received no comments on our assumptions regarding burden for these measures calculated from administrative data.

g. Information Collection Burden To Publicly Report Data for the Median Time for Discharged ED Patients—Psychiatric/Mental Health Patients Stratification on Care Compare Beginning in CY 2025

In section XV.F.2 of this final rule with comment period, we are finalizing the public reporting of data for the Median Time for Discharged ED Patients—Psychiatric/Mental Health Patients stratification on Care Compare beginning in CY 2025. Because we are not requiring HOPDs to collect or submit any additional data for purposes of this public reporting, this policy will not result in a change in burden associated with OMB control number 0938–1109.

We received no comments on our assumptions regarding burden.

h. Information Collection Burden To Require EHR Technology To Be Certified to All eCQMs Available To Report Beginning With the CY 2025 Reporting Period/CY 2027 Payment Determination

In section XV.E.2.b of this final rule with comment period, we are requiring EHR technology to be certified to all eCQMs available to report beginning with the CY 2025 reporting period/CY 2027 payment determination. We do not expect HOPDs will experience an increase in information collection burden associated with this policy because the use of EHR technology that is certified to all available eCQMs is already required for the Promoting Interoperability Program (83 FR 41672) and the Hospital IQR Program (84 FR 42604).

We received no comments on our assumptions regarding burden.

g. Summary of Information Collection Burden Estimates for the Hospital OQR Program

In summary, we estimate that the policies in this final rule with comment period will result in a total HOPD burden increase of 18,342,190 hours at a cost of $449,266,093 annually for all 3,200 program-eligible HOPDs from the CY 2025 reporting period/CY 2027 payment determination through the CY 2027 reporting period/CY 2029 payment determination. We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1109. (See Tables 178, 179, and 180.)

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TABLE 178: SUMMARY OF FINALIZED HOSPITAL OQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2025 REPORTING PERIOD/CY 2027 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2025 Reporting Period							
Activity	**Estimated time per record (minutes)**	**Number of reporting quarters per year**	**Number of HOPDs reporting**	**Average number records per HOPDs per quarter**	**Annual burden (hours) per HOPD**	**Finalized annual burden (hours) across HOPDs**	**Previously finalized annual burden (hours) across HOPDs**	**Net difference in annual burden hours**
Addition of the HCHE Measure	10	1	3,200	1	0.167	533	0	+533
Addition of the Screening for SDOH Measure (Voluntary Survey)	2	1	1,600	32,238	1,075	1,719,380	0	+1,719,380
Addition of the Screening for SDOH Measure (Voluntary Reporting)	10	1	1,600	1	0.167	267	0	+267
Addition of the Screen Positive Rate for SDOH (Voluntary Reporting)	10	1	1,600	1	0.167	267	0	+267
	Total Change in Information Collection Burden Hours: +1,720,447							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+1,720,447) = **$42,166,706**							

TABLE 179: SUMMARY OF FINALIZED HOSPITAL OQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2026 REPORTING PERIOD/CY 2028 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2026 Reporting Period							
Activity	**Estimated time per record (minutes)**	**Number of reporting quarters per year**	**Number of HOPDs reporting**	**Average number records per HOPD per quarter**	**Annual burden (hours) per HOPD**	**Finalized annual burden (hours) across HOPDs**	**Previously finalized annual burden (hours) across HOPDs**	**Net difference in annual burden hours**
Addition of the HCHE Measure	10	1	3,200	1	0.167	533	0	+533
Addition of the Screening for SDOH Measure (Mandatory Survey)	2	1	3,200	64,477	2,149	6,877,522	0	+ 6,877,522
Addition of the Screening for SDOH Measure (Mandatory Reporting)	10	1	3,200	1	0.167	533	0	+533
Addition of the Screen Positive Rate for SDOH (Mandatory Reporting)	10	1	3,200	1	0.167	533	0	+533
Addition of the Information Transfer PRO-PM (Voluntary Survey)	5	1	1,600	21,492	1,792	2,865,634	0	+2,865,634
Addition of the Information Transfer PRO-PM (Voluntary Reporting)	10	1	1,600	1	0.167	267	0	+267
	Total Change in Information Collection Burden Hours: +9,745,022							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+9,745,022) = **$238,713,231**							

TABLE 180: SUMMARY OF FINALIZED HOSPITAL OQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE BEGINNING WITH THE CY 2027 REPORTING PERIOD/CY 2029 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2027 Reporting Period							
Activity	**Estimated time per record (minutes)**	**Number of reporting quarters per year**	**Number of HOPDs reporting**	**Average number records per HOPD per quarter**	**Annual burden (hours) per HOPD**	**Finalized annual burden (hours) across HOPDs**	**Previously finalized annual burden (hours) across HOPDs**	**Net difference in annual burden hours**
Addition of the HCHE Measure	10	1	3,200	1	0.167	533	0	+533
Addition of the Screening for SDOH Measure (Mandatory Survey)	2	1	3,200	64,477	2,149	6,877,522	0	+6,877,522
Addition of the Screening for SDOH Measure (Mandatory Reporting)	10	1	3,200	1	0.167	533	0	+533
Addition of the Screen Positive Rate for SDOH (Mandatory Reporting)	10	1	3,200	1	0.167	533	0	+533
Addition of the Information Transfer PRO-PM (Mandatory Survey)	5	1	3,200	42,985	3,582	11,462,536	0	+11,462,536
Addition of the Information Transfer PRO-PM (Mandatory Reporting)	10	1	3,200	1	0.167	533	0	+533
	Total Change in Information Collection Burden Hours: +18,342,190							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+18,342,190) = **$449,266,093**							

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We requested comment on how we can reduce burden on HOPDs for both these new information collections as well as recommendations for the removal of existing information collections to offset these new burdens. We received no comments regarding the burden estimates associated with these new information collections; however, some commenters expressed their belief that CMS underestimates the burden of requirements for the Hospital OQR Program, in general. A few commenters recommended removal of measures in general to reduce information collections burden currently included in the Hospital OQR Program. We thank the commenters for their input but disagree that the burden of the Hospital OQR Program is underestimated, as this burden has been estimated in a manner aligned with other quality reporting programs, such as the Hospital IQR Program, and measure type burden has been approved under OMB control number 0938–1109. This burden accurately reflects the reporting burden estimate for the Hospital OQR Program. We appreciate their recommendations

and may consider them in future rulemaking.

B. ICRs for the Rural Emergency Hospitals Quality Reporting (REHQR) Program

a. Background

In section XVI of this final rule with comment period, we discuss the requirements for the REHQR Program. The REHQR Program is generally aligned with the CMS quality reporting program for HOPDs known as the Hospital OQR Program. We refer readers to the CY 2024 OPPS/ASC final rule with comment period (88 FR 82148 through 82149) for detailed discussions of the previously finalized REHQR Program ICRs, which are currently approved under OMB control number 0938–1454 (expiration date April 30, 2027).

In this final rule with comment period, we are adopting three web-based measures that will impact previously approved burden estimates: (1) the Hospital Commitment to Health Equity (HCHE) measure, beginning with the CY 2025 reporting period/CY 2027 program determination; (2) the Screening for Social Drivers of Health (SDOH) measure, beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 program determination; and (3) the Screen Positive Rate for SDOH measure, beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 program determination.

We are also finalizing our proposal to extend the reporting period for the previously adopted Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery measure beginning with the CY 2027 program determination. We believe this policy will not impact the previously approved burden estimates.

In the CY 2024 OPPS/ASC final rule with comment period, we calculated reporting burden estimates for the REHQR Program by utilizing the BLS mean hourly wage rate for Medical Records Specialists (88 FR 82148). Specifically, we used the ''general medical and surgical hospitals'' industry to estimate the mean wage, as this categorization aligns the closest with the REHQR Program care setting compared to other medical record specialist related industries, such as ''office of physicians'' or ''nursing care facilities.'' The most recent data from BLS' May 2023 National Occupational Employment and Wage Estimates reflects a mean hourly wage of $27.69 per hour for medical records specialists working in ''general medical and surgical hospitals'' (SOC 29–2072).[744] We calculated the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage, consistent with previous years. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly by employer and methods of estimating these costs vary widely in the literature. Nonetheless, we believe that doubling the hourly wage rate ($27.69 × 2 = $55.38) to estimate total cost is a reasonably accurate estimation method. Accordingly, unless otherwise specified, we will calculate cost burden to REHs using a wage plus benefits estimate of $55.38 per hour throughout the discussion in this section of this rule for the REHQR Program.

In the CY 2024 OPPS/ASC final rule with comment period, our burden estimates were based on an assumption that approximately 746 hospitals could transition to REH status assuming that all eligible hospitals in states which have passed or amended necessary legislation enabling transition to occur as of March 2023 choose to do so and we stated that we would update our estimates once more information was made available (88 FR 82148). For this final rule with comment period, based on the actual number of acute care and critical access hospital conversions to REH status as of September 27, 2024, we estimate that 33 REHs will report data to the REHQR Program during the CY 2025 reporting period unless otherwise noted. While the exact number of REHs required to submit data may vary due to status changes to and from an REH, as reiterated in section XVI.A of this final rule with comment period, REHs are required by statute to submit quality data. Therefore, for purposes of estimating burden, we assume that all 33 REHs will submit data under the REHQR Program beginning with the CY 2025 reporting period.

b. Information Collection Burden for the Adoption of the Hospital Commitment to Health Equity (HCHE) Measure Beginning With the CY 2025 Reporting Period/CY 2027 Program Determination

In section XIV.B.1 of this final rule with comment period, we are adopting the web-based HCHE measure beginning with the CY 2025 reporting period/CY 2027 program determination. For this measure, REHs will be required to report on attestations of ''yes'' or ''no'' to a set of five domains related to organizational efforts towards health equity, as described in section XIV.B.1.b of this final rule with comment period.

We estimate the reporting burden associated with this measure to be, on average across all 33 REHs, no more than 10 minutes per REH per year, as we believe the burden that is annually reported by hospital inpatient departments under the Hospital IQR Program will be very similar to annual reporting by REHs on the same measure. We refer readers to the currently approved burden for the HCHE measure in the Hospital IQR Program under OMB control number 0938–1022 (expiration date January 31, 2026) and as discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49385).

Using an estimate of 10 minutes (or 0.167 hours) per REH per year, we estimate that this measure adoption will result in a total annual burden increase of six hours (0.167 hours × 33 REHs) at a cost of $332 (6 hours × $55.38/hr) across all REHs.

We received no comments on our burden estimates.

c. Information Collection Burden for the Adoption of the Screening for Social Drivers of Health (SDOH) Measure Beginning With Voluntary Reporting for the CY 2025 Reporting Period Followed by Mandatory Reporting Beginning With the CY 2026 Reporting Period/CY 2028 Program Determination

In section XIV.B.2 of this final rule with comment period, we are adopting the Screening for SDOH measure beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 program determination. We refer readers to the currently approved burden for the Screening for SDOH measure for the Hospital IQR Program under OMB control number 0938–1022. For this measure, REHs will be required to report whether they screened patients for five health-related social need (HRSN) domains as described in section XIV.B.2.a of this final rule with comment period.

REHs will be able to collect data for the measure using a self-selected screening tool. We expect that most REHs will collect data through a screening tool incorporated into their EHR or other patient intake process, such as those we describe as examples in section XIV.B.2.e of this final rule with comment period. We estimate the information collection burden related to conducting patient screening associated

[744] U.S. Bureau of Labor Statistics. Occupational Outlook Handbook, Medical Records Specialists. Accessed April 29, 2024. Available at: *https://www.bls.gov/oes/current/oes292072.htm.*

with this measure to be two minutes (0.033 hours) per patient. This is based on the currently approved burden estimate for the Hospital IQR Program for the same measure with patient screening for the same HRSN domains and the same frequency of data reporting, as discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49385 through 49386).

To provide an estimate of patient volume for the purposes of calculating the information collection burden associated with this measure, we utilized data derived from a Definitive Healthcare survey which calculated that Medicare FFS patients account for 35.6 percent of hospital payer mix and a MedPAC report that determined hospitals which have converted to REH status average 4,200 outpatient visits for Medicare FFS beneficiaries to estimate that each year 11,798 (4,200 ÷ 35.6 percent) patients will be screened per REH when reporting on the measure becomes mandatory.[745] [746] We therefore estimate a total of approximately 389,334 patients (11,798 patients × 33 REHs) will be screened across all 33 REHs. As submission rates among hospitals may vary, we conservatively estimate that for voluntary reporting for the CY 2025 reporting period, 50 percent of REHs will screen 50 percent of patients, and beginning with the first mandatory reporting period, REHs will screen 100 percent of patients.

We determine the cost for patients (or their representative) undertaking administrative and other tasks, such as filling out a survey or intake form, using a post-tax wage of $24.49/hr based on the report ''Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices,'' which identifies the approach for valuing time when individuals undertake activities on their own time.[747] To derive the costs for patients (or their representatives), a measurement of the usual weekly earnings of wage and salary workers of $1,139 is divided by 40 hours to calculate an hourly pre-tax wage rate of $28.48/hr.[748] This rate is adjusted downwards by an estimate of the effective tax rate for median income households of about 14 percent calculated by comparing pre- and post-tax income,[749] resulting in the post-tax hourly wage rate of $24.49/hr. Unlike our State and private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and other indirect costs since the individuals' activities, if any, will occur outside the scope of their employment.

Measure data aggregated to the hospital level as a numerator and a denominator will be submitted via the HQR system annually. Similar to the currently approved burden estimate for web-based measures reported via the HQR system for the Hospital OQR Program under OMB control number 0938–1109 (expiration date February 28, 2025), which REHs will have been eligible to report under prior to conversion to REH status, we estimate a burden of 10 minutes per REH to report the measure data. Therefore, we estimate that each REH will spend 10 minutes (0.167 hours) annually to report the Screening for SDOH measure data to CMS.

For the CY 2025 voluntary reporting period, we estimate a total collection and reporting burden increase for patients of 3,343 hours (11,798 patients × 50 percent response rate × 17 REHs × 0.033 hours per patient) at a cost of $81,870 (3,343 hours × $24.49/hr). Beginning with the CY 2026 reporting period, we estimate a total collection and reporting burden increase for patients of 12,978 hours (389,334 patients × 0.033 hours per patient) at a cost of $317,831 (12,978 hours × $24.49/hr).

For the CY 2025 voluntary reporting period, we estimate a total collection and reporting burden increase for REHs of three hours (33 REHs × 50 percent of REHs × 0.167 hours) at a cost of $166 (3 hours × $55.38/hr). Beginning with the CY 2026 reporting period, we estimate a total collection and reporting burden increase for REHs of six hours (33 REHs × 0.167 hours) at a cost of $332 (4 hours × $55.38/hr).

We received no comments on our burden estimates.

d. Information Collection Burden for the Adoption of the Screen Positive Rate for Social Drivers of Health (SDOH) Measure Beginning With Voluntary Reporting for the CY 2025 Reporting Period Followed by Mandatory Reporting Beginning With the CY 2026 Reporting Period/CY 2028 Program Determination

In section XIV.B.3 of this final rule with comment period, we are adopting the Screen Positive Rate for SDOH measure beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 program determination. We refer readers to the currently approved burden estimate for the Screen Positive Rate for SDOH measure in the Hospital IQR Program under OMB control number 0938–1022 for the same measure and the same frequency of data reporting, as discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49386).

For this measure, REHs will be required to report on an annual basis the number of patients who screened positive for one or more of the five domains (reported as five separate rates to reflect each of the five HRSN domains) divided by the total number of patients screened.

We previously included the burden associated with screening patients in our discussion of the Screening for SDOH measure. Thus, for the Screen Positive Rate for SODH measure, we estimate only the additional burden for a REH reporting via the HQR system since patients will not need to provide, and REHs will not need to collect, any additional information for this measure. We continue to estimate that, for voluntary reporting for the CY 2025 reporting period, 50 percent of REHs will screen 50 percent of patients, and beginning with the first mandatory period, REHs will survey 100 percent of patients.

Measure data aggregated to the hospital level as a numerator and a denominator will be submitted via the HQR system annually. Similar to the currently approved burden estimate for web-based measures reported via the HQR system for the Hospital OQR Program under OMB control number 0938–1109, which REHs will have been eligible to report under prior to conversion to REH status, we estimate a burden of 10 minutes per REH to report the measure data. Therefore, we estimate that each REH will spend 10 minutes (0.167 hours) annually to report

[745] Definitive Healthcare, Breaking down U.S. hospital payor mixes, July 14, 2023. Available at *https://www.definitivehc.com/resources/healthcare-insights/breaking-down-us-hospital-payor-mixes.*

[746] Medicare Payment Advisory Commission, Medicare and the Health Care Delivery System, June 2021. Available at *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun21_medpac_report_to_congress_sec.pdf.*

[747] Office of the Assistant Secretary for Planning an Evaluation, Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices, September 17, 2017. Available at *https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework.*

[748] Bureau of Labor and Statistics, Usual Weekly Earnings of Wage and Salary Workers, First Quarter 2024. Available at *https://www.bls.gov/news.release/pdf/wkyeng.pdf.* Accessed April 16, 2024.

[749] U.S. Census Bureau, End of Pandemic-Era Expanded Federal Tax Programs Results in Lower Income, Higher Poverty, September 12, 2023. Available at *https://www.census.gov/library/stories/2023/09/median-household-income.html.* Accessed April 16, 2024.

the Screen Positive Rate for SDOH measure data to CMS.

For the CY 2025 voluntary reporting period, we estimate a total collection and reporting burden increase of three hours (0.167 hours × 33 REHs × 50 percent of REHs) at a cost of $166 (3 hours × $55.38/hr), and beginning with the CY 2026 reporting period, we estimate a total annual collection and reporting burden increase for REHs of six hours (0.167 hours × 33 REHs) at a cost of $332 (6 hours × $55.38/hr) across all REHs.

We received no comments on our burden estimates.

e. Information Collection Burden To Extend the Reporting Period From for the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery Measure Beginning With the CY 2027 Program Determination

In section XVI.C.2 of this final rule with comment period, we are extending the reporting period from one year to two years for the Risk-Standardized Hospital Visits within 7 Days after Hospital Outpatient Surgery measure, beginning with the CY 2027 program determination. We refer readers to a similar policy which was finalized for the claims-based Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy measure under the Hospital OQR Program in the CY 2019 OPPS/ASC final rule (83 FR 59106).

Because this claims-based measure is calculated using data that are already reported to the Medicare program for payment purposes, there is no burden associated with the collection and submission of data for this measure. Accordingly, our policy to extend the reporting period from one to two years will not result in additional burden for REHs.

We received no comments on our assumptions regarding burden.

f. Summary of Information Collection Burden Estimates for the REHQR Program

In summary, we estimate that the policies in this final rule with comment period will result in an increase of 12,996 hours at a cost of $318,827 for 33 REHs annually from the CY 2025 reporting period through the CY 2026 reporting period. We will submit these information collection estimates to OMB for approval under OMB control number 0938–1454. (See Tables 181 and 182.)

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TABLE 181: SUMMARY OF FINALIZED REHQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2025 REPORTING PERIOD/CY 2027 PROGRAM DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1454 for the CY 2025 Reporting Period							
Activity	**Estimated time per record (minutes)**	**Number of reporting quarters per year**	**Number of REHs reporting**	**Average number records per REH per quarter**	**Annual burden (hours) per REH**	**Finalized annual burden (hours) across REHs**	**Previously finalized annual burden (hours) across REHs**	**Net difference in annual burden hours**
Addition of the HCHE Measure	10	1	33	1	0.167	6	0	+6
Addition of the Screening for SDOH Measure (Voluntary Survey)	2	1	17	5,899	196.6	3,343	0	+3,343
Add Screening for SDOH Measure (Voluntary Reporting)	10	1	17	1	0.167	3	0	+3
Addition of the Screen Positive Rate for SDOH (Voluntary Reporting)	10	1	17	1	0.167	3	0	+3
	Total Change in Information Collection Burden Hours: +3,355							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+3,355) = **$82,534**							

TABLE 182: SUMMARY OF FINALIZED REHQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE BEGINNING WITH THE CY 2026 REPORTING PERIOD/CY 2028 PROGRAM DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1454 for the CY 2026 Reporting Period							
Activity	**Estimated time per record (minutes)**	**Number of reporting quarters per year**	**Number of REHs reporting**	**Average number records per REH per quarter**	**Annual burden (hours) per REH**	**Finalized annual burden (hours) across REHs**	**Previously finalized annual burden (hours) across REHs**	**Net difference in annual burden hours**
Addition of the Hospital Commitment to Health Equity (HCHE) Measure	10	1	33	1	0.167	6	0	+6
Addition of the Screening for Social Drivers of Health (SDOH) Measure (Mandatory Survey)	2	1	33	11,798	393.3	12,978	0	+12,978
Addition of the Screening for SDOH Measure (Mandatory Reporting)	10	1	33	1	0.167	6	0	+6
Addition of the Screen Positive Rate for SDOH (Mandatory Reporting)	10	1	33	1	0.167	6	0	+6
	Total Change in Information Collection Burden Hours: +12,996							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+12,996) = **$318,827**							

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We requested comment on how we can reduce burden on REHs for both these new information collections as well as recommendations for the removal of existing information collections to offset these new burdens. We received neither comments regarding the burden estimates for these new information collections nor recommendations for removal of existing information collections under the REHQR Program.

C. ICRs for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

a. Background

In section XVII of this final rule with comment period, we discuss the requirements for the ASCQR Program. We refer readers to the CY 2024 OPPS/ASC final rule with comment period (88 FR 82140 through 82148) for detail regarding the previously finalized ASCQR Program ICRs which are currently approved under OMB control number 0938–1270 (expiration date August 31, 2025).

In section XIV.B of this final rule with comment period, we are adopting three measures that will impact previously approved burden estimates: (1) the Facility Commitment to Health Equity (FCHE) measure, beginning with the CY 2025 reporting period/CY 2027 payment determination; (2) the Screening for Social Drivers of Health (SDOH) measure, beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; and (3) the Screen Positive Rate for SDOH measure, beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026

reporting period/CY 2028 payment determination. In section XVII.E.2.a of this final rule with comment period, we are finalizing that ASCs that ASCs will submit data annually for these measures using the CMS-designated information system (currently, the Hospital Quality Reporting [HQR] system).

In the CY 2024 OPPS/ASC final rule with comment period, we calculated reporting burden estimates for the ASCQR Program by utilizing the BLS mean hourly wage rate for Medical Records Specialists (88 FR 82140). Specifically, we used the ''general medical and surgical hospitals'' industry to estimate the mean wage, as this categorization aligns the closest with the ASCQR Program care setting compared to other medical record specialist related industries, such as ''office of physicians'' or ''nursing care facilities.'' The most recent data from BLS' May 2023 National Occupational Employment and Wage Estimates reflects a mean hourly wage of $27.69 per hour for medical records specialists working in ''general medical and surgical hospitals'' (SOC 29–2072).[750] We calculated the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage, consistent with previous years. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly by employer and methods of estimating these costs vary widely in the literature. Nonetheless, doubling the hourly wage rate ($27.69 × 2 = $55.38) to estimate total cost is a reasonably accurate estimation method. Accordingly, unless otherwise specified, we will calculate cost burden to ASCs using a wage plus benefits estimate of $55.38 per hour throughout the discussion in this section of this rule for the ASCQR Program.

Based on the most recent analysis of the CY 2024 payment determination data, we found that, of the 5,536 ASCs that were actively billing Medicare, 4,196 were required to participate in the ASCQR Program. Of the 1,340 ASCs not required to participate in the program, 279 ASCs did so and met full requirements. On this basis, we estimate that 4,475 ASCs (4,196 + 279) will submit data for the ASCQR Program for the CY 2025 reporting period/CY 2027 payment determination.

[750] U.S. Bureau of Labor Statistics. Occupational Outlook Handbook, Medical Records Specialists. Accessed April 29, 2024. Available at: *https://www.bls.gov/oes/current/oes292072.htm.*

b. Information Collection Burden for the Adoption of the Facility Commitment to Health Equity (FCHE) Measure Beginning With the CY 2025 Reporting Period/CY 2027 Payment Determination

In section XIV.B.1 of this final rule with comment period, we are adopting the FCHE measure for the ASCQR Program beginning with the CY 2025 reporting period/CY 2027 payment determination. For this measure, ASCs will be required to report an attestation of ''yes'' or ''no'' to a set of five domains related to organizational efforts towards health equity, as described in section XIV.B.1.b of this final rule with comment period.

We estimate the reporting burden associated with this measure to be, on average across all 4,475 ASCQR Program eligible facilities, no more than 10 minutes per ASC per year, based on the currently approved burden for the same measure under the Hospital IQR Program under OMB control number 0938–1022 (expiration date January 31, 2026). This also aligns with our estimated burden per providers for HOPDs and REHs, discussed above.

Using an estimate of 10 minutes (0.167 hours) per ASC per year, we estimate that this measure adoption will result in a total annual collection and reporting burden increase of 746 hours (0.167 hours × 4,475 ASCs) at a cost of $41,313 (746 hours × $55.38/hr) across program-eligible ASCs.

We received no comments on our burden estimates.

c. Information Collection Burden for the Adoption of the Screening for Social Drivers of Health (SDOH) Measure Beginning With Voluntary Reporting for the CY 2025 Reporting Period Followed by Mandatory Reporting Beginning With the CY 2026 Reporting Period/CY 2028 Payment Determination

In section XIV.B.2 of this final rule with comment period, we are adopting the Screening for SDOH measure for the ASCQR Program beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. For this measure, ASCs will be required to report whether they screened patients for five health-related social need (HSRN) domains as described in section XIV.B.2.a of this final rule with comment period.

As described in section XIV.B.2.e of this final rule with comment period, ASCs will be able to collect data for this measure using a self-selected screening tool. We expect that most ASCs will collect data through a screening tool incorporated into their EHR or other patient intake process, such as those we describe as examples in section XIV.B.2.e of this final rule with comment period. We estimate the information collection burden related to conducting patient screening associated with this measure will be 2 minutes (0.033 hours) per patient. This estimate is based on the currently approved burden for the Hospital IQR Program for the same measure, requiring the reporting of patient screening for the same HRSN domains and the same frequency of data reporting, as discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49385 through 49386).

To provide an estimate of patient volume for the purposes of calculating the information collection burden associated with this measure, we utilized data derived from the ASC Quality Collaborative (ASCQC) related to ASC patient fall benchmarking data as this metric applies to all patients rather than a subset. In the CY 2025 OPPS/ASC proposed rule, we estimated approximately 10,427,619 patients would be screened annually (89 FR 59526). Based on public comments received, we are correcting our estimate. Since we expect that ASCs reporting data to the ASCQC will tend to be larger facilities with larger patient populations than non-reporting ASCs, we conservatively estimate that each year approximately 21,322,000 patients ((10,434,676 admissions[751] ÷ 2,190 ASCs reporting) × 4,475 ASCs) with an average of 4,765 patients per ASC (21,322,000 admissions ÷ 4,475 ASCs) will be screened annually when reporting on the measure becomes mandatory. As submission rates among facilities may vary, we conservatively estimate that, for voluntary reporting for the CY 2025 reporting period, 50 percent of ASCs will survey 50 percent of patients, and beginning with the first mandatory reporting period, ASCs will survey and report on 100 percent of patients.

We determine the cost for patients (or their representative) undertaking administrative and other tasks, such as filling out a survey or intake form, using a post-tax wage of $24.49/hr based on the report ''Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices,'' which identifies the approach for valuing time when

[751] ASC Quality Collaboration, ASC Quality Collaboration Quality Report. Available at *https://ascquality.org/benchmarking/*. Accessed September 12, 2024.

individuals undertake activities on their own time.[752] To derive the costs for patients (or their representatives), a measurement of the usual weekly earnings of wage and salary workers of $1,139 is divided by 40 hours to calculate an hourly pre-tax wage rate of $28.48/hr.[753] This rate is adjusted downwards by an estimate of the effective tax rate for median income households of about 14 percent calculated by comparing pre- and post-tax income,[754] resulting in the post-tax hourly wage rate of $24.49/hr. Unlike our state and private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and other indirect costs because the individuals' activities, if any, will occur outside the scope of their employment.

Measure data aggregated to the ASC level as a numerator and a denominator will be submitted via the HQR system annually. Similar to the currently approved burden estimate for web-based measures reported via the HQR system for the ASCQR Program under OMB control number 0938–1270, we estimate a burden of 10 minutes per ASC to report the measure data. Therefore, we estimate that each ASC will spend 10 minutes (0.167 hours) annually to report the Screening for SDOH measure data to CMS.

For the CY 2025 voluntary reporting period, we estimate a total collection and reporting burden increase for patients of 177,723 hours (21,322,000 patients × 50 percent response rate × 50 percent of ASCs × 0.033 hours per patient) at a cost of $4,352,436 (177,723 hours × $24.49/hr). Beginning with the CY 2026 reporting period, we estimate a total collection and reporting burden increase for patients of 710,733 hours (21,322,000 patients × 0.033 hours per patient) at a cost of $17,405,851 (710,733 hours × $24.49/hr).

For the CY 2025 voluntary reporting period, we estimate a total collection and reporting burden increase for program-eligible ASCs of 373 hours (4,475 ASCs × 50 percent of ASCs × 0.167 hours) at a cost of $20,657 (373 hours × $55.38/hr). Beginning with the CY 2026 reporting period, we estimate a total collection and reporting burden increase for program-eligible ASCs of 746 hours (4,475 ASCs × 0.167 hours) at a cost of $41,313 (746 hours × $55.38/hr).

Comment: One commenter stated that the burden estimate for this information collection was calculated in error due to CMS incorrectly using the number of 4,475 ASCs to determine the average number of patients per ASC instead of the correct value of 2,190 ASCs as stated in the referenced data source.

Response: We thank the commenter and have clarified our rationale and process for the burden estimate. In the CY 2025 OPPS/ASC proposed rule, we estimated a total of 10,427,619 patients would be screened when the measure becomes mandatory based on a total number of ASC admissions over a 12-month period as reported by the ASCQC (89 FR 59526). In this final rule with comment period, we have revised our calculation of the number of ASC admissions using the ASCQC data, dividing by the 2,190 ASCs reporting to ASCQC to calculate an average number of annual admissions per ASC and multiplying the average per ASC by 4,475 total ASCs which could report the measure under the ASCQR Program.

d. Information Collection Burden for the Adoption of the Screen Positive Rate for Social Drivers of Health (SDOH) Measure Beginning With Voluntary Reporting for the CY 2025 Reporting Period Followed by Mandatory Reporting Beginning With the CY 2026 Reporting Period/CY 2028 Payment Determination

In section XIV.B.3 of this final rule with comment period, we are adopting the Screen Positive Rate for SDOH measure beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. We refer readers to the currently approved burden for the Screen Positive Rate for SDOH measure in the Hospital IQR Program under OMB control number 0938–1022 for the same measure and the same frequency of data reporting, as discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49386). For this measure, ASCs will be required to report annually the number of patients who screened positive for one or more of the five domains (reported as five separate rates to reflect each of the five HRSN domains) divided by the total number of patients screened.

We previously included the burden associated with screening patients in our discussion of the Screening for SDOH measure. Thus, for the Screen Positive Rate for SDOH measure, we estimate only the additional burden for an ASC reporting via the HQR system since patients will not need to provide, and ASCs will not need to collect, any additional information for this measure. We continue to estimate that for voluntary reporting for the CY 2025 reporting period, for the 4,475 ASCs estimated for reporting purposed, 50 percent of these ASCs will screen 50 percent of patients, and beginning with the first mandatory reporting period, 100 percent of these ASCs will submit data.

Measure data aggregated to the hospital level as a numerator and a denominator will be submitted via the HQR system annually. Similar to the currently approved burden estimate for web-based measures reported via the HQR system for the ASCQR Program under OMB control number 0938–1270 (expiration date August 31, 2025), we estimate a burden of 10 minutes per ASC to report the measure data. Therefore, we estimate that each ASC will spend 10 minutes (0.167 hours) annually to report the Screen Positive Rate for SDOH measure data to CMS.

For the CY 2025 voluntary reporting period, we estimate a total collection and reporting burden increase of 373 hours (0.167 hours × 4,475 ASCs × 50 percent of ASCs) at a cost of $20,657 (373 hours × $55.38). Beginning with the CY 2026 reporting period, we estimate a total annual collection and reporting burden increase for ASCs of 746 hours (0.167 hours × 4,475 ASCs) at a cost of $41,313 (746 hours × $55.38/hr) across program-eligible ASCs.

We received no comments on our burden estimates.

e. Summary of Information Collection Burden Estimates for the ASCQR Program

In summary, we estimate that the policies in this final rule with comment period will result in an increase of 712,971 hours at a cost of $17,529,790 for 4,475 program-eligible ASCs from the CY 2025 reporting period/CY 2027 payment determination through the CY 2026 reporting period/CY 2028 payment determination. We will submit the revised information collection estimates

[752] Office of the Assistant Secretary for Planning an Evaluation, Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices, September 17, 2017. Available at *https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework.*

[753] Bureau of Labor and Statistics, Usual Weekly Earnings of Wage and Salary Workers, First Quarter 2024. Available at *https://www.bls.gov/news.release/pdf/wkyeng.pdf.* Accessed April 16, 2024.

[754] U.S. Census Bureau, End of Pandemic-Era Expanded Federal Tax Programs Results in Lower Income, Higher Poverty, September 12, 2023. Available at *https://www.census.gov/library/stories/2023/09/median-household-income.html.* Accessed April 16, 2024.

to OMB for approval under OMB control number 0938–1270. (See Tables 183 and 184.)

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TABLE 183: SUMMARY OF FINALIZED ASCQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2025 REPORTING PERIOD/CY 2027 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1270 for the CY 2025 Reporting Period							
Activity	**Estimated time per record (minutes)**	**Number of reporting quarters per year**	**Number of ASCs reporting**	**Average number records per ASC per quarter**	**Annual burden (hours) per ASC**	**Finalized annual burden (hours) across ASCs**	**Previously finalized annual burden (hours) across ASCs**	**Net difference in annual burden hours**
Addition of the FCHE Measure	10	1	4,475	1	0.167	746	0	+746
Addition of the Screening for SDOH Measure (Voluntary Survey)	2	1	2,238	4,764	79.4	177,723	0	+177,723
Addition of the Screening for SDOH Measure (Voluntary Reporting)	10	1	2,238	1	0.167	373	0	+373
Addition of the Screen Positive Rate for SDOH (Voluntary Reporting)	10	1	2,238	1	0.167	373	0	+373
	Total Change in Information Collection Burden Hours: +179,215							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+179,215) = **$4,435,063**							

TABLE 184: SUMMARY OF FINALIZED ASCQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2026 REPORTING PERIOD/CY 2028 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1270 for the CY 2026 Reporting Period							
Activity	**Estimated time per record (minutes)**	**Number of reporting quarters per year**	**Number of ASCs reporting**	**Average number records per ASC per quarter**	**Annual burden (hours) per ASC**	**Finalized annual burden (hours) across ASCs**	**Previously finalized annual burden (hours) across ASCs**	**Net difference in annual burden hours**
Addition of the FCHE Measure	10	1	4,475	1	0.167	746	0	+746
Addition of the Screening for SDOH Measure (Mandatory Survey)	2	1	4,475	4,765	158.8	710,733	0	+710,733
Addition of the Screening for SDOH Measure (Mandatory Reporting)	10	1	4,475	1	0.167	746	0	+746
Addition of the Screen Positive Rate for SDOH (Mandatory Reporting)	10	1	4,475	1	0.167	746	0	+746
	Total Change in Information Collection Burden Hours: +712,971							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+712,971) = **$17,529,790**							

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D. ICRs Related to Medicaid Clinic Services Four Walls Exceptions

As discussed in section XVII of this final rule, we are finalizing our proposal for three additional exceptions to the four walls requirement under the Medicaid clinic services benefit at 42 CFR 440.90. Specifically, we are adding a mandatory four walls exception for IHS/Tribal clinics at § 440.90(c) and optional exceptions for behavioral health clinics and clinics located in rural areas at § 440.90(d) and (e). To attest to compliance with § 440.90(c) and to effectuate the options at § 440.90(d) and (e), States that cover the clinic services benefit will have to submit one or more Medicaid State plan amendments (SPAs).

The burden associated with submitting the SPAs implementing the proposed Medicaid clinic services four walls exceptions will be addressed as part of an associated SPA preprint being developed by CMS and submitted to OMB for approval under OMB control number 0938–1148 (CMS–10398).

E. ICRs for Changes to the Review Timeframes for Hospital Outpatient Department (OPD) Prior Authorization Process

In the CY 2020 OPPS/ASC final rule with comment period, we established a prior authorization process for certain hospital OPD services using our authority under section 1833(t)(2)(F) of the Act, which allows the Secretary to develop a method for controlling unnecessary increases in the volume of covered OPD services (84 FR 61142, 61446 through 61456).[755] As part of the CY 2021 OPPS/ASC final rule with comment period, we added additional service categories to the prior authorization process (85 FR 85866, 86236 through 86248). Through the CY 2023 OPPS/ASC final rule with comment period, we added an eighth service category to the prior authorization process for certain hospital OPD services (87 FR 71748, 72224 through 72233). The regulations governing the prior authorization process are located in subpart I of 42 CFR part 419, specifically at §§ 419.80 through 419.89.

In alignment with the CMS Interoperability and Prior Authorization final rule (89 FR 8758), we are finalizing our proposal to change the current review timeframes for provisionally affirmed or non-affirmed requests from 10-business days to 7-calendar days for standard reviews after receiving the prior authorization request for OPD services under Medicare FFS. The ICR associated with prior authorization requests for these covered outpatient department services is the required documentation submitted by providers. The prior authorization request must include all relevant documentation

[755] See also Correction Notification issued January 3, 2020 (85 FR 224).

necessary to show that the service meets applicable Medicare coverage, coding, and payment rules, and the request must be submitted before the service is provided to the beneficiary and before the claim is submitted for processing.

The burden associated with the changes in review timeframes for the OPD prior authorization process will be the time and effort necessary for the submitter to locate and obtain the relevant supporting documentation to show that the service meets applicable coverage, coding, and payment rules. The submitter will then forward the information to CMS or its contractor (MAC) for review and determination of a provisional affirmation. We expect that this information will generally be maintained by providers within the normal course of business and that this information will be readily available. We estimate that the average time for office clerical activities associated with this task will be 30 minutes, equivalent to normal prepayment or postpayment medical review. We anticipate that most prior authorization requests will be sent by means other than mail, such as electronically or by fax. However, we estimate a cost of $5 per request for mailing medical records. Based on data from 2019–2022, we estimate that there will be 127,397 initial requests mailed per year. In addition, we estimate there will be 41,806 resubmissions of a request mailed following a non-affirmed decision. Therefore, the total mailing cost is estimated to be $846,015 (169,203 mailed requests × $5). We also estimate that an additional 3 hours per provider will be required for attending educational meetings and reviewing training documents.

The average labor costs (including 100 percent fringe benefits) used to estimate the costs were calculated using data from the Bureau of Labor Statistics (BLS) and based on the 2022 median rate for Miscellaneous Healthcare Support Occupations.[756] Based on the BLS information, we estimate an average clerical hourly rate of $18.53 with a loaded rate of $37.06. The prior authorization program does not create any new documentation or administrative requirements. Instead, it just requires the same documents needed to support claim payments to be submitted earlier in the claim process. We use the clerical rate since we do not believe that clinical staff will need to spend more time completing the documentation than they would need to in the absence of the prior authorization policy. The hourly rate reflects the time needed for the additional clerical work of submitting the prior authorization request itself. We estimate that the total annual number of submissions will be 564,010 (394,808 submissions through fax or electronic means + 169,203 mailed submissions). Therefore, we estimate that the annual burden hours allotted across all providers will be 316,412 hours (.5 hours × 564,010 submissions plus 3 hours × 11,469 providers for education). The annual burden cost is $12,572,244 (316,412 hours × $37.06 plus $846,015 for mailing costs). We estimate the annual burden to be 316,412 hours and $12,572,244. The ICR approved under OMB control number 0938–1368 will be revised and submitted to OMB for approval of this extension.

Table 185 below is a chart reflecting the total burden and associated costs for the provisions included in this final rule with the comment period. The previously approved Paperwork Reduction Act package (CMS–10711) is currently undergoing the renewal process. We did not make any changes to the information collection, such as the number of respondents, responses, or other information collection requirements. However, there is a 1-hour change in the burden hours, from 316,413 to 316,412, likely due to rounding up in the previous year's calculations. The burden costs have increased from $11,561,950 to $12,572,244 due to an increase in the average clerical hourly rate from $17.13 in 2019 to $18.53 in 2022.

TABLE 185: TOTAL BURDEN FOR REVIEW TIMEFRAME

Information Collection Requests	Burden Hours Increase/Decrease (+/-)*	Cost (+/-)*
Review Timeframe for Hospital Outpatient Department (OPD) Prior Authorization Process	-1	+$1.0 million

* Numbers rounded.

F. ICRs for the Hospital Inpatient Quality Reporting (IQR) Program

In section XXII.B.2 of this final rule with comment period, we are finalizing that for the FY 2026 payment determination, the submission of CCDEs and linking variables associated with the Hybrid Hospital-Wide Readmission (HWR) measure and the Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (HWM) measure will remain voluntary. Additionally, based on public comment, we are extending voluntary reporting of CCDEs and linking variables for an additional year for the performance period of July 1, 2024, through June 30, 2025, impacting the FY 2027 payment determination for the Hospital IQR Program.

In the FY 2020 IPPS/LTCH PPS final rule and the FY 2022 IPPS/LTCH PPS final rule, we estimated the burden for voluntary reporting for the Hybrid HWR (84 FR 42603 and 42604) and Hybrid HWM measures (86 FR 45508), respectively. In both final rules, we stated that we encourage all hospitals to submit data for the Hybrid HWR and Hybrid HWM measures during the voluntary reporting period. Our previously finalized burden estimates assume that all hospitals will participate during the voluntary reporting period in order to not underestimate the burden on participating hospitals. Therefore, we estimate no changes to the burden currently approved for the Hospital IQR Program under OMB control number 0938–1022 (expiration date January 31, 2026).

We did not receive any public comments on our burden estimates.

G. ICRs for Continuous Eligibility (42 CFR 435.926 and 457.342)

In section XX of this final rule with comment period, we are finalizing our proposal to align the Medicaid and CHIP regulations with the continuous

[756] *https://www.bls.gov/oes/current/oes_nat.htm.*

eligibility requirements under section 5112 of Title V, subtitle B (hereafter, ''section 5112'') of the CAA, 2023. To comply with section 5112 of the CAA, 2023, States must submit a CHIP SPA and a Medicaid SPA to provide continuous eligibility for children if they do not already do so in their CHIP or Medicaid State plans, or if their current continuous eligibility SPAs do not comply with the CAA, 2023 requirements. CMS has already received approval for the burden estimates for the CHIP continuous eligibility SPA under OMB control number 0938–1148 (CMS–10398) and for the Medicaid continuous eligibility SPA under OMB control number 0938–1188 (CMS–10434). States may provide extended continuous eligibility through an 1115 demonstration, which they would do by submitting a demonstration application or amendment.

We did not receive any public comments on the information collection requirements for our proposal and therefore, we are finalizing our provisions as proposed.

H. ICRs Regarding Organization, Staffing and Delivery of Services for Hospitals (§ 482.59(a) and (b)) and CAHs (§ 485.649(a) and (b))

We proposed that if a hospital or Critical Access Hospital (CAH) provides OB services, such services must be well-organized and in accordance with nationally recognized acceptable standards of practices for physical and behavioral health of pregnant, birthing, and postpartum patients. We also proposed that any outpatient OB services would be consistent in quality with inpatient OB services in accordance with the complexity of services offered. In addition, we proposed that the organization of the OB service be appropriate to the scope of services offered by the facility and integrated with other departments of the facility. We further proposed that the OB patient care units be supervised by an individual with the necessary education and training, and specify that person should be an experienced registered nurse, certified nurse midwife, nurse practitioner, physician assistant, or a doctor of medicine or osteopathy. In addition, we proposed that hospitals and CAHs must delineate and document obstetrical privileges for all practitioners providing obstetrical care in accordance with the competencies of each practitioner.

For delivery of services, we proposed that OB services must be consistent with the needs and resources of the facility. We proposed that policies governing OB care must be designed to ensure the achievement and maintenance of high standards of medical practice and patient care and safety. We additionally proposed that labor & delivery room suites have certain basic resuscitation equipment readily available, including a call-in-system, cardiac monitor, and fetal doppler or monitor. Furthermore, we proposed that the service must ensure that it has adequate provisions and protocols, consistent with nationally recognized and evidence-based guidelines for OB emergencies, complications, immediate post-delivery care, and other patient health and safety events as identified as part of the facility's QAPI program.

Comment: The Joint Commission (TJC) questioned our assumption that there would be no burden for TJC-accredited facilities to develop policies and procedures to ensure that OB services are well organized, provide high-quality care that is appropriate to the level of services provided, and integrated with other departments of the facility, and that facilities have internal standards and protocols to ensure compliance with nationally accepted guidelines for OB emergencies, complications, immediate post-delivery care, and other patient health and safety events. They indicated that the other proposed requirements would exceed their requirements in some areas and would impose additional costs on facilities.

Response: We appreciate the feedback on the burden for TJC-accredited facilities. Rather than assuming that TJC-accredited hospitals and CAHs will have no burden for these requirements, in this final rule with comment period we modify our cost estimate and assume that there is only a 50 percent overlap between the proposed organization, staffing, and delivery of service policy development requirements and current standards for TJC-accredited hospitals and CAHs. For all other proposed OB services requirements, we maintain the same approach we used in the proposed rule and do not assume any overlap between our proposed requirements and TJC requirements.

After consideration of the public comments we received and as indicated in section XXI.C.2 of this final rule with comment period, we are finalizing the proposed policies for hospitals (§ 482.59(a) through (b)) and CAHs (§ 485.649(a) through (b)) that offer obstetrical (OB) services with the modification to reference the requirements of the medical staff bylaws for hospitals and CAHs rather than requiring hospitals and CAHs with OB services to delineate and document obstetrical privileges for all practitioners. In addition, we are clarifying that basic equipment must be kept at the hospital and CAH and be readily available for treating obstetrical cases to meet the needs of patients. Below, we provide the burden estimate for the final requirements that include the following modifications: (1) a higher burden for TJC-accredited hospitals to develop policies and procedures to ensure that OB services are well organized and (2) the removal of the cost for facilities to delineate and document obstetrical privileges for all practitioners providing obstetrical care.

To identify the number of hospitals and CAHs subject to the finalized provisions, we utilized the Center for Medicare and Medicaid Services' Provider of Services File—Hospital and Non-Hospital Facilities. We excluded hospitals and CAHs that do not offer obstetric services, as well as Rural Emergency Hospitals that are not subject to these CoPs. Using this methodology, we obtained a total of 513 CAHs and 4,415 hospitals that offer obstetric services.[757]

We calculated the estimated hourly rates for staff members involved in developing these policies based upon the national mean salary for that particular position increased by 100 percent to account for overhead costs and fringe benefits using the May 2023 National Occupational Employment and Wage Estimates, Bureau of Labor Statistics (BLS) at *https://www.bls.gov/oes/current/oes_nat.htm.* The wage and salary data from the BLS do not include health, retirement, and other fringe benefits, or the rent, utilities, information technology, administrative, and other types of overhead costs supporting each employee. The HHS-wide guidance on preparation of regulatory and paperwork burden estimates states that doubling salary costs is a good approximation for including these overhead and fringe benefit costs.

Table 186 presents the BLS occupation code and title, the facility provider position, the estimated average or mean hourly wage, and the adjusted hourly wage (with a 100 percent markup of the salary to include fringe benefits and overhead costs).

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[757] Provider of Services File—Hospital & Non-Hospital Facilities. Available at *https://data.cms.gov/provider-characteristics/hospitals-and-other-facilities/provider-of-services-file-hospital-non-hospital-facilities/data.* Accessed April 10, 2024.

TABLE 186: ESTIMATED HOURLY WAGE BY OCCUPATIONAL GROUP

BLS (NAICS) Occupation Code	BLS Occupation Category	Mean Hourly Wage *(a)*	Loaded Hourly Wage (b = a × 2)	Loaded Average Hourly Wage for Group (c =b1+b2…+bn/n)
Leadership & Senior Staff:				$194
11-1011	Chief Executive	$124.47	$248.94	
11-9111	Medical and Health Services Manager	$64.64	$129.28	
23-1011	Lawyer	$84.84	$169.68	
29-1210	Physician	$126.85	$253.70	
11-3031	Financial Manager	$84.05	$168.10	
Administrative Staff:				$68
11-3010	Administrative Services & Facilities Manager	$56.56	$113.12	
19-3022	Survey Researchers	$32.05	$64.10	
19-3099	Social Scientists	$49.14	$98.28	
43-6013	Medical Secretary	$20.85	$41.70	
29-2072	Medical Records Specialist	$25.81	$51.62	
43-4000	Information and Record Clerk	$20.49	$40.98	
Care Staff:				$104
29-1210	Physician	$126.85	$253.70	
29-1071	Physician Assistant	$62.74	$125.48	
29-1171	Nurse Practitioner	$61.78	$123.56	
29-1141	Registered Nurse	$45.42	$90.84	
21-1022	Healthcare Social Worker	$32.42	$64.84	
31-1131	Nursing Assistant	$19.04	$38.08	
31-1120	Home Health and Personal Care Aide	$16.05	$32.10	
19-3033	Clinical and Counseling Psychologist	$51.25	$102.50	
Technical Staff:				$112
15-0000	All Computer and Mathematical Occupations	$54.39	$108.78	

BLS (NAICS) Occupation Code	BLS Occupation Category	Mean Hourly Wage *(a)*	Loaded Hourly Wage (b = a × 2)	Loaded Average Hourly Wage for Group (c =b1+b2…+bn/n)
15-2051	Data Scientists	$57.23	$114.46	
All Staff (Average)				$109
All Staff with Triple Weight to Care Staff (Average)				$130
Patients:				$31
00-000	All Occupations Average	$31.48	$62.96	

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We expect that most hospitals and CAHs that offer OB services already have internal standards and protocols to ensure that OB services are well organized and to provide high-quality care that is appropriate to the level of services provided and integrated with other departments of the facility. We also expect that they have internal standards and protocols to ensure compliance with nationally accepted guidelines for OB emergencies, complications, immediate post-delivery care, and other patient health and safety events. Many hospital accrediting organizations also have specific requirements governing care for pregnant and postpartum patients that will meet part of these finalized requirements. For example, TJC has wide-ranging requirements for hospitals that provide perinatal care, covering everything from providing information to families in a way that is easy to understand to providing initial care for complications such as hemorrhage, hypertensive disorders, fetal heart rate abnormalities.[758] We expect, however, that all hospitals and CAHs will need to spend time ensuring that these standards and their sources are well-documented.

As outlined in 84 FR 51732, writing new policies related to patient care is estimated to take eight hours for each member of the staff involved in the care policy. We have estimated wages as indicated in Table 186 and included the involvement of a physician at $2,029.60 (8 × $253.70), a lawyer at $1357.44 (8 × $169.68), a registered nurse at $726.72 (8 × $90.84), a medical secretary at $333.6 (8 × $41.70), and a medical and health services manager at $1,034.24 (8 × $129.28) for a total estimated cost of $5,481.60 per policy. This estimate leads to an average hourly cost of $137.04 ($5,481.60 ÷ 40) per staff member involved in ensuring that these standards and their sources are well-documented. We assume that documentation will consist of one comprehensive policy per facility.

We do not expect that all facilities will need to spend 40 hours to meet these requirements. We expect that the burden will be lower for TJC-accredited facilities since the organization has wide-ranging requirements for hospitals and CAHs, with the requirements increasing as the complexity of OB care offered increases. We estimate that there is a 50 percent overlap between TJC requirements and our finalized requirements. To account for this reduction in the overall burden, we used CMS' CASPER (Certification and Survey Provider Enhanced Reports) [759] to identify TJC-accredited hospitals and CAHs. According to CASPER, approximately 72.2 percent of Medicare and Medicaid approved hospitals are accredited by TJC, as well as 25 percent of Critical Access Hospitals (CAHs). We then multiply the respective shares of TJC-accredited hospitals and CAHs by 0.5 to account for the 50 percent overlap in requirements.

To calculate the hourly burden for this requirement, in Table 187 we multiply the number of facilities by the number of responses per facility, applying the discount for hospitals and CAHs that are accredited by TJC, by the hourly burden estimate. To determine the associated cost, we multiply the revised hourly burden estimate by the average hourly labor cost. Using this formula, in Table 187 we estimate a total burden of 13,802 hours at a cost of $17,925,161.

Table 188 provides the annual burden estimate over a 10-year period for these finalized requirements. We do not estimate a burden for updating these policies and procedures after their initial development in year 1 since regularly reviewing and updating policies is a standard business practice for healthcare facilities that must comply with applicable Federal, state, and local laws, regulations and ordinances that periodically change. As such, the total estimate over 10 years is 130,802 hours at a cost of $17,925,161.

For the requirements that OB patient care units be supervised by an individual with the necessary education and training, as well as ensuring that OB patient care units have certain basic equipment readily available, and that the facility has adequate provisions for obstetrical emergencies, we provide the estimated cost in the regulatory impact analysis section below.

[758] The Joint Commission Edition. Program: Perinatal Care, ''Chapter: Provision of Care, Treatment, and Services.'' Available at *https://e-dition.jcrinc.com/MainContent.aspx.* Accessed April 10, 2024.

[759] Quality, Certification & Oversight Reports (QCOR). CASPER (4/16/2024). *qcor.cms.gov.*

TABLE 187: BURDEN ESTIMATE FOR ORGANIZATION, STAFFING, AND DELIVERY OF SERVICES REQUIREMENT BY PROVIDER TYPE

Provider Type	Number of Providers (a)	Number of Responses (b = a × 1)	Annualized Hourly Burden (c)	TJC Overlap Discount (d = 1 - TJC overlap discount)	Hourly Wage Cost (e)	Total Hourly Burden (f = b × c × d × e)	Total Hourly Burden Cost (g = e × f)
Hospital	4,415	4,415	40	0.639	$137.04	112,847	$15,464,608
CAH	513	513	40	0.875	$137.04	17,955	$2,460,553
Total	4,928	4,928				130,802	$17,925,161

TABLE 188: 10 YEAR BURDEN ESTIMATE FOR ORGANIZATION, STAFFING, AND DELIVERY OF SERVICES REQUIREMENT

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	Total 10 Year Burden
Hourly Burden	130,802	0	0	0	0	0	0	0	0	0	130,802
Hourly Burden Cost	$17,925,161	$0	$0	$0	$0	$0	$0	$0	$0	$0	$17,925,161

I. ICRs Regarding OB Staff Training for Hospitals (§ 482.59(c)) and CAHs (§ 485.649(c))

We proposed that hospitals and CAHs that offer OB services must develop policies and procedures to ensure that staff are trained on select topics related to improving the delivery of maternal care. The training must reflect the scope and complexity of services offered and must include, but is not limited to, facility-identified evidence-based best practices and protocols to improve the delivery of maternal care within the facility. They would also need to be trained in any additional topics as identified by the facility's QAPI program. We also proposed that the governing body must identify and document which staff must complete annual training on these topics. The facility must further document that training was successfully completed and must be able to demonstrate staff knowledge on these topics. Lastly, we proposed that the efficacy of the training must be reviewed and assessed on an ongoing basis, based on the results of data, measures, and quality indicators from the facility's QAPI program.

Comment: A commenter said that increased demand for training material for facilities to meet the proposed training requirement could cause vendors to raise their prices.

Response: We appreciate the comment regarding vendor prices. Facilities have the flexibility to determine which topics they train staff on to improve the delivery of maternal care and which vendors they use for their training. While some vendors could raise the prices for training materials in response to higher demand, others may choose to maintain or even lower it given the increased demand. Facilities may also choose to use free training resources such as those outlined in section XXI.C.3 of this final rule with comment period. Given the availability of free and low-cost resources for many training topics and likely variation across vendors, we are not including any additional burden related to vendor pricing.

Comment: A few commenters said that CMS should consider the disproportionate financial impact that the requirements will have on some provider types, particularly hospitals and CAHs that are most at risk of closing their OB units, which could lead to increased burden on other hospitals and result in patients having to travel greater distance to access maternal care.

Response: We appreciate commenters' suggestions to consider differences across providers. The CY 2025 OPPS/ASC proposed rule assessed likely variation in burden across different providers, taking into account variation in facility size, the number of patients, and staff size that we believe accurately reflects the likely burden for each facility type. We have also taken several steps to reduce burden and ensure that all hospitals and CAHs are able to successfully meet the requirements. First, we are implementing the requirements in three phases (see section XXI.A.7 of this final rule with comment period) to reduce potential implementation burden or unintended consequences. Second, as we discuss in more detail in the regulatory impact analysis, we are also reducing the frequency of the obstetrical services training requirement from annually to biannually (every other year), which leads to a large reduction in cost. Finally, we are not finalizing the requirement that hospitals and CAHs delineate and document obstetrical privileges for all practitioners providing obstetrical care.

After consideration of the public comments we received, and as indicated in section XXI.C.3 of this final rule with comment period, we are finalizing the policies for hospitals (§ 482.59(c)) and CAHs (§ 485.649(c)) that offer OB services with the modification that the effective date of the staff training requirement is January 1, 2027, and that the governing body in hospitals and CAHs must identify and document which staff must complete an initial training and subsequent biannual training.

As outlined in 84 FR 51732, writing new policies related to patient care is estimated to take eight hours for each member of the staff involved in the care policy. We have estimated wages as indicated in Table 186 and included the involvement of a physician at $2,029.60 (8 × $253.70), a lawyer at $1357.44 (8 × $169.68), a registered nurse at $726.72 (8 × $90.84), a medical secretary at $333.6 (8 × $41.70), and a medical and health services manager at $1,034.24 (8 × $129.28) for a total estimated cost of $5,481.60 per policy. This estimate leads to an average hourly cost of $137.04 ($5481.60 ÷ 40) per staff member involved in ensuring that these standards and their sources are well-documented. We assume that documentation will consist of one comprehensive policy per facility. We do not estimate a burden for reviewing and assessing the efficacy of these efforts since we address this below in section XXVI.J. We do not estimate a burden for documenting that training was completed as updating employee records is also a customary business practice. As indicated in Table 189 and Table 190, we estimate that the development of the finalized OB staff training policies and procedures will take 197,120 hours to complete and cost $27,013,325. We discuss the burden for staff training in the regulatory impact analysis below.

TABLE 189: YEAR 1 BURDEN ESTIMATE FOR OB STAFF TRAINING POLICIES AND PROCEDURES BY PROVIDER TYPE

Provider Type	Number of Providers (a)	Number of Responses (b = a × 1)	Annualized Hourly Burden (c)	Hourly Wage Cost (d)	Total Hourly Burden (e = b × c)	Total Hourly Burden Cost (f = d × e)
Hospital	4,415	4,415	40	$137.04	176,600	$24,201,264
CAH	513	513	40	$137.04	20,520	$2,812,061
Total	4,928	4,928			197,120	$27,013,325

TABLE 190: 10 YEAR BURDEN ESTIMATE FOR OB STAFF TRAINING POLICIES AND PROCEDURES

Year	Hourly Burden	Hourly Burden Cost
1	197,120	$27,013,325
2	0	0
3	0	0
4	0	0
5	0	0
6	0	0
7	0	0
8	0	0
9	0	0
10	0	0
10 Year total Cost	191,120	$27,013,325

J. ICRs Regarding Revisions to QAPI Standards for OB Services in Hospitals (§ 482.21) and CAHs (§ 485.641)

We proposed that hospitals and CAHs with OB services must use their QAPI program to address health disparities among OB patients on an ongoing basis. They must also measure and monitor for health disparities among OB patients and develop and implement actions to address these disparities and monitor subsequent results. Moreover, on an annual basis, they must conduct at least one performance improvement project focused on reducing maternal health disparities. In addition to the proposed QAPI requirements, we proposed that OB leadership be engaged in the facility's QAPI requirement. We further proposed that if a Maternal Mortality Review Committee (MMRC) is available at the state or local jurisdiction in which the facility is located, the facility must and have a process for incorporating MMRC data and recommendations into the facility's QAPI program.

Comment: One commenter said that full utilization of quality improvement activities often requires significant financial investment and administrative support to be successful. Another commenter noted that many metrics used in obstetrics cannot be assessed using administrative data and instead requires a time-consuming manual chart review. Some commenters indicated that the rule did not take into account increases in staff wages and salaries.

Response: We appreciate the comments regarding utilization of QAPI and that some obstetrical metrics could require manual chart reviews. We believe that the estimated costs in the proposed rule that included costs for data system modifications, data stratification, incorporation of MMRC recommendations into the QAPI program, and carrying out an annual project provide an accurate estimate of the likely average burden for facilities to engage in these activities. We agree that growth in staff wages and salaries needs to be considered when calculating costs.

According to the Bureau of Labor Statistics,[760] RNs in 2015 earned a mean hourly rate of $34.14 with the nominal mean hourly rate in 2023 [761] increasing to $45.42. Inflation,[762] however, accounts for 3.49 percentage points annually over these eight years, leaving a compound annual real growth rate of approximately 0.44 percent. To address concerns that wage costs are underestimated, we are including a 0.44 annual increase in real wage rates for staff involved in carrying out this requirement.

After consideration of the public comments we received, and as indicated in section XXI.C.4 of this final rule with comment period, we are finalizing the proposed revision to existing QAPI standards (§ 482.21; § 485.641) for hospitals and CAHs that offer obstetrical services without modifications. To account for growth in staff wage rates, we are including a 0.44 percent annual increase in real wage rates.

The costs associated with data collection will include the cost for facilities to modify their information technology infrastructure to ensure that they capture all features relevant for the diverse subpopulations that the facility identifies. Given that many facilities already collect some of these patient characteristics, such as race and ethnicity, we estimate that planning, programming, and performing quality checks will take 8 hours in the first year and 4 hours in all subsequent years. We anticipate a mixture of staff from computer and mathematical occupations will oversee these changes at an average hourly cost of $108.78. This leads to an average cost of $870.24 (8 × $108.78) per provider in the first year. For subsequent years, we estimate that the requirement will take 4 hours to complete and include a 0.44 percent annual increase in the average hourly cost to account for growth in real wage rates. As indicated in Table 191 we estimate that in the first year, updating infrastructure will cost a total of $4,288,543. In Table 192, we provide the estimated total 10-year cost which we estimate at $24,016,571.

Based on our experience working with healthcare data, we anticipate that stratification of data and quality indicators, together with monitoring the results after actions are taken to address these disparities, will take 8 hours annually. We anticipate that data scientists will oversee these efforts at an average hourly cost of $114.46. Since the requirements do not go into effect until year 2, we estimate that there will be no burden in year 1. For subsequent years, we increase the estimated burden to include a 0.44 percent annual increase in the average hourly cost to account for growth in real wage rates. For year 2, we estimate an average cost of $919.71 per provider. Table 193 provides the estimated cost in year 2 and Table 194 provides the estimated cost over 10 years. We estimate an average annual cost of annual cost of $4,532,326 with a total cost of $41,516,273 over 10 years.

TABLE 191: YEAR 1 BURDEN ESTIMATE FOR QAPI DATA SYSTEM MODIFICATIONS BY PROVIDER TYPE

Provider Type	Number of Providers (a)	Number of Responses (b = a × 1)	Annualized Hourly Burden (c)	Hourly Wage Cost (d)	Total Hourly Burden (e = b × c)	Total Hourly Burden Cost (f = d × e)
Hospital	4,415	4,415	8	$108.78	35,320	$3,842,110
CAH	513	513	8	$108.78	4,104	$446,433
Total	4,928	4,928				$4,288,543

TABLE 192: 10 YEAR BURDEN ESTIMATE FOR QAPI DATA SYSTEM MODIFICATIONS

Year	Hourly Burden	Hourly Burden Cost
1	39,424	$4,288,543
2	19,712	$2,153,706
3	19,712	$2,163,182
4	19,712	$2,172,700
5	19,712	$2,182,260
6	19,712	$2,191,862
7	19,712	$2,201,506
8	19,712	$2,211,193
9	19,712	$2,220,922
10	19,712	$2,230,694
10 Year total Cost	216,832	$24,016,571

[760] U.S. Bureau of Labor Statistics. Occupational Employment and Wages—May 2015. Accessed September 25, 2024. *https://www.bls.gov/news.release/archives/ocwage_03302016.pdf.*

[761] U.S. Bureau of Labor Statistics. Occupational Employment and Wages, May 2023: 29–1141 Registered Nurses. Accessed September 25, 2024. *https://www.bls.gov/oes/current/oes291141.html.*

[762] Federal Reserve Bank of Minneapolis. Inflation Calculator. Accessed February September 25, 2024. *https://www.minneapolisfed.org/about-us/monetary-policy/inflation-calculator.*

TABLE 193: YEAR 2 BURDEN ESTIMATE FOR QAPI DATA STRATIFICATION AND MONITORING BY PROVIDER TYPE

Provider Type	Number of Providers (a)	Number of Responses (b = a × 1)	Annualized Hourly Burden (c)	Hourly Wage Cost (d)	Total Hourly Burden (e = b × c)	Total Hourly Burden Cost (f = d × e)
Hospital	4,415	4,415	8	$114.96	35,320	$4,060,515
CAH	513	513	8	$114.96	4,104	$471,811
Total	4,928	4,928			39,424	$4,532,326

TABLE 194: 10 YEAR BURDEN ESTIMATE FOR QAPI DATA STRATIFICATION AND MONITORING

Year	Hourly Burden	Hourly Burden Cost
1	0	$0
2	39,424	$4,532,326
3	39,424	$4,552,268
4	39,424	$4,572,298
5	39,424	$4,592,416
6	39,424	$4,612,623
7	39,424	$4,632,918
8	39,424	$4,653,303
9	39,424	$4,673,778
10	39,424	$4,694,342
10 Year total Cost	354,816	$41,516,273

K. ICRS Regarding Emergency Services Readiness in Emergency Services for Hospitals (§ 482.55(c)) and CAHs (§ 485.618(e))

We proposed a new standard for emergency services readiness and to improve staff readiness for providing emergency services to all patients, including pregnant and postpartum patients. The first proposed standard would require hospitals and CAHs with emergency services to have adequate provisions and protocols, consistent with nationally recognized and evidence-based guidelines, for the care of patients with emergency conditions (including but not limited to patients with OB emergencies, complications, immediate post-delivery care). Applicable staff would be required to be trained on these protocols and provisions. We also proposed that equipment, supplies, and medication used in treating emergency cases are kept at the hospital and are readily available for treating emergency cases.

Comment: A commenter said that the emergency services requirements may require additional investment by facilities, such as establishing proper storage, tracking, and protocols related to the necessary products.

Response: CMS expects that facilities would already have protocols in place for the storage and tracking of emergency products. As such, we do not estimate any additional burden for this requirement.

After consideration of the public comments we received and as indicated in section XXI.C.5 of this final rule with comment period, we are finalizing the proposed emergency services readiness standard for hospitals and CAHs without modifications. We are also finalizing the burden estimates as proposed.

As outlined in 84 FR 51732, writing new policies related to patient care is estimated to take eight hours for each member of the staff involved in the care policy. Since the finalized standard for emergency services involves adding a new standard to an existing policy, we estimate that it will take half the amount of time as writing a new policy, or 4 hours for each staff member involved. We have estimated wages as indicated in Table 186 and included the involvement of a physician at $1,014.80 (4 × $253.70), a lawyer at $678.72 (4 × $169.68), a registered nurse at $363.36 (4 × $90.84), a medical secretary at $166.80 (4 × $41.70), and a health services manager at $517.12 (4 × $129.28) for a total estimated cost of $2,740.80 per policy. This estimate leads to an average hourly cost of $137.04 ($2,740.80 ÷ 20) per staff member involved in developing this standard. We do not estimate a burden for updating standards since reviewing and updating policies and procedures is a customary business practice. As indicated in Table 195 and Table 196, we estimate that creating this standard will cost hospitals $17,294,448 with a total hourly burden of 126,200 hours.

TABLE 195: YEAR 1 BURDEN ESTIMATE FOR EMERGENCY SERVICES READINESS

Provider Type	Number of Providers (a)	Number of Responses (b = a × 1)	Annualized Hourly Burden (c)	Hourly Wage Cost (d)	Total Hourly Burden (e = b × c)	Total Hourly Burden Cost (f = d × e)
Hospital	5,797	5,797	20	$137.04	115,940	$15,888,418
CAH	513	513	20	137.04	10,260	$1,406,030

TABLE 196: 10 YEAR BURDEN ESTIMATE FOR EMERGENCY SERVICES READINESS

Year	Hourly Burden	Hourly Burden Cost
1	115,940	$17,294,448
2	0	0
3	0	0
4	0	0
5	0	0
6	0	0
7	0	0
8	0	0
9	0	0
10	0	0
10 Year total Cost	126,200	$17,294,448

L. Transfer Protocols in Discharge Planning (§ 482.43) for Hospitals

We proposed transfer protocol requirements for hospitals transferring patients under their care to the appropriate level of care, including to another hospital, as necessary to meet the needs of the patient and stabilize any emergency conditions (including but not limited to patients with OB emergencies, complications, immediate post-delivery care).

After consideration of the comments, and as indicated in section XXI.C.6 of this final rule with comment period, we are finalizing the proposed emergency services readiness standard for hospitals with the modification that acute care hospitals are required to provide annual training to the relevant staff (as determined by the facility) regarding the hospital policies and procedures for transferring patients under its care. We did not receive any comments on the estimated cost to develop transfer protocols and are finalizing our estimate for this requirement as proposed.

In 87 FR 40350, we estimated that for rural emergency hospitals (REHs), developing a transfer agreement with at least one hospital would require 2 hours of work from an administrator and a clerical person. We believe that hospitals will face a similar burden for this requirement. Using estimated wages as indicated in Table 186, we estimate that this requirement will include the involvement of a medical secretary at $83.40 (2 × 41.70) and a medical and health services manager at $258.56 (2 × 129.28) for a total estimate cost of $341.96 per hospital. This estimate leads to an average hourly cost of $85.49 ($341.96 ÷ 4) per staff member involved in developing this standard. We do not estimate a burden for updating transfer protocols since reviewing and updating policies and procedures is a customary business practice. As indicated in Table 197 and Table 198, we estimate that creating these protocols will cost hospitals $1,982,342 with a total hourly burden of 23,188 hours.

TABLE 197: YEAR 1 BURDEN ESTIMATE FOR TRANSFER PROTOCOLS

Provider Type	Number of Providers (a)	Number of Responses (b = a × 1)	Annualized Hourly Burden (c)	Hourly Wage Cost (d)	Total Hourly Burden (e = b × c)	Total Hourly Burden Cost (f = d × e)
Hospital	5,797	5,797	4	$85.49	23,188	$1,982,342

TABLE 198: 10 YEAR BURDEN ESTIMATE FOR TRANSFER PROTOCOLS

Year	Hourly Burden	Hourly Burden Cost
1	23,188	$1,982,342
2	0	0
3	0	0
4	0	0
5	0	0
6	0	0
7	0	0
8	0	0
9	0	0
10	0	0
10 Year total Cost	23,188	$1,982,342

M. Total Costs for all ICRs Related to Maternal Health

In Tables 199 and 227, we provide the total hourly burden estimate and cost for all collection of information requirements related to maternal health as outlined in Tables 188, 190, 192, 194, 196, and 198. Overall, we estimate that the finalized requirements will have a total burden of 1,048,958 hours over 10 years at a cost of $129,748,120.

TABLE 199: MATERNAL HEALTH COLLECTION OF INFORMATION REQUIREMENTS HOURLY BURDEN

Year	Organization, Staffing, and Delivery of Services	OB Staff Training Policies and Procedures	QAPI Data System Modifications	QAPI Data Stratification and Monitoring	Emergency Services Readiness	Transfer Protocols	Hourly Burden Cost for All Requirements
1	130,802	197,120	39,424	0	126,200	23,188	516,734
2	0	0	19,712	39,424	0	0	59,136
3	0	0	19,712	39,424	0	0	59,136
4	0	0	19,712	39,424	0	0	59,136
5	0	0	19,712	39,424	0	0	59,136
6	0	0	19,712	39,424	0	0	59,136
7	0	0	19,712	39,424	0	0	59,136
8	0	0	19,712	39,424	0	0	59,136
9	0	0	19,712	39,424	0	0	59,136
10	0	0	19,712	39,424	0	0	59,136
10 Year Total Cost	130,802	197,120	216,832	354,816	126,200	23,188	1,048,958

TABLE 200: MATERNAL HEALTH COLLECTION OF INFORMATION REQUIREMENTS HOURLY BURDEN COST

Year	Organization, Staffing, and Delivery of Services	OB Staff Training Policies and Procedures	QAPI Data System Modifications	QAPI Data Stratification and Monitoring	Emergency Services Readiness	Transfer Protocols	Hourly Burden Cost for All Requirements
1	$17,925,161	$27,013,325	$4,288,543	$0	$17,294,448	$1,982,342	$68,503,819
2	$0	$0	$2,153,706	$4,532,326	$0	$0	$6,686,032
3	$0	$0	$2,163,182	$4,552,268	$0	$0	$6,715,451
4	$0	$0	$2,172,700	$4,572,298	$0	$0	$6,744,999
5	$0	$0	$2,182,260	$4,592,416	$0	$0	$6,774,677
6	$0	$0	$2,191,862	$4,612,623	$0	$0	$6,804,485
7	$0	$0	$2,201,506	$4,632,918	$0	$0	$6,834,425
8	$0	$0	$2,211,193	$4,653,303	$0	$0	$6,864,496
9	$0	$0	$2,220,922	$4,673,778	$0	$0	$6,894,700
10	$0	$0	$2,230,694	$4,694,342	$0	$0	$6,925,037
10 Year Total Cost	$17,925,161	$27,013,325	$24,016,571	$41,516,273	$17,294,448	$1,982,342	$129,748,120

XXVII. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble; and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

XXVIII. Economic Analyses

A. Statement of Need

This final rule with comment period is necessary to make updates to the Medicare hospital OPPS rates. It is also necessary to make changes to the payment policies and rates for outpatient services furnished by hospitals and CMHCs in CY 2025. We are required under section 1833(t)(3)(C)(ii) of the Act to update annually the OPPS conversion factor used to determine the payment rates for APCs. We also are required under section 1833(t)(9)(A) of the Act to review, not less often than annually, and revise the groups, the relative payment weights, and the wage and other adjustments described in section 1833(t)(2) of the Act. We must review the clinical integrity of payment groups and relative payment weights at least annually. We are revising the APC relative payment weights using claims data for services furnished on and after January 1, 2023, through and including December 31, 2023, and processed through June 30, 2024, and updated HCRIS cost report information.

This final rule with comment period is also necessary to make updates to the ASC payment rates for CY 2025, enabling CMS to make changes to payment policies and payment rates for covered surgical procedures and covered ancillary services that are performed in ASCs in CY 2025. Because ASC payment rates are based on the OPPS relative payment weights for most of the procedures performed in ASCs, the ASC payment rates are updated annually to reflect annual changes to the OPPS relative payment weights. In addition, we are required under section 1833(i)(1) of the Act to review and update the list of surgical procedures that can be performed in an ASC, not less frequently than every 2 years.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59075 through 59079), we finalized a policy to update the ASC payment system rates using the hospital market basket update instead of the CPI–U for CY 2019 through 2023. In the CY 2024 OPPS/ASC final rule, we finalized a policy to extend the 5-year interim period by an additional 2 years, through CY 2024 and CY 2025, to enable us to more accurately analyze whether the application of the hospital market basket update to the ASC payment system resulted in a migration of services from the hospital setting to the ASC setting (88 FR 81960).

This final rule is also necessary to create three additional exceptions to the four walls requirement under the Medicaid clinic services benefit at 42 CFR 440.90. Specifically, we are finalizing our proposal to add a mandatory four walls exception for IHS/Tribal clinics at 42 CFR 440.90(c) and optional exceptions for behavioral health clinics and clinics located in rural areas at 42 CFR 440.90(d) and (e). As discussed in section XVIII.A of this final rule, our current regulation at 42 CFR 440.90(b) allows for an exception to the four walls requirement only for certain clinic services furnished to individuals who are unhoused.

This final rule is also necessary to codify the requirements of the CAA, 2023 for States to provide 12 months of continuous eligibility to children under the age of 19 in Medicaid and CHIP, with limited exceptions. Specifically, we are finalizing our proposal to remove the option to provide continuous eligibility to a subgroup of Medicaid and CHIP enrollees and for a time period of less than 12 months. For CHIP, we are finalizing removal of the option to disenroll children from CHIP during a continuous eligibility period for failure to pay premiums.

This final rule is necessary to make policy changes under the OPPS or ASC payment system for hospital outpatient

departments (HOPDs), rural emergency hospitals (REHs), and ASCs reporting data under the Hospital Outpatient Quality Reporting (OQR), REH Quality Reporting (REHQR), and ASC Quality Reporting (ASCQR) Programs, respectively. The primary objective of these quality reporting programs is to promote higher quality, more efficient health care for Medicare beneficiaries by collection and reporting on quality-of-care metrics. This information is made available to consumers, both to empower Medicare beneficiaries and inform decisionmaking, as well as to incentivize healthcare facilities to make continued improvements.

This final rule with comment period is also necessary to improve the quality of obstetrical services in hospitals and Critical Access Hospitals (CAHs). The United States has the highest maternal mortality rate among OECD countries.[763] This mortality rate has increased sharply in recent years rising from 17.4 deaths per 100 thousand live births in 2018, to 32.9 deaths per 100 thousand live births in 2021,[764] with most of the increased deaths in 2020 and 2021 being Covid–19 related deaths.[765] The causes of pregnancy-related deaths has shifted in recent years with a decline in traditional causes, such as hemorrhage, hypertensive disorders of pregnancy, and thromboembolism, and an increase in cardiovascular problems and other medical conditions.[766] [767] Nearly a third of all pregnancy-related deaths occur between the day of delivery and the 6 days that follow, with another 20 percent of deaths occurring 7 to 42 days postpartum.[768]

Within the United States, there are widespread differences in maternal mortality rates based on age, race, and geographical location. According to the National Center for Health Statistics, the maternal mortality rates for women in the United States over 40 years of age in 2021 was nearly 8 times greater than for women under 25 years of age, with mortality rates for non-Hispanic black women over 40 years of age more than 21 times higher than the rate for Hispanic women under 25 years of age.[769] Similarly, pregnancy-related mortality rates are higher in rural areas vis-à-vis urban areas.[770] Beyond deaths, maternal morbidity, defined as ''any health condition attributed to and/or aggravated by pregnancy and childbirth that has a negative impact on the woman's wellbeing,'' [771] remains a common occurrence, with rates also varying by age and race.[772] [773]

Pregnancy-related mortality and morbidity have large health and economic costs. One study estimates that between 2018 and 2020, pregnancy-related mortalities lead to nearly 114,000 years of potential life lost (YPLL) and cost more than $27.4 billion based on the value of statistical life (VSL).[774] Another study finds that severe maternal morbidity, as measured by 21 ICD–10 codes that the Centers for Disease Control and Prevention (CDC) identified, is associated with a 75 percent increase in costs for Medicaid patients and a more than doubling in costs for commercially insured patients during the prenatal to 30 days post-partum period.[775] Focusing specifically on nine maternal morbidities among the 2019 US birth cohort from birth to 5-years postpartum, researchers estimated they had a cost of $32.3 billion for birthing parents and their children, with $18.7 billion due to medical costs and $13.6 billion from non-medical costs.[776]

Although the studies vary in their methodology, time period pre-post birth analyzed, medical conditions analyzed, and cost estimates, they overall suggest that maternal morbidity and mortality impose a high health, safety, and economic cost on birth parents, children, and society.[777] Given these costs, we are implementing conditions of participation (COPs) that are designed to help reduce maternal mortality and morbidity.

We are finalizing requirements that hospital and CAH OB patient care units be supervised by an individual with the necessary education and training and have equipment at the hospital and CAH and readily available for treating obstetrical cases to meet the needs of patients. Facilities offering obstetrical services must also have adequate provisions that include equipment, supplies and medication used in treating emergency cases for obstetrical emergencies, complications, immediate post-delivery care, and other patient health and safety events as identified as part of the QAPI program. We also are finalizing requirements that staff involved with OB services be trained on key topics related to improving the delivery of maternal care. Hospitals and CAHs will also be required to utilize data from their QAPI program to implement one quality improvement project to address disparities in maternal care and to integrate information from MMRCs into their QAPI program. We are also finalizing requirements that hospitals and CAHs train their staff on emergency procedures for all patients and that hospitals have provisions including equipment, supplies, and medication used in treating emergency cases. Finally, we are finalizing the requirement that relevant acute care hospital staff receive annual training on proper transfer protocols.

B. Overall Impact of Provisions of This Final Rule With Comment Period

We have examined the impacts of this rule, as required by Executive Order 12866, as amended, on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 14094, titled ''Modernizing Regulatory Review'' (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), Executive

[763] Tikkanen, R., et al., *Maternal Mortality and Maternity Care in the United States Compared to 10 Other Developed Countries.* 2020, Commonwealth Fund.

[764] Hoyert, D.L., *Maternal Mortality Rates in the United States, 2021.* 2023, NCHS Health E-Stats.

[765] United States Government Accountability Office, *MATERNAL HEALTH: Outcomes Worsened and Disparities Persisted During the Pandemic.* 2022.

[766] Creanga, A.A., et al., *Pregnancy-Related Mortality in the United States, 2011–2013.* Obstetrics & Gynecology, 2017. 130(2): 366–373.

[767] Wang, S., et al., *Maternal Mortality in the United States: Trends and Opportunities for Prevention.* Annual Review of Medicine, 2023. 74(1): 199–216.

[768] Peterson, E.E., et al., *Vital Signs: Pregnancy-Related Deaths, United States, 2011–2015, and Strategies for Prevention, 13 States, 2013–2017.* Morbidity and Mortality Weekly Report, 2019. 68(18): 423–429.

[769] Hoyert, D.L., *Maternal Mortality Rates in the United States, 2021.* 2023, NCHS Health E-Stats.

[770] Merkt, P.T., et al., *Urban-rural differences in pregnancy-related deaths, United States, 2011–2016.* American Journal of Obstetrics and Gynecology, 2021. 225(2): 183.e1–183.e16.

[771] Firoz, T., et al., *Measuring maternal health: focus on maternal morbidity.* Bull World Health Organ, 2013. 91(10): 794–796.

[772] Liese, K.L., et al., *Racial and Ethnic Disparities in Severe Maternal Morbidity in the United States.* Journal of Racial and Ethnic Health Disparities, 2019. 6(4): p. 790–798.

[773] Leonard, S.A., et al., *Racial and ethnic disparities in severe maternal morbidity prevalence and trends.* Annals of Epidemiology, 2019. 33: 30–36.

[774] White Robert, S., et al., *Economic burden of maternal mortality in the USA, 2018–2020.* Journal of Comparative Effectiveness Research, 2022. 11(13): 927–933.

[775] Black, C.M., et al., *Costs of Severe Maternal Morbidity in U.S. Commercially Insured and Medicaid Populations: An Updated Analysis.* Women's Health Reports, 2021. 2(1): 443–451.

[776] O'Neil, S.S., et al., *Societal cost of nine selected maternal morbidities in the United States.* PLOS ONE, 2022. 17(10): e0275656.

[777] Moran, P.S., et al., *Economic burden of maternal morbidity—A systematic review of cost-of-illness studies.* PLOS ONE, 2020. 15(1): e0227377.

Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866, as amended, and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 14094 amends section 3(f) of Executive Order 12866. The amended section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $200 million or more in any 1 year (adjusted every 3 years by the Administrator of OMB's Office of Information and Regulatory Affairs (OIRA) for changes in gross domestic product), or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in this Executive order, as specifically authorized in a timely manner by the Administrator of OIRA in each case.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with significant effects as per section 3(f)(1) ($200 million or more in any 1 year). Based on our estimates, OIRA has determined this rulemaking is significant per section 3(f)(1) as measured by an effect on the economy of $200 million or more in any 1 year. Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act), OIRA has also determined that this rule meets the criteria set forth in 5 U.S.C. 804(2). Accordingly, we have prepared an RIA that to the best of our ability presents the costs and benefits of the rulemaking. Therefore, OMB has reviewed this final rule with comment period, and the Departments have provided the following assessment of their impact.

We estimate that the total increase in Federal Government expenditures under the OPPS for CY 2025, compared to CY 2024, due to the changes to the OPPS in this final rule with comment period, will be approximately $1.98 billion. Taking into account our estimated changes in enrollment, utilization, and case-mix for CY 2025 we estimate that the OPPS expenditures, including beneficiary cost-sharing, for CY 2025 would be approximately $87.7 billion, which is approximately $4.7 billion higher than estimated OPPS expenditures in CY 2024. Table 201 of this final rule with comment period displays the distributional impact of the CY 2025 changes in OPPS payment to various groups of hospitals and for CMHCs.

We note that under our final CY 2025 policy, drugs and biologicals are generally paid at ASP plus 6 percent, WAC plus 6 percent, or 95 percent of AWP, as applicable.

We estimate that the final update to the conversion factor will increase total OPPS payments by 2.9 percent in CY 2025. The final changes to the APC relative payment weights, the final changes to the wage indexes, the final continuation of a payment adjustment for rural SCHs, including EACHs, and the final payment adjustment for cancer hospitals would not increase total OPPS payments because these changes to the OPPS are budget neutral. However, these updates would change the distribution of payments within the budget neutral system. We estimate that the total change in payments between CY 2024 and CY 2025, considering all budget-neutral payment adjustments, changes in estimated total outlier payments, the application of the frontier State wage adjustment, in addition to the application of the OPD fee schedule increase factor after all adjustments required by sections 1833(t)(3)(F), 1833(t)(3)(G), and 1833(t)(17) of the Act will increase total estimated OPPS payments by 3.0 percent.

We estimate the total increase (from changes to the ASC provisions in this final rule with comment period, as well as from enrollment, utilization, and case-mix changes) in Medicare expenditures (not including beneficiary cost-sharing) under the ASC payment system for CY 2025 compared to CY 2024, to be approximately $240 million. Tables 202 and 203 of this final rule with comment period display the redistributive impact of the CY 2025 changes regarding ASC payments, grouped by specialty area and then grouped by procedures with the greatest ASC expenditures, respectively.

We estimate that finalizing three additional exceptions to the Medicaid clinic services benefit four walls requirement for IHS/Tribal clinics, behavioral health clinics, and clinics located in rural areas would cause total Medicaid transfers to increase by $1.18 billion for fiscal years 2025 through 2029. This includes a Federal impact of $1.15 billion and State impact of $30 million.

For the OB services provisions of this final rule with comment period, in Tables 231 and 232, we provide the total estimated cost and hourly burden of these finalized requirements both annually and over 10 years, excluding collection of information costs that we have already estimated above. Overall, we estimate that these finalized requirements will cost an average of approximately $410 million and take $2.24 million hours to complete. Over 10 years, we estimate that the total cost will be approximately $4.10 billion and take $22.4 million hours to complete. Below, we provide the cost estimates for each of the finalized requirements.

C. Detailed Economic Analyses

1. Estimated Effects of OPPS Changes in This Final Rule With Comment Period

a. Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the final CY 2025 policy changes on various hospital groups. We post our hospital-specific estimated payments for CY 2025 on the CMS website with the other supporting documentation for this final rule with comment period. To view the hospital-specific estimates, we refer readers to the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient*. On the website, select ''Regulations and Notices'' from the left side of the page and then select ''CMS–1809–FC'' from the list of regulations and notices. The hospital-specific file layout and the hospital-specific file are listed with the other supporting documentation for this final rule with comment period. We show hospital-specific data only for hospitals whose claims were used for modeling the impacts shown in Table 201 of this final rule with comment period. We do not show hospital-specific impacts for hospitals whose claims we were unable to use. We refer readers to section II.A of this final rule with comment period for a discussion of the hospitals whose claims we do not use for ratesetting or impact purposes.

We estimate the effects of the individual policy changes by estimating payments per service, while holding all other payment policies constant. We use the best data available but do not attempt to predict behavioral responses to our policy changes in order to isolate

the effects associated with specific policies or updates, but any policy that changes payment could have a behavioral response. In addition, we have not made any adjustments for future changes in variables, such as service volume, service-mix, or number of encounters.

b. Estimated Effects of OPPS Changes on Hospitals

Table 201 shows the estimated impact of the proposed rule on hospitals. Historically, the first line of the impact table, which estimates the change in payments to all facilities, has always included cancer and children's hospitals, which are held harmless to their pre-Balanced Budget Act (BBA) amount. We also include CMHCs in the first line that includes all providers. We include a second line for all hospitals, excluding permanently held harmless hospitals and CMHCs.

We present separate impacts for CMHCs in Table 201, and we discuss them separately below, because CMHCs have historically been paid only for partial hospitalization services under the OPPS and are a different provider type from hospitals. In the CY 2024 OPPS/ASC final rule with comment period (88 FR 81833), we finalized paying CMHCs for partial hospitalization services and intensive outpatient services under APCs 5851 through 5854. For CY 2025, we are maintaining the same APC structure and updating each APC payment rate to reflect the most recent available cost data.

The estimated increase in the total payments made under the OPPS is determined largely by the increase to the conversion factor under the statutory methodology. The distributional impacts presented do not include assumptions about changes in volume and service-mix. The conversion factor is updated annually by the OPD fee schedule increase factor, as discussed in detail in section II.B of this final rule with comment period.

Section 1833(t)(3)(C)(iv) of the Act provides that the OPD fee schedule increase factor is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act, which we refer to as the IPPS market basket percentage increase. The final IPPS market basket percentage increase applicable to the OPD fee schedule for CY 2025 is 3.4 percent. Section 1833(t)(3)(F)(i) of the Act reduces that 3.4 percent by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is 0.5 percentage point for CY 2025 (which is also the productivity adjustment for FY 2025 in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69344)) resulting in the final CY 2025 OPD fee schedule increase factor of 2.9 percent. We are using the OPD fee schedule increase factor of 2.9 percent in the calculation of the final CY 2025 OPPS conversion factor. Section 10324 of the Affordable Care Act, as amended by HCERA, further authorized additional expenditures outside budget neutrality for hospitals in certain frontier States that have a wage index less than 1.0000. The amounts attributable to this frontier State wage index adjustment are incorporated in the estimates in Table 201 of this final rule with comment period.

To illustrate the impact of the CY 2025 changes, our analysis begins with a baseline simulation model that uses the CY 2024 relative payment weights, the FY 2024 final IPPS wage indexes that include reclassifications, and the final CY 2024 conversion factor. Table 201 shows the estimated redistribution of the increase or decrease in payments for CY 2025 over CY 2024 payments to hospitals and CMHCs as a result of the following factors: the impact of the APC reconfiguration and recalibration changes between CY 2024 and CY 2025 (Column 2); the wage indexes and the provider adjustments (Column 3); the combined impact of all of the changes described in the preceding columns plus the 2.9 percent OPD fee schedule increase factor update to the conversion factor (Column 4); the estimated impact taking into account all payments for CY 2025 relative to all payments for CY 2024, including the impact of changes in estimated outlier payments and changes to the pass-through payment estimate (Column 5).

We did not model an explicit budget neutrality adjustment for the rural adjustment for SCHs because we are maintaining the current adjustment percentage for CY 2025. Because the final updates to the conversion factor (including the update of the OPD fee schedule increase factor), the estimated cost of the rural adjustment, and the estimated cost of projected pass-through payment for CY 2025 are applied uniformly across services, observed redistributions of payments in the impact table for hospitals largely depend on the mix of services furnished by a hospital (for example, how the APCs for the hospital's most frequently furnished services would change), and the impact of the wage index changes on the hospital. However, total payments made under this system and the extent to which this final rule would redistribute money during implementation also will depend on changes in volume, practice patterns, and the mix of services billed between CY 2024 and CY 2025 by various groups of hospitals, which CMS cannot forecast.

Overall, we estimate that the final rates for CY 2025 will increase Medicare OPPS payments by an estimated 3.0 percent. Removing payments to cancer and children's hospitals because their payments are held harmless to the pre-OPPS ratio between payment and cost and removing payments to CMHCs results in an estimated 3.2 percent increase in Medicare payments to all other hospitals. These estimated payments will not significantly impact other providers.

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 201 shows the total number of facilities (3,562), including designated cancer and children's hospitals and CMHCs, for which we were able to use CY 2023 hospital outpatient and CMHC claims data to model CY 2024 and CY 2025 payments, by classes of hospitals, for CMHCs and for dedicated cancer hospitals. We excluded all hospitals and CMHCs for which we could not plausibly estimate CY 2024 or CY 2025 payment and entities that are not paid under the OPPS. The latter entities include CAHs, IHS and tribal hospitals, and hospitals located in Guam, the U.S. Virgin Islands, Northern Mariana Islands, American Samoa, and the State of Maryland. This process is discussed in greater detail in section II.A of this final rule with comment period. At this time, we are unable to calculate a DSH variable for hospitals that are not also paid under the IPPS because DSH payments are only made to hospitals paid under the IPPS. Hospitals for which we do not have a DSH variable are grouped separately and generally include freestanding psychiatric hospitals, rehabilitation hospitals, and long-term care hospitals. We show the total number of OPPS hospitals (3,460), excluding the hold harmless cancer and children's hospitals and CMHCs, on the second line of the table. We excluded cancer and children's hospitals because section 1833(t)(7)(D) of the Act permanently holds harmless cancer hospitals and children's hospitals to their ''pre-BBA amount'' as specified under the terms of the statute, and therefore, we removed them from our impact analyses. We show the isolated impact on the 35 CMHCs at the bottom of the impact table (Table 201) and discuss that impact separately below.

Column 2: APC Recalibration—All Changes

Column 2 shows the estimated effect of APC recalibration. Column 2 also reflects any changes in multiple procedure discount patterns or conditional packaging that occur as a result of the changes in the relative magnitude of payment weights. As a result of APC recalibration, we estimate that urban hospitals would experience a 0.1 increase, with the impact ranging from a decrease of 0.1 percent to an increase of 0.4, depending on the number of beds. Rural hospitals will experience an estimated decrease of 0.4 overall. Major teaching hospitals will experience an estimated decrease of 0.1 percent.

Column 3: Wage Indexes and the Effect of the Provider Adjustments

Column 3 demonstrates the combined budget neutral impact of the APC recalibration, the updates for the wage indexes with the FY 2025 IPPS post-reclassification wage indexes including the low wage index hospital policy, the rural adjustment, the frontier adjustment, and the cancer hospital payment adjustment. We modeled the independent effect of the budget neutrality adjustments and the OPD fee schedule increase factor by using the relative payment weights and wage indexes for each year and using a CY 2024 conversion factor that included the OPD fee schedule increase and a budget neutrality adjustment for differences in wage indexes.

Column 3 reflects the independent effects of the updated wage indexes, including the application of budget neutrality for the rural floor policy on a nationwide basis, as well as the final CY 2025 changes in wage index policy, discussed in section II.C of this final rule with comment period. We note that the final CY 2025 OPPS wage index includes the low wage index hospital policy, as proposed. We did not model a budget neutrality adjustment for the rural adjustment for SCHs because we proposed to continue the rural payment adjustment of 7.1 percent to rural SCHs for CY 2025, as described in section II.E of this final rule with comment period. We modeled a budget neutrality adjustment for the final cancer hospital payment adjustment because the proposed payment-to-cost ratio target for the cancer hospital payment adjustment in CY 2025 is 0.87, which is different from the 0.88 PCR target adopted in the CY 2024 OPPS/ASC final rule with comment period (88 FR 81589). We note that, in accordance with section 16002 of the 21st Century Cures Act, we are applying a budget neutrality factor calculated as if the cancer hospital adjustment target payment-to-cost ratio was 0.88, not the 0.87 target payment-to-cost ratio we are finalizing in section II.F of this final rule with comment period.

We modeled the independent effect of updating the wage indexes by varying only the wage indexes, holding APC relative payment weights, service-mix, and the rural adjustment constant and using the CY 2025 scaled weights and a CY 2024 conversion factor that included a budget neutrality adjustment for the effect of the changes to the wage indexes between CY 2024 and CY 2025.

Column 4: All Budget Neutrality Changes Combined With the Market Basket Update

Column 4 demonstrates the combined impact of all the final changes previously described and the update to the conversion factor of 2.9 percent. Overall, these changes would increase payments to urban hospitals by 3.2 percent and to rural hospitals by 3.3 percent. Rural sole community hospitals would receive an estimated increase of 3.3 percent while other rural hospitals would receive an estimated increase of 3.5 percent.

Column 5: All Changes for CY 2025

Column 5 depicts the full impact of the final CY 2025 policies on each hospital group by including the effect of all changes for CY 2025 and comparing them to all estimated payments in CY 2024. Column 5 shows the combined budget neutral effects of Columns 2 and 3; the OPD fee schedule increase; the impact of estimated OPPS outlier payments, as discussed in section II.G of final rule with comment period; the change in the Hospital OQR Program payment reduction for the small number of hospitals in our impact model that failed to meet the reporting requirements (discussed in section XIV of this final rule with comment period); and other rule adjustments to the CY 2025 OPPS payments.

Of those hospitals that failed to meet the Hospital OQR Program reporting requirements for the full CY 2024 update (and assumed, for modeling purposes, to be the same number for CY 2025), we included 98 hospitals in our model because they had both CY 2023 claims data and recent cost report data. We estimate that the cumulative effect of all changes for CY 2025 would increase payments to all facilities by 3.0 percent for CY 2024. We modeled the independent effect of all changes in Column 5 using the final relative payment weights for CY 2024 and the proposed relative payment weights for CY 2025. We used the final conversion factor for CY 2024 of $87.382 and the final CY 2025 conversion factor of $89.169 discussed in section II.B of this final rule with comment period.

Column 5 contains simulated outlier payments for each year. We used the 1-year charge inflation factor used in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69660) of 4.1 percent (1.04118) to increase charges on the CY 2023 claims, and we used the overall CCR in the July 2024 Outpatient Provider-Specific File (OPSF) to estimate outlier payments for CY 2024. Using the CY 2023 claims and a 4.1 percent charge inflation factor, we currently estimate that outlier payments for CY 2024, using a multiple threshold of 1.75 and a fixed-dollar threshold of $7,750, would be approximately 0.83 percent of total payments. The estimated current outlier payments of 0.83 percent are incorporated in the comparison in Column 5. We used the same set of claims and a charge inflation factor of 8.5 percent (1.08406) and the CCRs in the July 2024 OPSF, with an adjustment of 1.015192 (89 FR 69960), to reflect relative changes in cost and charge inflation between CY 2023 and CY 2025, to model the proposed CY 2025 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a fixed dollar threshold of $7,175. The charge inflation and CCR inflation factors are discussed in detail in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69955 through 69960).

Overall, we estimate that facilities will experience an increase of 3.0 percent under this final rule in CY 2025 relative to total spending in CY 2024. This projected increase (shown in Column 5) of Table 201 of this final rule reflects the final 2.9 percent OPD fee schedule increase factor, adding the 0.17 difference in estimated outlier payments between CY 2024 (0.83 percent) and CY 2025 (1.0 percent), minus 0.10 percent for the change in the pass-through payment estimate between CY 2024 and CY 2025. We estimate that the combined effect of all changes for CY 2025 would increase payments to urban hospitals by 3.2 percent. Overall, we estimate that rural hospitals would experience a 3.2 percent increase as a result of the combined effects of all the changes for CY 2025.

Among hospitals, by teaching status, we estimate that the impacts resulting from the combined effects of all changes include an increase of 2.7 percent for major teaching hospitals and an increase of 3.3 percent for nonteaching hospitals. Minor teaching hospitals will

experience an estimated increase of 3.5 percent.

In our analysis, we also have categorized hospitals by type of ownership. Based on this analysis, we estimate that voluntary hospitals will experience an increase of 3.1 percent, proprietary hospitals will experience an increase of 4.9 percent, and governmental hospitals will experience an increase of 2.6 percent.

c. Estimated Effects of OPPS Changes on CMHCs

The last line of Table 201 demonstrates the isolated impact on CMHCs, which historically have only furnished partial hospitalization services under the OPPS. As discussed in section VIII.C of this final rule with comment period, we are finalizing the proposal for CY 2025 to continue paying CMHCs using APCs 5851 through 5854. We modeled the impact of this APC policy, assuming CMHCs will continue to provide the same PHP care as seen in the CY 2023 claims used for ratesetting in the proposed rule. We note that the CY 2023 claims used for the CY 2025 final rule do not include any provision of IOP services. We did not exclude days with one or two services from our modeling for CY 2025, because our final rule policy would pay the per diem rate for APC 5853 for such days beginning in CY 2025. As a result of the final PHP APC changes for CMHCs, we estimate that CMHCs would experience a 11.9 percent increase in CY 2025 payments relative to their CY 2024 payments (shown in Column 5). For a detailed discussion of our final PHP policies, please see section VIII of this final rule with comment period.

Column 3 shows the estimated impact of adopting the final FY 2025 wage index values, which result in an estimated change of 0.0 percent to CMHCs. Column 4 shows that combining the OPD fee schedule increase factor, along with the proposed changes in APC policy for CY 2025 and the proposed FY 2025 wage index updates, will result in an estimated increase of 11.9 percent.

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TABLE 201: ESTIMATED IMPACT OF THE FINAL CY 2025 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

		(1)	(2)	(3)	(4)	(5)
		Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**All Budget Neutral Changes (combined cols 2 and 3) with Market Basket Update**	**All Changes**
ALL PROVIDERS *		3,562	0.0	0.1	3.0	3.0
ALL HOSPITALS		3,460	0.1	0.2	3.2	3.2
	(excludes hospitals held harmless and CMHCs)					
URBAN HOSPITALS		2,775	0.1	0.1	3.2	3.2
	LARGE URBAN	1,311	0.2	-0.4	2.7	2.9
	(GT 1 MILL.)					
	OTHER URBAN	1,464	0.1	0.5	3.5	3.4
	(LE 1 MILL.)					
RURAL HOSPITALS		685	-0.4	0.9	3.3	3.2
	SOLE COMMUNITY	350	-0.4	0.8	3.3	3.0
	OTHER RURAL	335	-0.4	1.0	3.5	3.4
BEDS (URBAN)						
	0 - 99 BEDS	972	0.4	0.4	3.7	3.6
	100-199 BEDS	761	0.2	0.4	3.5	3.4
	200-299 BEDS	424	0.3	0.0	3.1	3.2
	300-499 BEDS	384	0.2	0.2	3.3	3.3
	500 + BEDS	234	-0.1	-0.1	2.7	2.9
BEDS (RURAL)						
	0 - 49 BEDS	327	-0.4	0.9	3.4	3.2
	50- 100 BEDS	201	-0.4	0.9	3.4	3.1
	101- 149 BEDS	85	-0.6	0.4	2.7	2.7
	150- 199 BEDS	42	-0.4	1.4	4.0	3.7
	200 + BEDS	30	-0.4	0.6	3.1	3.2
REGION (URBAN)						
	NEW ENGLAND	124	-0.2	1.0	3.7	3.8
	MIDDLE ATLANTIC	298	0.0	-1.3	1.6	1.8
	SOUTH ATLANTIC	452	0.2	0.9	4.1	4.2

	EAST NORTH CENT.	418	0.0	1.4	4.3	4.4
	EAST SOUTH CENT.	169	0.1	1.3	4.4	4.4
	WEST NORTH CENT.	186	0.1	0.5	3.5	2.7
	WEST SOUTH CENT.	471	0.6	0.8	4.3	4.4
	MOUNTAIN	221	0.3	0.3	3.5	3.0
	PACIFIC	387	0.3	-2.5	0.6	0.9
	PUERTO RICO	49	0.7	-0.3	3.4	3.5
REGION (RURAL)						
	NEW ENGLAND	21	-0.6	0.5	2.8	2.9
	MIDDLE ATLANTIC	52	-0.6	1.5	3.8	3.9
	SOUTH ATLANTIC	110	-0.4	-0.1	2.4	2.4
	EAST NORTH CENT.	110	-0.4	2.3	4.9	5.0
	EAST SOUTH CENT.	130	-0.4	1.3	3.8	3.9
	WEST NORTH CENT.	77	-0.4	0.6	3.1	2.4
	WEST SOUTH CENT.	119	-0.2	1.2	3.9	4.0
	MOUNTAIN	42	-0.5	1.3	3.8	2.0
	PACIFIC	24	-0.7	-2.3	-0.2	-0.1
TEACHING STATUS						
	NON-TEACHING	2,125	0.1	0.3	3.3	3.3
	MINOR	893	0.2	0.5	3.7	3.5
	MAJOR	442	-0.1	-0.3	2.5	2.7
DSH PATIENT PERCENT						
	0	11	0.0	1.4	4.4	4.6
	GT 0 - 0.10	218	0.8	0.8	4.6	4.3
	0.10 - 0.16	211	0.4	0.4	3.8	3.6
	0.16 - 0.23	529	0.5	0.4	3.8	3.8
	0.23 - 0.35	1,132	0.0	0.5	3.4	3.3
	GE 0.35	918	-0.2	-0.4	2.3	2.5
	DSH NOT AVAILABLE **	441	2.3	-0.1	5.2	5.3
URBAN TEACHING/DSH						
	TEACHING & DSH	1,176	0.1	0.1	3.1	3.1
	NO TEACHING/DSH	1,147	0.3	0.2	3.4	3.3
	NO TEACHING/NO DSH	11	0.0	1.4	4.4	4.6
	DSH NOT AVAILABLE2	441	2.3	-0.1	5.2	5.3
TYPE OF OWNERSHIP						
	VOLUNTARY	1,975	0.0	0.2	3.1	3.1
	PROPRIETARY	1,059	1.0	1.0	4.9	4.9
	GOVERNMENT	426	-0.1	-0.3	2.5	2.6

CMHCs		35	9.1	0.0	12.2	11.9

Column (1) shows total hospitals and/or CMHCs.

Column (2) includes all final CY 2025 OPPS policies and compares those to the CY 2024 OPPS.

Column (3) shows the budget neutral impact of updating the wage index by applying the FY 2025 hospital inpatient wage index, including the low wage index hospital policy. The rural SCH adjustment continues our current policy of 7.1 percent so the budget neutrality factor is 1. The final budget neutrality adjustment for the cancer hospital adjustment is 1.0005 because the final CY 2025 target payment-to-cost ratio is less than the CY 2024 PCR target.

Column (4) shows the impact of all budget neutrality adjustments and the addition of the final 2.9 percent OPD fee schedule update factor (3.4 percent reduced by 0.5 percentage point for the productivity adjustment).

Column (5) shows the additional adjustments to the conversion factor resulting from a change in the pass-through estimate and adding estimated outlier payments. Note that previous years included the frontier adjustment in this column, but we have included the frontier adjustment to Column 3 in this table.

* These 3,562 providers include children's and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.

** Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.

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d. Estimated Effect of OPPS Changes on Beneficiaries

For services for which the beneficiary pays a copayment of 20 percent of the payment rate, the beneficiary's payment would increase for services for which the OPPS payments would rise and decrease for services for which the OPPS payments would fall. For further discussion of the calculation of the national unadjusted copayments and minimum unadjusted copayments, we refer readers to section II.H of this final rule with comment period. In all cases, section 1833(t)(8)(C)(i) of the Act limits beneficiary liability for copayment for a procedure performed in a year to the hospital inpatient deductible for the applicable year.

We estimate that the aggregate beneficiary coinsurance percentage would be approximately 18.0 percent for all services paid under the OPPS in CY 2025. The estimated aggregate beneficiary coinsurance reflects general system adjustments, including the final CY 2025 comprehensive APC payment policy discussed in section II.A.2.b of this final rule with comment period. We note that the individual payments, and therefore copayments, associated with services may differ based on the setting in which they are furnished. However, at the aggregate system level, we do not currently observe significant impact on beneficiary coinsurance as a result of those policies.

e. Estimated Effects of OPPS Changes on Other Providers

The relative payment weights and payment amounts established under the OPPS affect the payments made to ASCs, as discussed in section XIII of this final rule with comment period. Hospitals, CMHCs, and ASCs would be affected by the changes in this final rule. Additionally, the payment policies we established for IOP services affect RHCs and FQHCs. These providers of IOP are not paid under the OPPS and are not included in the impact analysis shown in Table 201. However, the final payment amount for OPPS APC 5861 would affect payments to RHCs and FQHCs since under sections 1834(o)(5)(A) and 1834(y)(3)(A) of the Act payment for IOP services in these settings is required to be equal to the payment determined for IOP services in the hospital outpatient department.

f. Estimated Effects of OPPS Changes on the Medicare and Medicaid Programs

The effect of the update on the Medicare program is expected to be an increase of $1.98 billion in program payments for OPPS services furnished in CY 2025. The effect on the Medicaid program is expected to be limited to copayments that Medicaid may make on behalf of Medicaid recipients who are also Medicare beneficiaries. We estimate that the changes in this final rule with comment period will increase these Medicaid beneficiary payments by approximately $165 million in CY 2025. Currently, there are approximately 11.5 million dual-eligible beneficiaries, which represent approximately 40 percent of Medicare Part B fee-for-service beneficiaries. The impact on Medicaid was determined by taking 40 percent of the beneficiary cost-sharing impact. The national average split of Medicaid payments is 58 percent Federal payments and 42 percent State payments. Therefore, for the estimated $165 million Medicaid increase, approximately $95 million will be from the Federal Government and $70 million will be from State governments.

g. Alternative OPPS Policies Considered

Alternatives to the OPPS changes we proposed and the reasons for our selected alternatives are discussed throughout this final rule with comment period.

h. Add-On Payment for High-Cost Drugs to the Indian Health Service (IHS) All-Inclusive Rate (AIR)

For CY 2025, we proposed to pay Indian Health Service (IHS) and tribal hospitals separately for high-cost drugs (Part B drugs with daily costs over $1,334) furnished in hospital outpatient departments through an add-on payment, in addition to the All-Inclusive Rate (AIR), using the IHS authority [778] under which the annual AIR is calculated. This policy is projected to increase Medicare program expenditures by approximately $30

[778] Sections 321(a) and 322(b) of the Public Health Service Act (42 U.S.C. 248), Public Law 83–568 (42 U.S.C. 2001(a)), and the Indian Health Care Improvement Act (25 U.S.C. 1601 *et seq.*).

million in CY 2025. We refer readers to section X.C of this final rule with comment period for further discussion of this policy.

2. Estimated Effects of CY 2025 ASC Payment System Changes

Most ASC payment rates are calculated by multiplying the ASC conversion factor by the ASC relative payment weight. As discussed fully in section XIII of this final rule with comment period, we are setting the CY 2025 ASC relative payment weights by scaling the final CY 2025 OPPS relative payment weights by the finalized CY 2025 ASC scalar of 0.872. The estimated effects of the updated relative payment weights on payment rates are varied and are reflected in the estimated payments displayed in Tables 202 and 203.

Beginning in CY 2011, section 3401 of the Affordable Care Act requires that the annual update to the ASC payment system after application of any quality reporting reduction be reduced by a productivity adjustment. In CY 2019, we adopted a policy for the annual update to the ASC payment system to be the hospital market basket update for CY 2019 through CY 2023. In the CY 2024 OPPS/ASC final rule with comment period, we extended this 5-year interim period an additional 2 years through CYs 2024 and 2025. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (as projected by the Secretary for the 10-year period, ending with the applicable fiscal year, year, cost reporting period, or other annual period). For ASCs that fail to meet their quality reporting requirements, the CY 2025 payment determinations would be based on the application of a 2.0 percentage point reduction to the annual update factor, which is the hospital market basket update for CY 2025. We calculated the finalized CY 2025 ASC conversion factor by adjusting the CY 2024 ASC conversion factor by 0.9969 to account for changes in the pre-floor and pre-reclassified hospital wage indexes between CY 2024 and CY 2025, which includes our final policy to limit wage index declines of greater than 5 percent, and by applying the CY 2025 productivity-adjusted hospital market basket update factor of 2.9 percent (which is equal to the final inpatient hospital market basket percentage increase of 3.4 percent reduced by a productivity adjustment of 0.5 percentage point). The final CY 2025 ASC conversion factor is $54.895 for ASCs that successfully meet the quality reporting requirements.

a. Limitations of Our Analysis

Presented here are the projected effects of the final changes for CY 2025 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service-mix between CY 2023 and CY 2025 with precision. We believe the net effect on Medicare expenditures resulting from the final CY 2025 changes would be small in the aggregate for all ASCs. However, such changes may have differential effects across surgical specialty groups, as ASCs continue to adjust to the payment rates based on the policies of the revised ASC payment system. We are unable to accurately project such changes at a disaggregated level. Clearly, individual ASCs would experience changes in payment that differ from the aggregated estimated impacts presented below.

b. Estimated Effects of ASC Payment System Policies on ASCs

Some ASCs are multispecialty facilities that perform a wide range of surgical procedures from excision of lesions to hernia repair to cataract extraction; others focus on a single specialty and perform only a limited range of surgical procedures, such as eye, digestive system, or orthopedic procedures. The combined effect of the final update to the CY 2025 payments on an individual ASC would depend on a number of factors, including, but not limited to, the mix of services the ASC provides, the volume of specific services provided by the ASC, the percentage of its patients who are Medicare beneficiaries, and the extent to which an ASC provides different services in the coming year. The following discussion includes tables that display estimates of the impact of the final CY 2025 updates to the ASC payment system on Medicare payments to ASCs, assuming the same mix of services, as reflected in our CY 2023 claims data. Table 202 depicts the estimated aggregate percent change in payment by surgical specialty or ancillary items and services group by comparing estimated CY 2024 payments to estimated CY 2025 payments, and Table 203 shows a comparison of estimated CY 2024 payments to estimated CY 2025 payments for procedures that we estimate would receive the most Medicare payment in CY 2024.

In Table 202, we have aggregated the surgical HCPCS codes by specialty group, grouped all HCPCS codes for covered ancillary items and services into a single group, and then estimated the effect on aggregated payment for surgical specialty and ancillary items and services groups. The groups are sorted for display in descending order by estimated Medicare program payment to ASCs. The following is an explanation of the information presented in Table 202.

- Column 1—Surgical Specialty or Ancillary Items and Services Group indicates the surgical specialty into which ASC procedures are grouped and the ancillary items and services group, which includes all HCPCS codes for covered ancillary items and services. To group surgical procedures by surgical specialty, we used the CPT code range definitions and Level II HCPCS codes and Category III CPT codes, as appropriate, to account for all surgical procedures to which the Medicare program payments are attributed.
- Column 2—Estimated CY 2024 ASC Payments were calculated using CY 2023 ASC utilization data (the most recent full year of ASC utilization) and CY 2024 ASC payment rates. The surgical specialty groups are displayed in descending order based on estimated CY 2024 ASC payments.
- Column 3—Estimated CY 2025 Percent Change is the aggregate percentage increase or decrease in Medicare program payment to ASCs for each surgical specialty or ancillary items and services group that is attributable to final updates to ASC payment rates for CY 2025 compared to CY 2024.

As shown in Table 202, for the six specialty groups that account for the most ASC utilization and spending, we estimate that the final update to ASC payment rates for CY 2025 will result in a 3 percent increase in aggregate payment amounts for eye and ocular adnexa procedures, a 3 percent increase in aggregate payment amounts for musculoskeletal system procedures, a 3 percent increase in aggregate payment amounts for nervous system procedures, a 5 percent increase in aggregate payment amounts for digestive system procedures, a 3 percent increase in aggregate payment amounts for cardiovascular system procedures, and a 3 percent increase in aggregate payment amounts for genitourinary system procedures. We note that these changes can be a result of different factors, including updated data, payment weight changes, and changes in policy. In general, spending in each of these categories of services is increasing due to the 2.9 percent payment rate update which is offset by roughly 0.3 percentage points as a result of the final CY 2025 ASC wage indexes and the final ASC wage index scalar of 0.9969,

resulting in a net 2.6 percent payment rate update. After the payment rate update is accounted for, aggregate payment increases or decreases for a category of services can be higher or lower than a 2.6 percent increase, depending on if payment weights in the OPPS APCs that correspond to the applicable services increased or decreased or if the most recent data show an increase or a decrease in the volume of services performed in an ASC for a category. For example, we estimate a 5 percent increase in gastrointestinal procedure payments. The increase in payment rates for gastrointestinal procedures is a result of relative increase in the OPPS relative weights for the Upper GI Procedures clinical family. These changes are further increased by the 2.6 percent ASC overall net payment rate increase for these procedures. For estimated changes for selected procedures, we refer readers to Table 202 provided later in this section.

TABLE 202: ESTIMATED IMPACT OF THE CY 2025 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2024 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical Specialty Group (1)	Estimated CY 2024 ASC Payments (in Millions) (2)	Estimated CY 2025 Percent Change (3)
Total	$6,864	3
Eye	$2,019	3
Musculoskeletal	$1,319	3
Nervous System	$1,242	3
Gastrointestinal	$1,015	5
Cardiovascular	$335	3
Genitourinary	$262	3

Table 203 shows the estimated impact of the updates to the revised ASC payment system on aggregate ASC payments for selected surgical procedures during CY 2025. The table displays 30 of the procedures receiving the greatest estimated CY 2024 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending order by estimated CY 2024 program payment.

- Column 1–CPT/HCPCS code.
- Column 2–Short Descriptor of the HCPCS code.
- Column 3–Estimated CY 2024 ASC Payments were calculated using CY 2023 ASC utilization (the most recent full year of ASC utilization) and the CY 2024 ASC payment rates. The estimated CY 2024 payments are expressed in millions of dollars.
- Column 4–Estimated CY 2025 Percent Change reflects the percent differences between the estimated ASC payment for CY 2024 and the estimated payment for CY 2025 based on the final update.

TABLE 203: ESTIMATED IMPACT OF THE FINAL CY 2025 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS Code (1)	Short Descriptor (2)	Estimated CY 2024 ASC Payment (in millions) (3)	Estimated CY 2025 Percent Change (4)
66984	Xcapsl ctrc rmvl w/o ecp	$1,339	3
27447	Total knee arthroplasty	$334	3
45380	Colonoscopy and biopsy	$259	4
45385	Colonoscopy w/lesion removal	$244	4
63685	Ins/rplc spi npg/rcvr pocket	$216	5
63650	Implant neuroelectrodes	$184	3
43239	Egd biopsy single/multiple	$180	7
27130	Total hip arthroplasty	$168	3
66991	Xcapsl ctrc rmvl insj 1+	$128	1
64483	Njx aa&/strd tfrm epi l/s 1	$108	1
64590	Ins/rpl prph sac/gstr npg/r	$106	4
66982	Xcapsl ctrc rmvl cplx wo ecp	$98	3
64635	Destroy lumb/sac facet jnt	$88	3
29827	Sho arthrs srg rt8tr cuf rpr	$85	4
36902	Intro cath dialysis circuit	$76	4
64493	Inj paravert f jnt l/s 1 lev	$72	1
64561	Implant neuroelectrodes	$70	4
66821	After cataract laser surgery	$66	-2
G0105	Colorectal scrn; hi risk ind	$65	4
0784T	Ins/rplmt eltrd ra spi nstim	$53	-8
0275T	Perq lamot/lam lumbar	$49	5
65820	Relieve inner eye pressure	$49	2
G0121	Colon ca scrn not hi rsk ind	$44	3
C9740	Cysto impl 4 or more	$43	7
62323	Njx interlaminar lmbr/sac	$43	4
15823	Revision of upper eyelid	$41	4
64721	Carpal tunnel surgery	$39	4
64628	Trml dstrj ios bvn 1st 2 l/s	$35	2
27279	Arthrd si jt perq/min nvas	$35	4
27446	Revision of knee joint	$32	2

c. Estimated Effects of ASC Payment System Policies on Beneficiaries

We estimate that the CY 2025 update to the ASC payment system will be generally positive (that is, result in lower cost-sharing) for beneficiaries with respect to the new procedures to be designated as office-based for CY 2025. First, other than certain preventive services where coinsurance and the Part B deductible is waived to comply with sections 1833(a)(1) and (b) of the Act, the ASC coinsurance rate for all procedures is 20 percent. This contrasts with procedures performed in HOPDs under the OPPS, where the beneficiary is responsible for copayments that range from 20 percent to 40 percent of the procedure payment (other than for certain preventive services), although the majority of HOPD procedures have a 20-percent copayment. Second, in almost all cases, the ASC payment rates under the ASC payment system are lower than payment rates for the same procedures under the OPPS. Therefore, the beneficiary coinsurance amount under the ASC payment system will usually be less than the OPPS copayment amount for the same services. (The only exceptions will be if the ASC coinsurance amount exceeds the hospital inpatient deductible since the statute requires that OPPS copayment amounts not exceed the hospital inpatient deductible. Therefore, in limited circumstances, the ASC coinsurance amount may exceed the hospital inpatient deductible and, therefore, the OPPS copayment amount for similar services.) Beneficiary coinsurance for services migrating from physicians' offices to ASCs may decrease or increase under the ASC payment system, depending on the particular service and the relative payment amounts under the MPFS compared to the ASC. While the ASC payment system bases most of its payment rates on hospital cost data used to set OPPS relative payment weights, services that are performed a majority of the time in a physician office are generally paid the lesser of the ASC amount according to the standard ASC ratesetting methodology or at the nonfacility practice expense-based amount payable under the PFS. For those additional procedures that we are finalizing to designate as office-based in CY 2025, the beneficiary coinsurance amount under the ASC payment system generally will be no greater than the

beneficiary coinsurance under the PFS because the coinsurance under both payment systems generally is 20 percent (except for certain preventive services where the coinsurance is waived under both payment systems).

Accounting Statements and Tables for OPPS and ASC Payment System

As required by OMB Circular A–4 (available on the Office of Management and Budget website at: *https://www.whitehouse.gov/wp-content/uploads/2023/11/CircularA-4.pdf*), we have prepared accounting statements to illustrate the impacts of the OPPS and ASC changes in this final rule with comment period. The first accounting statement, Table 204, illustrates the classification of expenditures for the CY 2025 estimated hospital OPPS incurred benefit impacts associated with the final CY 2024 OPD fee schedule increase. The second accounting statement, Table 205, illustrates the classification of expenditures associated with the 3.1 percent CY 2025 update to the ASC payment system, based on the provisions of the proposed rule and the baseline spending estimates for ASCs. Both tables classify most estimated impacts as transfers. The third accounting statement, Table 206, contains the classification of the costs associated with the finalized health and safety standards for obstetrical services in hospitals and critical access hospitals. This includes the total cost, benefits and transfers as outlined in the collection of information section in Table 200, and the regulatory impact analysis as provided in Table 231. Since there are no transfers and we are not able to quantify the benefits of these provisions, we do not include them in the table. This statement provides our best estimate for the finalized health and safety standards for obstetrical services in hospitals and critical access hospitals provisions. Finally, the fourth accounting statement, Table 207, shows the impact of the Medicaid clinic services four walls exceptions included in this final rule. Table 207 illustrates the classification of expenditures associated with the addition of exceptions to the Medicaid clinic services four walls requirement for IHS/Tribal clinics, behavioral health clinics, and clinics located in rural areas. The table classifies the estimated impacts as transfers and they are discounted at a rate of 2 percent.

TABLE 204: ACCOUNTING STATEMENT: CY 2025 ESTIMATED HOSPITAL OPPS TRANSFERS FROM CY 2024 TO CY 2025 ASSOCIATED WITH THE CY 2025 HOSPITAL OUTPATIENT OPD FEE SCHEDULE INCREASE

Category	Transfers
Annualized Monetized Transfers	$1,980 million
From Whom to Whom	Federal Government to outpatient hospitals and other providers who receive payment under the hospital OPPS

TABLE 205: ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2024 TO CY 2025 AS A RESULT OF THE CY 2025 UPDATE TO THE ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers	$160 million
From Whom to Whom	Federal Government to Medicare Providers and Suppliers
Total	$160 million

TABLE 206: ACCOUNTING STATEMENT: HEALTH AND SAFETY STANDARDS FOR OBSTETRICAL SERVICES IN HOSPITALS AND CRITICAL ACCESS HOSPITALS

Category	Estimate	Units		
		Year Dollar	Discount Rate	Period Covered
Annualized Monetized Costs ($million/year)	430	2023	2%	2025-2034

TABLE 207: FOUR WALLS: ACCOUNTING STATEMENT: MEDICAID CLINIC SERVICES FOUR WALLS EXCEPTIONS

Transfers						
Annual monetized transfers	Primary estimate (in millions of dollars)	Low estimate (in millions of dollars)	High estimate (in millions of dollars)	Units		
				Year dollars	Discount rate (percent)	Period covered
From Federal Government to States….	213.6	102.3	339.1	2025	2	2025-2029
From States to Health Care Providers….	219.6	103.8	357.8	2025	2	2025-2029

3. Effects of Changes in Requirements for the Hospital Outpatient Quality Reporting (OQR) Program

a. Background

We refer readers to the CY 2024 OPPS/ASC final rule with comment period (88 FR 81961 through 82012) for the previously estimated effects of changes to the Hospital OQR Program for the CY 2026 payment determination and subsequent years. Of the 3,062 hospital outpatient departments (HOPDs) that met eligibility requirements for the CY 2024 payment determination for the Hospital OQR Program, we determined that 109 HOPDs did not meet the program requirements to receive the full annual Outpatient Department (OPD) fee schedule increase factor while an additional 58 HOPDs elected not to participate. In the CY 2025 OPPS/ASC proposed rule, we erroneously stated that 117 HOPDs did not meet the program requirements to receive the full annual OPD fee schedule increase factor (89 FR 59553); we are correcting the number to 109 HOPDs in this final rule.

b. Impact of CY 2025 OPPS/ASC Final Rule Policies

In this final rule with comment period, we are adopting four measures: (1) the Hospital Commitment to Health Equity (HCHE) measure, beginning with the CY 2025 reporting period/CY 2027 payment determination; (2) the Screening for Social Drivers of Health (SDOH) measure, beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; (3) the Screen Positive Rate for SDOH measure, beginning with voluntary reporting for the CY 2025 reporting period and mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; and (4) the Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance Measure (Information Transfer PRO–PM), beginning with voluntary reporting for the CY 2026 reporting period and mandatory reporting beginning with the CY 2027 reporting period/CY 2029 payment determination.

In addition, we are removing two claims-based measures beginning with the CY 2025 reporting period/CY 2027 payment determination: (1) the MRI Lumbar Spine for Low Back Pain measure; and (2) the Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery measure.

We are further requiring electronic health record (EHR) technology to be certified to all electronic clinical quality measures (eCQMs) in the Hospital OQR Program measure set and available to report for the CY 2025 reporting period/CY 2027 payment determination and subsequent years.

We are modifying the public reporting of data for the Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients (Median Time for Discharged ED Patients)—Psychiatric/Mental Health Patients stratification so that it may be published on Care Compare in addition to the *data.cms.gov* downloadable files beginning in CY 2025.

Lastly, we are finalizing our proposal regarding our immediate measure suspension policy in the Hospital OQR Program such that in cases where we determine there is evidence that the collection and reporting of a measure raises potential patient safety concerns, we would suspend the measure from the program (as applicable) until potential removal can be proposed through the rulemaking process. This policy will not result in any additional burden or costs for hospitals as its impact would only be to reduce the number of measures hospitals are required to report, if necessary.

We refer readers to section XXVI.B (Collection of Information) of this final rule with comment period for a detailed discussion of the calculations estimating the changes to the information collection and reporting burden for finalized data requirements under the Hospital OQR Program for the estimated 3,200 program-eligible HOPDs. A summary table (see Table 180) shows an estimated total information collection and reporting burden increase of 18,342,190 hours at a cost of $449,266,093 annually associated with our policies for the CY 2027 reporting period/CY 2029 payment determination and subsequent years compared to our currently approved information collection burden estimates.

In section XIV.B.1 of this final rule with comment period, we are adopting the HCHE measure. For HOPDs For HOPDs to receive a point for each of the domains in the measure, affirmative attestations are required for each of the elements within a domain. To attest affirmatively to all the domains in the measure, HOPDs may incur costs associated with activities such as updating facility policies, engaging senior leadership, participating in new quality improvement activities, performing additional data analysis, and training staff. The extent of these costs will vary depending on what activities the HOPD is already performing, HOPD size, and the choices each HOPD makes in order to meet the criteria necessary to attest affirmatively.

In section XIV.B.2 of this final rule with comment period, we are adopting the Screening for SDOH measure. HOPDs that are not currently administering some screening mechanism and elect to begin doing so as a result of this measure adoption will

likely incur some non-recurring costs associated with changes in workflow and information systems to collect the data. The extent of these costs is difficult to quantify as different HOPDs may utilize different modes of data collection (for example, paper-based, electronically patient-directed, clinician-facilitated, etc.). In addition, depending on the method of data collection utilized, the time required to complete the screening may add a negligible amount of time to patient visits.

In section XIV.B.3 of this final rule with comment period, we are adopting the Screen Positive Rate for SDOH measure, which will not result in any additional economic impacts beyond those discussed for the associated Screening for SDOH measure or in section XXVI.B (Collection of Information) of this final rule with comment period.

In section XV.C.1.b of this final rule with comment period, we are adopting the Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance Measure (Information Transfer PRO–PM). For HOPDs that are not currently collecting these data and elect to begin doing so as a result of this measure there will be some costs associated with changes in workflow and information systems to collect the data. The extent of these costs is difficult to quantify as HOPDs may utilize different modes of data collection (collected by facilities or authorized third-party vendors post-discharge through a web-based survey instrument, distributed electronically) and have differing response rates influencing data volume. While we assume the majority of hospitals will report data for this measure directly to CMS, we assume some hospitals may elect to submit measure data via a third-party survey vendor, for which there are associated costs. Under OMB control number 0938–1240 for the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey (expiration date November 30, 2026), an estimate of approximately $4,000 per hospital is used to account for these costs.

In section XV.E.2.b of this final rule with comment period, we are requiring EHR technology to be certified to all eCQMs available to report. We do not expect HOPDs will experience an increase in information collection burden for the Hospital OQR Program as discussed in section XXVI.B (Collection of Information) of this final rule with comment period, because this policy does not require HOPDs to submit new data to CMS and the use of EHR technology that is certified to all available eCQMs is already required for the Medicare Promoting Interoperability Program (83 FR 41672) and the Hospital Inpatient Quality Reporting (IQR) Program (84 FR 42604). In addition, due to the differences in the build of respective CEHRT deployed in HOPDs, the mapping required to capture required data for measure calculation, and the range of HOPD participation in the development, implementation, and testing of new CEHRT functionality, an estimated cost impact of the policy is not quantifiable as it will vary by CEHRT and HOPD. For certifying a new eCQM in the measure set specifically, we expect some costs for HOPDs so that the eCQM is available for HOPDs to report.

In section XV.F.2 of this final rule with comment period, we are finalizing to publicly report data for the Median Time for Discharged ED Patients—Psychiatric/Mental Health Patients stratification on Care Compare, which will not result in any additional economic impacts because we are not requiring HOPDs to collect or submit any additional data for purposes of this public reporting.

4. Effects of Changes in Requirements for the Rural Emergency Hospital Quality Reporting (REHQR) Program

a. Background

We refer readers to the CY 2024 OPPS/ASC final rule with comment period (88 FR 82149) for the previously estimated effects of changes to the REHQR Program for the CY 2024 reporting period and subsequent years. For the CY 2025 reporting period, we have estimated there will be 33 REHs required to report under the REHQR Program based on hospital conversions as of September 27, 2024. We use this number of REHs for our impact analyses knowing that more jurisdictions will pass or amend necessary legislation enabling transitions, acknowledging that the number of conversions could be less than or significantly greater than this estimate with time.

b. Impact of CY 2025 OPPS/ASC Final Rule Policies

In this final rule with comment period, we are adopting three measures: (1) the Hospital Commitment to Health Equity (HCHE) measure beginning with the CY 2025 reporting period; (2) the Screening for Social Drivers of Health (SDOH) measure beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period; and (3) the Screen Positive Rate for SDOH measure beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period. We are also extending the reporting period for the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery measure beginning with the CY 2025 reporting period.

We refer readers to section XXVI.C (Collection of Information) of this final rule with comment period for a detailed discussion of the calculations estimating the changes to the information collection and reporting burden for finalized data requirements under the REHQR Program for the estimated 33 REHs. A summary table (see Table 182) demonstrates an estimated total information collection and reporting burden for 33 REHs of 12,996 hours at a cost of $318,827 annually associated with our policies for the CY 2026 reporting period/CY 2028 program determination and subsequent years.

In section XIV.B.1 of this final rule with comment period, we are adopting the HCHE measure. For REHs to receive a point for each of the domains in the measure, affirmative attestations are required for each of the statements within a domain. To attest affirmatively to all of the domains in the measure, REHs may incur costs associated with activities such as updating facility policies, engaging senior leadership, participating in new quality improvement activities, performing additional data analysis, and training staff. The extent of these costs will vary depending on what activities the REH is already performing, and the individual choices each REH makes in order to meet the criteria necessary to attest affirmatively.

In section XIV.B.2 of this final rule with comment period, we are adopting the Screening for SDOH measure. REHs that are not currently administering some screening mechanism and elect to begin doing so as a result of this measure adoption will likely incur some costs associated with changes in workflow and information systems to collect the data. The extent of these costs is difficult to quantify as different REHs may utilize different modes of data collection (for example paper-based, electronically patient-directed, clinician-facilitated, etc.). In addition, depending on the method of data collection utilized, the time required to complete the screening may add a negligible amount of time to patient visits.

In section XIV.B.3 of this final rule with comment period, we are adopting the Screen Positive Rate for SDOH measure, which will not result in any additional economic impacts beyond those discussed for the associated Screening for SDOH measure or in section XXVI.C (Collection of Information) of this final rule with comment period.

In section XVI.C.2 of this final rule with comment period, we are extending the reporting period for the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery measure from one to 2 years and establishing when an REH will be required to begin submitting data under the REHQR Program after converting to REH status, which will not result in any additional economic impacts because we are not requiring REHs to collect or submit any additional data.

5. Effects of Changes in Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

a. Background

We refer readers to the CY 2024 OPPS/ASC final rule with comment period (88 FR 82143) for the previously estimated effects of changes to the ASCQR Program for the CY 2027 payment determination. In section XVII of this final rule with comment period, we discuss our proposals affecting the ASCQR Program. Based on the most recent analysis of the CY 2024 payment determination data, we found that, of the 5,536 ambulatory surgical centers (ASCs) that were actively billing Medicare, 4,196 were required to participate in the ASCQR Program. Of the 1,340 ASCs not required to participate in the program, 279 ASCs did so and met full requirements. On this basis, we estimate that 4,475 ASCs (4,196 + 279) will submit data for the ASCQR Program for the CY 2025 reporting period unless otherwise noted. We note that this estimate is a decrease of 334 ASCs from our estimate of 4,809 provided in the CY 2024 OPPS/ASC final rule with comment period (88 FR 82143) due to results from more recent data analysis regarding numbers of eligible ASCs.

b. Impact of CY 2025 OPPS/ASC Final Rule Policies

In section XIV.B of this final rule with comment period, we are adopting three measures: (1) the Facility Commitment to Health Equity (FCHE) measure beginning with the CY 2025 reporting period/CY 2027 payment determination; (2) the Screening for Social Drivers of Health (SDOH) measure beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; and (3) the Screen Positive Rate for SDOH measure beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination.

In addition, we are finalizing our proposal regarding our immediate measure suspension policy in the Hospital OQR Program such that in cases where we determine there is evidence that the collection and reporting of a measure raises potential patient safety concerns, we would suspend the measure from the program (as applicable) until potential removal can be proposed through the rulemaking process. This policy will not result in any additional burden or costs for hospitals as its impact would only be to reduce the number of measures hospitals are required to report, if necessary.

We refer readers to section XXVI.D (Collection of Information) of this final rule with comment period for a detailed discussion of the calculations estimating the changes to the information collection and reporting burden for finalized data requirements under the ASCQR Program for the estimated 4,475 program-eligible ASCs. A summary table (see Table 184) demonstrates an estimated total information collection and reporting burden increase for 4,475 ASCs of 712,971 hours at a cost of $17,529,790 annually associated with our policies for the CY 2026 reporting period/CY 2028 payment determination and subsequent years, compared to our currently approved information collection burden estimates.

In section XIV.B.1 of this final rule with comment period, we are adopting the FCHE measure. For ASCs to receive a point for each of the domains in the measure, affirmative attestations are required for each of the statements within a domain. To attest affirmatively to all of the domains in the measure, ASCs may incur costs associated with activities such as updating facility policies, engaging senior leadership, participating in new quality improvement activities, performing additional data analysis, and training staff. The extent of these costs will vary depending on what activities the ASC is already performing, ASC size, and the individual choices each ASC makes in order to meet the criteria necessary to attest affirmatively.

In section XIV.B.2 of this final rule with comment period, we are adopting the Screening for SDOH measure. ASCs that are not currently administering some screening mechanism and elect to begin doing so as a result of this measure adoption will likely incur some non-recurring costs associated with changes in workflow and information systems to collect the data. The extent of these costs is difficult to quantify as different ASCs may utilize different modes of data collection (for example paper-based, electronically patient-directed, clinician-facilitated, etc.). In addition, depending on the method of data collection utilized, the time required to complete the screening may add a negligible amount of time to patient visits.

In section XIV.B.3 of this final rule with comment period, we are adopting the Screen Positive Rate for SDOH measure, which will not result in any additional economic impacts beyond those discussed for the associated Screening for SDOH measure or in section XXVI.D (Collection of Information) of this final rule.

6. Effects of Changes in Requirements for the Hospital Inpatient Quality Reporting (IQR) Program

In section XXII of this final rule with comment period, we are finalizing that for the FY 2026 and FY 2027 payment determinations, the submission of core clinical data elements and linking variables associated with the Hybrid Hospital-Wide Readmission (HWR) measure and the Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (HWM) measure will remain voluntary. This policy would not result in any economic impacts because we are not modifying either measure.

7. Effects of Changes for Individuals Currently or Formerly in the Custody of Penal Authorities

a. Medicare FFS No Legal Obligation To Pay Payment Exclusion and Incarceration (Revisions to 42 CFR 411.4)

The individuals currently or formerly in the custody of penal authorities provisions are discussed in section XXIII of this final rule with comment period. Section XXIII of this final rule with comment period describes the ''no legal obligation to pay'' payment exclusion codified in regulation at § 411.4. Specifically, we are narrowing the description of custody in § 411.4(b) and removing ''under arrest'' from the definition of ''custody'' because we no longer believe that certain classes of individuals should be presumed to be in custody for purposes of the no legal obligation to pay payment exclusion,

and we are including in regulation an illustrative list of individuals who are not considered to be in ''custody.'' We are also reorganizing and renumbering the regulation at § 411.4(b), making certain non-substantive edits to § 411.4(a) to align the regulatory text with the statutory no legal obligation to pay payment exclusion, and defining ''penal authority.''

We expect that narrowing the description of ''custody'' will reduce burden for individuals on bail, parole, probation, home detention or who are required to reside in halfway houses and those providers and suppliers that treat them, because it will no longer be necessary to rebut the presumption that such individuals do not have a legal obligation to pay for their own healthcare in order for Medicare to pay for their health care items or services. These revised policies will ensure that Medicare properly pays for services for individuals who are on bail, parole, probation, home detention or who are required to reside in halfway houses. We believe that these policies will have a negligible impact on Medicare costs, as they do not add new covered services or benefits; rather, the revisions merely remove a real or perceived barrier so that individuals on bail, parole, probation, home detention or who are required to reside in halfway houses can more easily access the Medicare benefits for which they are legally entitled. We received no comments on the financial impact of our proposals.

b. Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals

We proposed to revise the eligibility criteria for the Medicare special enrollment period (SEP) for formerly incarcerated individuals at §§ 406.27(d)(1) and 407.23(d)(1). Specifically, for releases on and after January 1, 2025, we proposed to base the determination of when an individual is no longer incarcerated on SSA's data collected in its systems for determining OASDI benefit suspensions in section 202(x)(1)(A) of the Act and any additional documentation provided by individuals to demonstrate that they have been released from incarceration. Our proposal would limit the current eligibility criteria for this SEP, which reference to the Medicare payment exclusion at § 411.4(b), to releases between January 1, 2023, and December 31, 2024.

The SEP for formerly incarcerated individuals at §§ 406.27(d)(1) (for Premium Part A) and 407.23(d)(1) (for Part B) starting in 2023 provides eligible individuals an opportunity to enroll in Medicare upon release from incarceration without waiting for the General Enrollment Period (GEP) and facing penalties for delayed enrollment. We anticipated that the proposed revisions to the SEP for formerly incarcerated individuals would provide clarity and make accessing this SEP easier upon release from incarceration, especially for a population facing many challenges reintegrating into society. However, we did not anticipate a significant impact on utilization of the SEP since there is no evidence that the current requirements have created barriers to those who want to use the SEP. As a result of this assumption, we expected a negligible impact on Medicare costs. We did not receive any comments related to this assumption.

8. Estimated Effects of Medicaid Clinic Services Four Walls Exceptions

a. Background

As discussed in more detail in section XVIII of this final rule, we are finalizing our proposal to add exceptions to the four walls requirement under the Medicaid clinic services benefit for IHS/Tribal clinics, behavioral health clinics, and clinics located in rural areas. The exception for IHS/Tribal clinics will be mandatory for States that cover the clinic services benefit while the exceptions for behavioral health clinics and clinics located in rural areas will be at State option. We believe that these additional exceptions to the four walls requirement will help States strengthen and improve access to Medicaid clinic services for the populations served by IHS/Tribal clinics, behavioral health clinics, and clinics located in rural areas, and that they are responsive to the concerns we have heard from Tribes, the TTAG, the STAC, States, and other interested parties. In addition, we believe this final rule will advance health equity and improve health care access for the populations served by IHS/Tribal clinics, behavioral health clinics, and clinics located in rural areas.

b. Overall Estimated Effects of Medicaid Clinic Services Four Walls Exceptions

The aggregate economic impact of this final rule is estimated to be $1.18 billion in transfers for fiscal years 2025–2029. This includes a Federal impact of $1.15 billion and impacts to States of $30 million. For the purposes of this analysis, we estimated the impacts separately for Medicaid clinic services furnished outside of the four walls for IHS/Tribal clinics, behavioral health clinics, and clinics located in rural areas. Uncertainties in the estimate result in an estimated range of $554 million to $1.82 billion in the Federal impact and a range of $7 million to $95 million in the State impact.

Current Medicaid clinic services expenditures were estimated using financial reporting for 2022. Estimated expenditures for IHS/Tribal Medicaid clinic services represent those expenditures not attributable to the following Medicaid services: inpatient hospital, outpatient hospital, prescription drugs, FQHC, and RHCs; in 2022, these expenditures included expenditures for IHS/Tribal Medicaid clinic services provided outside of the four walls (due to the grace period discussed below). We assumed that 15 percent of expenditures for Medicaid clinic services were related to behavioral health based on general behavioral health utilization and spending patterns. We assumed that 17 percent of remaining Medicaid clinic services expenditures were attributable to clinics in rural areas based on 17 percent of the Medicaid population residing in rural areas. Estimated baseline Federal Medicaid expenditures for Medicaid clinic services in 2025 are $934 million at IHS/Tribal clinics, $530 million for behavioral health services provided at Medicaid clinics, and $495 million for Medicaid clinic services provided in rural areas. The estimates for behavioral health services provided at Medicaid clinics and Medicaid clinic services provided in rural areas do not include Medicaid clinic services expenditures from IHS/Tribal clinics.

It is important to note that IHS/Tribal clinic services provided outside of the clinic's four walls are currently being paid for by Medicaid programs, under a CMS ''grace period'' that currently extends through February 11, 2025. For a more detailed discussion on this grace period please see section XVIII.A of this final rule. With the finalization of the exception for IHS/Tribal clinics in this final rule, States will be permitted to pay for Medicaid clinic services provided outside of the four walls of an IHS/Tribal clinic after February 11, 2025, when the grace period ends.

Table 208 demonstrates our estimates for the economic impact of an exception to the Medicaid clinic services four walls requirement for IHS/Tribal clinics. For the IHS/Tribal clinic exception at 42 CFR 440.90(c), we assumed that 19 percent of current total IHS/Tribal clinic services expenditures were for services provided outside of clinics, based on information provided by the Tribes. Allowing current claiming practices to continue, trended for changes in expected cost, utilization, and enrollment each year, we estimate that

Federal expenditures for services provided outside of clinics will be $1.09 billion for fiscal years 2025 through 2029. State expenditures on Medicaid clinic services provided to AI/AN Medicaid beneficiaries by IHS/Tribal clinics are Federally matched at 100 percent. State expenditures on Medicaid clinic services provided to Medicaid beneficiaries who are not AI/AN are matched at the otherwise applicable Federal matching percentage, which is generally less than 100 percent. The estimate assumes 100 percent Federal share for all IHS/Tribal clinic services expenditures, but we acknowledge that a very small portion of these IHS/Tribal clinic services expenditures may be attributed to Medicaid beneficiaries who are not AI/AN, resulting in some State expenditures. Data from which to estimate these State expenditures were unavailable for this analysis. We note that this impact estimate only reflects or accounts for the grace period through February 11, 2025; the baseline for the impact estimate does not reflect or account for the grace period for dates after the expiration of the grace period. From February 12, 2025, forward, the estimate compares projections under current law, which does not allow States to pay for Medicaid clinic services provided outside of clinics against projections under the final rule, which would permit States to pay for IHS/Tribal clinic services provided outside of clinics. When the grace period is factored into the analysis for dates after the expiration of the grace period and spending under the final rule is compared to expenditures under current practice, which allows payment for clinic services provided outside of IHS/Tribal clinics due to the grace period, we estimate little to no impact.

TABLE 208: IHS/TRIBAL CLINIC EXCEPTION FEDERAL SHARE IMPACT FOR 5 YEARS

	2025 (in millions)	2026 (in millions)	2027 (in millions)	2028 (in millions)	2029 (in millions)	5-year total (in millions)
High Estimate	$329	$328	$326	$325	$323	$1,631
Best Estimate	$219	$218	$217	$216	$216	$1,086
Low Estimate	$110	$109	$109	$108	$108	$544

Tables 209 and 210 demonstrate our estimates for the economic impact of exceptions to the four walls requirement under the Medicaid clinic services benefit for behavioral health clinics and clinics located in rural areas that are not IHS/Tribal clinics. We acknowledge that we included in the final rule text that a State adopting the exception for clinics located in rural areas must include a definition of rural area in its State plan that must be either a definition adopted and used by a Federal governmental agency for programmatic purposes, or a definition adopted by a State governmental agency with a role in setting State rural health policy. For purposes of our estimates of the economic impact of our exception to the four walls requirement for clinics located in rural areas, our analysis defines rural areas using the RUCA classifications. We also acknowledge that our exception to the four walls requirement for behavioral health clinics includes any clinic services furnished outside of the four walls by a behavioral health clinic, including non-behavioral clinic services such as physical health services. However, for purposes of our economic impact we are unable to quantify the cost of non-behavioral clinic services. For our behavioral health clinic exception at 42 CFR 440.90(d) and clinics located in rural areas exception at 42 CFR 440.90(e), we assumed a 5 percent increase in current spending in each category due to increased payments for clinic services performed outside of the four walls. Growth in utilization and expenditures for clinic services provided both by behavioral health clinics and clinics in rural areas is expected to be limited by provider shortages in these areas of practice. Because the exceptions at 42 CFR 440.90(d) and (e) are at State option, we assume that States representing 25 percent of States providing coverage of the Medicaid clinic services benefit will implement one or both of the optional exceptions. Estimated expenditures are trended each year for changes in expected cost, utilization, and enrollment. We estimate that Federal expenditures will be $35 million for fiscal years 2025 through 2029 for clinic services furnished by behavioral health clinics, and $30 million for fiscal years 2025 through 2029 for clinic services furnished by clinics in rural areas.

TABLE 209: BEHAVIORAL HEALTH CLINIC EXCEPTION IMPACT FOR 5 YEARS

	2025 (in millions)	2026 (in millions)	2027 (in millions)	2028 (in millions)	2029 (in millions)	5-year total (in millions)
Federal Share Impacts						
High Estimate	$18	$18	$18	$18	$18	$90
Best Estimate	$7	$7	$7	$7	$7	$35
Low Estimate	$1	$1	$1	$1	$1	$5
State Share Impacts						
High Estimate	$9	$9	$9	$9	$9	$45
Best Estimate	$3	$3	$3	$3	$3	$15
Low Estimate	$1	$1	$1	$1	$1	$5

TABLE 210: CLINIC LOCATED IN RURAL AREAS EXCEPTION IMPACT FOR 5 YEARS

Clinic located in rural areas exception (dollars in millions)	2025 (in million)	2026 (in millions)	2027 (in millions)	2028 (in millions)	2029 (in millions)	5-year total
Federal Share Impacts						
High Estimate	$20	$20	$20	$20	$20	$100
Best Estimate	$6	$6	$6	$6	$6	$30
Low Estimate	$1	$1	$1	$1	$1	$5
State Share Impacts						
High Estimate	$10	$10	$10	$10	$10	$50
Best Estimate	$3	$3	$3	$3	$3	$15
Low Estimate	$1	$1	$0	$0	$0	$2

Projected Medicaid clinic services expenditures may differ from our current estimates, including the amounts broken out for IHS/Tribal clinics, clinic services provided by behavioral health clinics, and clinic services provided by clinics in rural areas. There is uncertainty in how much current and projected IHS/Tribal Medicaid clinic services spending is attributable to Medicaid clinic services provided outside of the four walls. The IHS/Tribal clinic impact may range from $544 million to $1.63 billion over 5 years due to uncertainty in the level of spending for Medicaid clinic services provided outside of IHS/Tribal clinics. Uncertainty in provider availability and beneficiary demand result in uncertainty in the potential for changes in utilization and costs. The Federal impact for Medicaid clinic services furnished by behavioral health clinics may range from $5 million to $90 million and the Federal impact for clinic services furnished by clinics in rural areas may range from $5 million to $100 million over 5 years. State impacts over 5 years may range from $5 million to $45 million for clinic services furnished by behavioral health clinics and $2 million to $50 million for clinic services furnished by clinics in rural areas.

Table 211 demonstrates the total economic impact for our finalized exceptions to the four walls requirement under the Medicaid clinic services benefit for IHS/Tribal clinics, behavioral health clinics, and clinics located in rural areas. The total estimated impact of these exceptions over 5 years is $1.18 billion, including Federal impact of $1.15 billion and State impact of $30 million. The impact may range from a low of $561 million to a high of $1.92 billion, including a range in the Federal estimate of $554 million to $1.82 billion and a range in the State impact of $7 million to $95 million.

TABLE 211: TOTAL IMPACT ESTIMATES FOR FIVE YEARS

	Federal Share Impact (in millions)	State Share Impact (in millions)	Total Impact (in millions)
IHS/Tribal clinic exception	$1,086	$0	$1,086
Behavioral health clinic exception	$35	$15	$50
Clinics located in rural areas exception	$30	$15	$45
All clinic services exceptions	$1,151	$30	$1,181

c. Benefits of Medicaid Clinic Services Four Walls Exceptions

The changes to the Medicaid clinic services benefit are expected to benefit Medicaid beneficiaries, Tribes, and States by improving access to care for the populations served by IHS/Tribal clinics, behavioral health clinics, and clinics in rural areas. The exceptions to the four walls requirement under the Medicaid clinic services benefit for IHS/Tribal clinics, behavioral health clinics, and clinics located in rural areas would help improve access to care for these clinics' patient populations by allowing services to be furnished where the beneficiary is located. We refer readers to section XVIII.B of this final rule for more robust discussions on how the populations served by these clinics might benefit from exceptions to the Medicaid clinic services benefit four walls requirement and how these exceptions would improve access to care. These potential benefits cannot be monetarily quantified at this time.

d. Alternative Medicaid Clinic Services Four Walls Exceptions Considered

We considered a few different alternatives in determining the best way to address the concerns we heard from Tribes, the TTAG, the STAC, States, and other interested parties about the four walls requirement under the Medicaid clinic services benefit. We considered including an exception to the four walls requirement only for the population served by IHS/Tribal clinics, but we viewed that alternative as too limited. As we discuss in detail in section XVIII.B of this final rule, we concluded that the patient populations served by behavioral health clinics and clinics in rural areas might also benefit from exceptions to the four walls requirement for those clinics.

We also considered proposing an exception, in addition to the three exceptions we are finalizing in this rule, for any other populations that are identified by States as likely to meet the four criteria described in this final rule that warrant an exception to the four walls requirement and that have no alternative access to services through Medicaid benefits that are not subject to a four walls requirement under Federal Medicaid law. Ultimately, it is our understanding that other populations are better able to access services through Medicaid benefits to which a four walls requirement does not apply under Federal Medicaid law (for example, FQHC services, RHC services, outpatient hospital services, etc.) than the populations targeted by the exceptions we are finalizing. As we indicate in section XVIII.B of this final rule, we invited comment in the proposed rule on our assumptions about other populations that may benefit from an exception to the four walls requirement under the Medicaid clinic services benefit. We are finalizing this rule without including exceptions to the four walls requirement for additional populations (beyond the exceptions for IHS/Tribal clinics, behavioral health clinics, and clinics located in rural areas), and a summary of the comments received that recommend additional exceptions and our response can be found in section XVIII.B of this final rule.

We also considered making the exceptions to the four walls requirement mandatory for behavioral health clinics and clinics located in rural areas, but, as we discuss in more detail in section XVIII.B of this final rule, it is our understanding that there is greater State variability in the degree to which the populations targeted by the behavioral health and rural exceptions meet the four criteria we identified than there is for the population served by IHS/Tribal clinics. We also invited public comment on these assumptions in section XVIII.B of the CY 2025 OPPS/ASC proposed rule. We are finalizing that the exceptions to the four walls requirement for behavioral health clinics and clinics located in rural areas are at state option, and a summary of the comments received on this topic and our response can be found in section XVIII.B of this final rule.

Finally, as we discuss in section XVIII.B of this final rule, we did not propose a specific definition of rural for our exception for clinics located in rural areas and in the proposed rule invited public comment on the alternative possible definitions we considered and described in that section of the proposed rule. The final rule provides that a State must include a definition of rural area in its State plan that must be either a definition adopted and used by a Federal governmental agency for programmatic purposes, or a definition adopted by a State governmental agency with a role in setting State rural health policy. A summary of the comments received on the options we considered for defining rural for clinics located in rural areas and our response can be found in section XVIII.B of this final rule.

9. Effects of Continuous Eligibility in Medicaid and CHIP

As discussed in section XX of this final rule with comment period, we are finalizing our proposal to codify the requirement of the CAA, 2023 for States to provide 12 months of continuous eligibility for children under age 19 enrolled in Medicaid and CHIP, with limited exceptions. In addition, we are finalizing our proposal to remove the option to disenroll children from CHIP during a continuous eligibility period due to failure to pay premiums. These regulation changes implement the statutory requirement in section 5112 of Title V, subtitle B of the Consolidated Appropriations Act, 2023, and the entirety of the economic impact

discussed in this section below follows from this statutory provision.

The requirement to provide 12-months of continuous eligibility in Medicaid and CHIP is estimated to increase annual average enrollment in Medicaid and CHIP by approximately 124,000 by 2028 (75,000 in Medicaid and 49,000 in CHIP). The total estimated impact of this requirement over 5 years is $2,466 million, including Federal impact of $1,592 million and State impact of $874 million. Enrollment may range from an increase of around 92,000 to an increase of around 159,000 by 2028. The total impact may range from a low of $1,837 million to a high of $3,154 million, including a range in the Federal estimate of $1,185 million to $2,039 million and a range in the State impact of $652 million to $1,115 million. (See Tables 212 and 213.)

TABLE 212: IMPACT OF 12-MONTH CONTINUOUS ELIGIBILITY IN MEDICAID AND CHIP

(dollars in millions)	2024	2025	2026	2027	2028	5-year total
Federal Share Impacts						
Best Estimate	$250	$326	$332	$339	$345	$1,592
Low Estimate	$186	$243	$248	$252	$256	$1,185
High Estimate	$319	$419	$426	$434	$441	$2,039
State Share Impacts						
Best Estimate	$148	$177	$180	$183	$186	$874
Low Estimate	$111	$132	$134	$137	$138	$652
High Estimate	$189	$225	$230	$234	$237	$1,115

TABLE 213: ACCOUNTING STATEMENT FOR 12-MONTH CONTINUOUS ELIGIBILITY IN MEDICAID AND CHIP

Transfers						
Annual monetized transfers	Primary estimate (in millions of dollars)	Low estimate (in millions of dollars)	High estimate (in millions of dollars)	Units		
				Year dollars	Discount rate (percent)	Period covered
From Federal Government to States….	317.8	236.4	407	2025	2	2024-2028
From States to Health Care Providers…	174.8	130.3	222.7	2025	2	2024-2028

10. Effects of Requirements for Obstetrical Services in Hospitals and Critical Access Hospitals (CAHs)

In response to the CY 2025 OPPS/ASC proposed rule, we received multiple comments regarding the cost estimates for the proposed requirements for obstetrical services in hospitals and critical access hospitals (CAHs). Most of the comments were from professional organizations, State agencies, and hospital systems. In this final rule with comment period, we provide a summary of the public comments received for each proposal and our responses to them, including relevant changes in the RIA methodology and estimate.

Comment: A few commenters said that CMS should consider the disproportionate financial impact that the requirements will have on some provider types, particularly hospitals and CAHs that are most at risk of closing their obstetrical services units, which could lead to increased burden on other hospitals and result in patients having to travel greater distances to access maternal care.

Response: We appreciate the suggestions to consider differences across providers. The proposed rule assessed likely variation in burden across different providers, taking into account variation in facility size, the number of patients, and staff size that we believe accurately reflects the likely burden for each facility type. In this final rule with comment period, we have also taken several steps to reduce burden and ensure that all hospitals and CAHs are able to successfully meet the requirements. First, we are implementing the requirements in three phases over the course of two years to ensure that facilities have adequate time to meet these requirements and to reduce any potential implementation

burden or unintended consequences (see section XXI.A.7 of this final rule with comment period). Second, we are reducing the frequency of the obstetrical services training requirement from annually to biannually (every other year). Finally, as we outline below, we are not finalizing the requirement that hospitals and CAHs with obstetrical services delineate and document obstetrical privileges for all practitioners.

a. Organization, Staffing and Delivery of Services for Hospitals (§ 482.59(a) Through (b)) and CAHs (§ 482.649(a) Through (b))

As indicated in section XXI.C.2 of this final rule with comment period, we are finalizing the policies for hospitals (§ 482.59(a) through (b)) and CAHs (§ 485.649(a) through (b)) that provide obstetrical (OB) services as proposed with the modification to reference the requirements of the medical staff bylaws for hospitals and CAHs rather than requiring hospitals and CAHs with OB services to delineate and document obstetrical privileges for all practitioners. In addition, we are clarifying that basic equipment must be kept at the hospital and CAH and be readily available for treating obstetrical cases to meet the needs of patients. Below, we provide the comments we received on the proposed requirements as well as our modifications to the final cost estimate based on these comments and the final policies.

Comment: Some commenters said that the proposed rule underestimated the obstetrical services' equipment costs since it did not consider the cost for maintaining and replacing required equipment. Other commenters said that the requirement for hospitals and CAHs with OB services to have cardiac monitors and call-in systems will result in a higher cost than estimated since specialized training is needed for nurses to correctly monitor cardiac monitors and facilities will also need to purchase central monitoring stations. Some commenters said that the requirement for each room/suite to have a call-in system, cardiac monitor, and a fetal doppler or monitor was too burdensome and would result in equipment going unused. Given this issue, they asked for flexibility to have the equipment available on the unit. Other commenters questioned the decision to mandate specific equipment for OB services, noting that evolving practice guidelines may lead necessary equipment to change and requiring specific equipment could prevent the adoption of new technology.

Response: We agree that replacing equipment will add additional burden for facilities. Based on our experience, we estimate that the required equipment will need to be replaced once every 5 years. As a result, in the regulatory impact analysis below, we include additional burden in year 6 for hospitals and CAHs with OB services to replace cardiac monitors, fetal monitor or dopplers, and call-in systems. As we noted in our comment response in section XXI.C.2 of this final rule with comment period, several commenters asked for clarity regarding the expected availability of basic equipment, noting that it would be costly to purchase equipment for every room/suite. In that section and in the regulation text, we have clarified that required equipment includes a call-in-system (we note that for the purposes of this regulation, call-in system describes a call button), cardiac monitor, and fetal doppler or monitor kept at the hospital and CAH and readily available for treating obstetrical cases to meet the needs of patients in accordance with the scope, volume, and complexity of services offered. Further, facilities must have adequate provisions that include equipment, supplies and medication used in treating emergency cases. We would note that while facilities may choose to purchase central monitoring equipment, they are not required to do so. In addition, as we have clarified in this final rule with comment period, we are requiring equipment to be readily available for treating obstetrical cases in accordance with the scope, volume, and complexity of services offered but are not requiring facilities to have equipment in every room/suite in the OB unit. We expect that hospitals and CAHs already have staff members in the facility who are able to correctly monitor the equipment and that if that expertise was not available in the OB unit or if facilities have special areas for patients utilizing cardiac monitors, patients would be moved to areas where staff already have that knowledge. As such, we are not including burden for training staff members to monitor equipment and purchasing central monitoring systems. Rather than maintaining our assumption in the proposed rule that facilities will have equipment for twice the average number of daily patients per facility, we have modified the estimated cost based on commenters indicating that facilities were concerned that they would have a lot of unused equipment. In our final estimates, we now assume that with an average daily birth volume of 2.04 per facility, facilities will ensure that they will have supplies for four patients. Finally, we disagree that requiring equipment will prevent hospitals and CAHs from adopting new technology designed to improve maternal care. The equipment we are requiring is basic equipment to ensure the health and safety of pregnant and postpartum patients. We expect that hospitals and CAHs that are planning on investing in new technology to advance maternal healthcare would likely ensure that basic equipment is available first even without our requirements.

Comment: A few commenters said that the CY 2025 OPPS/ASC proposed rule did not consider the cost for attracting and retaining qualified medical personnel.

Response: We disagree with the comment that we did not consider the cost for attracting qualified medical personnel. In Table 144 of the CY 2025 OPPS/ASC proposed rule, we estimated that hiring a qualified OB supervisor will cost, on average, $54,757 per hospital and CAH. In addition, as we noted in section XXI.C.2, many hospitals and CAHs already have qualified practitioners on staff and would not need to hire additional staff members. The CY 2025 OPPS/ASC proposed rule included no fixed minimum staffing requirements and instead allows facilities with flexibility to provide services that are well-organized and in accordance with nationally recognized acceptable standards of practices.

Based on the finalized policies and the comments received, we are making the following modification below to the estimated costs for these finalized proposals: including additional cost in year 6 to account for equipment replace costs.

In section XXVI of this final rule with comment period, we have estimated the cost for hospitals and CAHs to develop internal standards and protocols to ensure that services are well organized and to provide high-quality care that is appropriate to the level of services provided and integrated with other departments of the facility, as well as to ensure compliance with nationally recognized and evidence-based guidelines for OB emergencies, complications, immediate post-delivery care, and other patient health and safety events. Below, we estimate the cost for ensuring that OB patient care units (*i.e.,* labor rooms, delivery rooms, including rooms for operative delivery, and post-partum/recovery rooms whether combined or separate) are supervised by an individual with the necessary education and training, and specify that person should be an experienced

registered nurse, certified nurse midwife, nurse practitioner, physician assistant, or a doctor of medicine or osteopathy. We also estimate the cost for equipment that includes a call-in-system, cardiac monitor, and fetal doppler or monitor kept at the hospital and CAH and readily available for treating obstetrical cases to meet the needs of patients in accordance with the scope, volume, and complexity of services offered.

While hospitals and CAHs are likely to already have an individual supervising the OB patient care unit, there is variation across facilities regarding whether they have the necessary education and training related to OB patient care. Many facilities, especially larger hospitals that have large birth volumes, are likely to already have an experienced individual with the necessary education and training. Smaller facilities with lower birth volumes, in contrast, may be less likely to have an experienced individual and need to recruit a new individual to meet the proposed requirement.

Given uncertainty about the number of facilities that already have an experienced individual who will meet the requirement, we assume that each facility will need to hire one individual, who we assume will be a registered nurse, to meet the requirement. To estimate the cost of hiring this individual, we reviewed research related to the cost of registered nurse turnover. A review of academic literature found that each RN turnover cost employers between $21,514 and $88,000.[779] We take the midpoint of these two estimates, or $54,757 per individual hired. As shown, in Tables 214 and 215, we estimate that this requirement will cost facilities $268,842,496 in year 1 and over 10 years.

TABLE 214: QUALIFIED OB SUPERVISOR COST

Provider Type	Number of Providers (a)	Staff Members Needed per Provider (b)	Total Staff Members Needed (c = a × b)	Average Cost per Staff Member (d)	Total Annual Cost (e = c × d)	Average Cost per Facility (f = e / b)
CAH	513	1	513	$54,757	$28,090,341	$54,757
Hospital	4,415	1	4,415	$54,757	$241,752,155	$54,757
Total	4,928		4,928		$269,842,496	$54,757

TABLE 215: QUALIFIED OB SUPERVISOR 10 YEAR COST

Year	Total Cost
1	$269,842,496
2	$0
3	$0
4	$0
5	$0
6	$0
7	$0
8	$0
9	$0
10	$0
10 Year Total Cost	$269,842,496

To estimate the cost for having basic equipment, including a call-in-system (we note that for the purposes of this regulation, call-in system describes a call button), cardiac monitor, and fetal doppler or monitor kept at the hospital and CAH and readily available for treating obstetrical cases to meet the needs of patients, we reviewed public data sources to estimate the cost of purchasing a call-in system, cardiac monitor, and a fetal doppler or monitor. While we were not able to identify public estimates for the price of call-in systems, based on our experience we estimate that they will cost $2,500 to $3,500 per system. Reviewing the web pages of various online suppliers, we found that fetal dopplers and fetal monitors cost between $502 and $8,995 [780] [781] and cardiac monitors cost between $1,071 and $10,246.[782] For each of these systems, we use the mid-point of the price estimate and assume that each call-in system will cost $3,000, each fetal monitor or fetal doppler will cost $4,749, and each cardiac monitor will cost $5,659.

According to the Centers for Disease Control and Prevention there were a

[779] Bae, S.H., *Noneconomic and economic impacts of nurse turnover in hospitals: A systematic review.* Int Nurs Rev, 2022. 69(3): 392–404.

[780] Medical, U. *FETAL DOPPLERS.* 2024 May 8, 2024 [cited 2024 May 8]; Available from: *https://www.usamedicalsurgical.com/fetal-dopplers/.*

[781] CardiacDirect. *Fetal Monitors.* 2024 [cited 2024 May 8]; Available from: *https://www.cardiacdirect.com/product-category/fetal-monitors/?utm_source=google&utm_medium=cpc&utm_term=fetal%20heart%20monitor&utm_content=!acq!v3!1163626993_kwd-295102856827__607346518010_g_c__&utm_campaign=FetalMonitor&gad_source=1&gclid=EAIaIQobChMIsLqpo8f-hQMVLyetBh3deAZuEAAYASAAEgIcx_D_BwE.*

[782] CardiacDirect. *Patient Monitors.* 2024 May 8, 2024 [cited 2024 May 8]; Available from: *https://www.cardiacdirect.com/product-category/patient-monitors/?min_price=0&max_price=10250&page=1.*

total of 3,667,758 births in 2022.[783] With a total of 4,928 hospitals and CAHs with obstetrical units, this leads to an average of 744 (3,667,758 ÷ 4,928) births per hospital and CAH or an average of 2.04 births per facility per day. We estimate that each birth will take 1 day on average. To account for variation in birth volumes throughout the year, we assume that each facility will need to prepare for double the number of average births per day, or 4.08 patients. Although equipment cannot be divided, based on the public comments received and discussed above, we assume that cost-conscious facilities will have equipment available for 4 patients daily. We also assume that each facility already has one fetal monitor and cardiac monitor but do not assume that each facility has a call-in system.

Based on our experience working in obstetrical units, we estimate a fetal doppler or monitor and a call-in system will need to be available for each patient, a call-in system will need to be available for each patient, and cardiac monitors will need to be available for half the patients. As such, we estimate that each facility will need to purchase three fetal monitors or fetal dopplers at $14,247 ($4,749 × 3), one cardiac monitor at $5,659 ($5,659 × 1), and four call-in systems at $12,000 ($3,000 × 4) for an average per facility cost of $31,906. As indicate in Table 216 we expect that this requirement will cost $157,232,768 in year 1. We also expect that under normal use, this equipment will need to be replaced in five years. In Table 217, we estimate that this equipment requirement will cost a total of $314,465,536 over 10 years.

TABLE 216: YEAR 1 OBSTETRICAL EQUIPMENT COST

Provider Type	Number of Providers (a)	Average Per Facility Cost (b)	Total Annual Cost (c = a × b)	Average Cost per Facility (d = c / b)
CAH	513	$31,906	$16,367,778	$31,906
Hospital	4,415	$31,906	$140,864,990	$31,906
Total	4,928	$31,906	$157,232,768	$31,906

TABLE 217: OBSTETRICAL EQUIPMENT 10 YEAR COST

Year	Total Cost
1	$157,232,768
2	$0
3	$0
4	$0
5	$0
6	$157,232,768
7	$0
8	$0
9	$0
10	$0
10 Year Total	$314,465,536

b. OB Staff Training for Hospitals (§ 482.59(c)) and CAHs (§ 485.649(c))

As indicated in section XXI.C.3 of this final rule with comment period, we are finalizing the policies for hospitals (§ 482.59(c)) and CAHs (§ 485.649(c)) that provide obstetrical (OB) services with the modification that the effective date of the staff training requirement is January 1, 2027 and that the governing body in hospitals and CAHs must identify and document which staff must complete an initial training and subsequent biannual training. Below, we provide the comments we received on the proposed requirements as well as our modifications to the final cost estimate based on these comments and the policies we are finalizing.

Comment: Several commenters expressed concern about the cost to train relevant OB staff. Other commenters said that the proposed rule underestimated training costs since it did not consider increases in wage and salaries for healthcare personnel. In addition, it did not consider staff turnover and the need to train new staff. One commenter thought that staff training could require more time than we have estimated.

Response: We appreciate the feedback regarding the cost estimates for OB staff training. As noted in section XXI.C.3 of this final rule with comment period, we are modifying the training requirements so that hospitals and CAHs will need to provide relevant OB staff with initial training upon hiring and then every other year, rather than every year. This reduction in training frequency reduces the training costs as outlined below in the regulatory impact analysis. We agree with the feedback regarding the need to

[783] Osterman, M.J.K.H., Brady E., Martin, Joyce A.; Driscoll, Anne K.; Valenzuela, Claudia P., *Births: Final Data for 2022,* in *National Vital Statistics Reports,* U.S.D.o.H.a.H. Services, Editor. 2024, Centers for Disease Control and Prevention.

include wage growth for healthcare staff in the cost estimates. When estimating costs, registered nurses (RNs) are the largest group of staff members who we assume will likely receive training. According to the Bureau of Labor Statistics,[784] RNs in 2015 earned a mean hourly rate of $34.14 with the nominal mean hourly rate in 2023 [785] increasing to $45.42. Inflation,[786] however, accounts for 3.49 percentage points annually over these 8 years, leaving a compound annual real growth rate of approximately 0.44 percent. To address concerns that wage costs are underestimated, we are including a 0.44 annual increase in real wage rates in the cost estimates for the OB services training requirements starting in year 2. To address concern regarding staff turnover, we are including training costs for new staff members based on a 21 percent annual staff turnover rate.

We appreciate the comment regarding the time allocated for staff training. As noted in section XXI.C.3 of this final rule with comment period, hospitals and CAHs have flexibility to identify which evidence-based best practices and protocols they will train on to improve the delivery of maternal care within their facility. We are not prescribing a specific format the training be conducted in, allowing facilities to carry out the training in a manner that best fits their needs. While some facilities could choose training that takes more time than we have estimated, others could choose training that takes less time. As such, we maintain the estimated time burden for training requirements for hospitals and CAHs that offer OB services.

Based on the comments received and the finalized policies, we are making the following modifications to the cost estimates: (1) including a 0.44 percent annual increase in hourly rates for training costs starting in year 2 to take into account growth in wages and salaries for healthcare workers, (2) including additional burden to account for the cost of training new staff members, and (3) reducing the burden based on the modification that the governing body identify and document which staff must complete an initial training and subsequent biannual training rather than annual training.

In section XXVI of this final rule with comment period, we have estimated the cost for developing policies and procedures to ensure that staff are trained on key topics related to improving the delivery of maternal care, as well as documentating that training was completed and staff knowledge on these topics. We estimate that staff training on evidence-based best practices and protocols will take 2 hours per employee and that each facility will spend 1 hour training staff on additional topics identified by the facility's QAPI program. This leads to a total hourly burden of 3 hours per employee trained.

While hospitals and CAHs have flexibility regarding which OB staff will receive training, we expect that they will likely focus their training on medical staff who are working directly with OB patients. This includes surgeons, physicians, physician assistants, nurse practitioners, nurse midwives, nurse anesthetists, registered nurses (RNs), and Licensed Practical Nurses/Licensed Vocational Nurses (LPNs/LVNs).

To estimate the number of employees in CAHs and hospitals that are likely receive training, we first obtained data from the Bureau of Labor Statistics (BLS) on the number of surgeons, physicians, physician assistants, nurse practitioners, nurse midwives, nurse anesthetists, RNs, and LPNs/LVNs working in hospitals (NAICS 622000). Since the BLS does not provide separate employment statistics for CAHs and hospitals, we assume that the number of employees needing training and, henceforth, the cost to train them will be in proportion to the size of facilities, specifically the number of certified beds. We obtained information on the number of certified beds in hospitals and CAHs from CMS' Q1 2024 Provider of Services File—Hospital & Non-Hospital Facilities.[787] Using this database, we estimate that 98.6 percent of certified beds for facilities that provide OB services are in hospitals with the remaining 1.4 percent in CAHs.

In hospitals, which have a larger number of beds, there is likely to be a greater division of staff among units, with medical staff specifically designated to work in OB units and with pregnant patients, while other medical staff members will not work with pregnant patients. In contrast, critical access hospitals (CAHs), which are smaller in size, are likely to have medical staff that work across units. Based on our experience, we estimate that between 10 and 30 percent of medical staff in hospitals and 60 to 100 percent of medical staff in CAHs will receive the training. Given the variation for hospitals and CAHs, we take the midpoint of the two estimates and assume that 20 percent of hospital medical staff and 80 percent of medical staff in CAHs will receive training. As indicated in Table 218, if initial training for all staff who need the training began in year 1, it would cost approximately $151 million and take $1.43 million hours to complete annually. Our finalized requirement, however, is that applicable staff receive initial training and then every 2 years. Since hospitals have an annual turnover rate of approximately 21 percent,[788] we estimate that in addition to training all applicable staff as identified above, the number of staff members that hospitals and CAHs will need to train will increase by 21 percent due to turnover. Since the training requirement goes into effect in year 2, we expect there to be no burden for year 1. In year 2, we expect that facilities will need to train 121 percent of the applicable staff to account for initial training for all existing staff as well as staff turnover. In year 3, training will be needed for 21 percent of existing staff who will leave and be replaced by new staff. In year 4, 21 percent of employees hired in year 3 will leave and their replacements will need training. In addition, 79 percent of the employees who received training 2 years ago will need to receive their biannual training. For all subsequent years, the share of staff who need to receive training will be 21 percent of staff hired in the previous year to account for regular staff turnover and 79 percent of staff who received training 2 years prior.

To calculate the total hourly burden cost over 10 years, we multiply the share of staff that will need training each year by the baseline cost for training all staff members, taking into account an annual 0.44 percent increase in real wage rates. As indicated in Table 219, we estimate the requirements will have an average annual cost of approximately $85 million, with a total cost of $849,937,432 over 10 years. Over 10 years, the requirements are estimated to take $7,875,903 million hours to complete.

[784] U.S. Bureau of Labor Statistics. Occupational Employment and Wages—May 2015. Accessed September 25, 2024. *https://www.bls.gov/news.release/archives/ocwage_03302016.pdf.*

[785] U.S. Bureau of Labor Statistics. Occupational Employment and Wages, May 2023: 29–1141 Registered Nurses. Accessed September 25, 2024. *https://www.bls.gov/oes/current/oes291141.html.*

[786] Federal Reserve Bank of Minneapolis. Inflation Calculator. Accessed February September 25, 2024. *https://www.minneapolisfed.org/about-us/monetary-policy/inflation-calculator.*

[787] Centers for Medicare and Medicaid Services. Provider of Services File—Hospital & Non-Hospital Facilities, Q1 2024. *https://data.cms.gov/provider-characteristics/hospitals-and-other-facilities/provider-of-services-file-hospital-non-hospital-facilities/data* (Accessed April 30, 2024).

[788] Nursing Solutions Incorporated, *2024 NSI National Health Care Retention & RN Staffing Report.* 2024.

This estimate is based on two assumptions. First, we assumed that when a staff member leaves, their replacement will be hired in the same year. If the replacement was not hired until the following year, then the cost would be lower than what we have estimated. Second, we assumed that employees who receive training and then quit 2 years after their training, would not receive their biannual training prior to leaving. If they did, then the actual cost would be higher than what we have estimated.

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TABLE 218: BASELINE OBSTETRICAL SERVICES STAFF TRAINING ANNUAL COST

Provider Type	Number of Providers (a)	Number of Certified Beds (b)	Share of all Hospital and CAH Certified Beds (c)	Total Yearly Cost if All Hospital and CAH Medical Staff were Trained (d)	Total Hospital and CAH Medical Staff (e)	Share of Medical Staff Receiving Training (f)	Total Number of Staff Members (g = c × e)	Total Hourly Annual Cost (h = c × d × f)	Total Hourly Burden (i = f × g × 3)	Average Cost per Staff Member (j = h /(f × g))	Average Cost per Facility (k = h / a)
CAH	513	12,582	0.014	$724,555,386	2,284,580	0.8	31,993	$8,117,290	76,783	$317	$15,823
Hospital	4,415	885,881	0.9860	$724,555,386	2,284,580	0.2	2,252,587	$142,881,755	1,351,552	$317	$32,363

TABLE 219: OBSTETRICAL SERVICES STAFF TRAINING 10-YEAR COST

Year	Baseline Burden Cost for Training 100% of OB Staff Members Needing Training including Annual Real Wage Increase (a)	Baseline Hourly Burden for Training 100% of OB Staff Members Needing Training (b)	Share of OB Staff Needing Training (c)	Total Hourly Burden Cost (d = a × c)	Total Hourly Burden (e = b × c)
1	$150,999,044.67	1,428,336	0.000	$0	0
2	$151,663,440.47	1,428,336	1.210	$183,512,763	1,728,286
3	$152,330,759.61	1,428,336	0.210	$31,989,460	299,950
4	$153,001,014.95	1,428,336	0.834	$127,618,147	1,191,375
5	$153,674,219.42	1,428,336	0.341	$52,412,283	487,150
6	$154,350,385.98	1,428,336	0.731	$112,762,497	1,043,487
7	$155,029,527.68	1,428,336	0.423	$65,555,192	603,980
8	$155,711,657.60	1,428,336	0.666	$103,695,186	951,191
9	$156,396,788.90	1,428,336	0.474	$74,117,148	676,895
10	$157,084,934.77	1,428,336	0.626	$98,274,757	893,589
10 Year Total				$849,937,432	7,875,903

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c. Quality Assessment and Performance Improvement Program (QAPI) for Hospitals (§ 482.21(b)(4)) and CAHs (§ 485.641(e)(2))

As indicated in section XXI.C.4 of this final rule with comment period, we are finalizing the proposed revision to existing QAPI standards (§ 482.21; § 485.641) for hospitals and CAHs that offer obstetrical services without modifications. Below, we provide the comments we received on the proposed requirements as well as our modifications to the cost estimates for the finalized revisions based on these comments.

Comment: Some commenters said that the proposed rule underestimated costs since it did not consider increases in wage and salaries for healthcare personnel. One commenter said that full utilization of quality improvement activities often requires significant financial investment and administrative support to be successful. Another commenter noted that many metrics used in obstetrical care cannot be assessed using administrative data and instead requires a time-consuming manual chart review.

Response: We appreciate and agree with the feedback regarding the need to include wage growth for healthcare staff in the cost estimates. As we noted in our comment response above regarding OB staff training costs, real wage costs for hospital staff are estimated to increase 0.44 percent annually so we are including a 0.44 annual increase in real wage rates starting in year 2 for all QAPI requirements. We also appreciate that full utilization of QAPI activities takes investment to be successful and that some obstetrical metrics could require manual chart reviews. We believe that the estimated costs in the proposed rule that included costs for data system modifications, data stratification, incorporation of MMRC recommendations into the QAPI program, and carrying out an annual project provide an accurate estimate of the average burden for facilities to engage in these activities.

Based on the comments received, we are making the following modification to the cost estimates: including a 0.44 percent annual increase in hourly rates for QAPI costs starting in year 2 to account for growing wages and salaries for healthcare workers.

In section XXVI of this final rule with comment period, we have already estimated the burden for collecting data and quality indicators for obstetric patients and their outcomes and disparities in processes of care and services and operations. We believe that these data will serve as the foundation to allow facilities to develop and implement actions to improve outcomes and reduce disparities when they exist. We expect that these data will likely be the focus of the required performance improvement project focused on improving health outcomes and reducing disparities among obstetrical patients.

To estimate the cost of tracking and implementing at least one quality improvement project, we utilized estimates from existing regulations governing QAPI program. Specifically, 81 FR 68688 estimates that collecting and analyzing data for all long-term care facilities' improvement projects will take 20 hours, with another 20 years annually spent on implementing and documenting improvement projects. Given that the requirement we are finalizing involves only a single improvement project and we have already accounted for the costs of collecting the data in the information collection requirement portion of this rule, we anticipate that the ongoing annual burden for each facility to analyze the data and implement and document their improvement project(s) will be 30 hours. Using loaded hourly wage rates from Table 186, we anticipate that this will include the participation of a hospital executive at $1,861.28 ($232.66 × 8 hours), an RN at $931.00 ($93.10 × 10 hours), a physician at $1,729.64 ($216.08 × 8 hours), and a data scientist at $368.96 ($92.24 × 4 hours). As indicated in Table 220, this would lead to a total per facility cost of $4,889.88 annually and an average hourly cost of $163 if the requirement went into effect in year 1. Since the requirement will not go into effect until year 2, we assume no burden in year 1. For years 2 to 10, we increase the estimated cost by 0.44 percent annually to account for growth in staff wage rates. As indicated in Tables 220 and 221, we estimate that this requirement will cost an average of $22,170,365 annually and $221,703,645 over 10 years.

TABLE 220: BASELINE ANNUAL COST FOR ADDRESSING HEALTH EQUITY THROUGH QAPI PROGRAM

Provider Type	Number of Providers (a)	Annualized Hourly Burden (b)	Hourly Wage Cost (c)	Total Hourly Burden (d = a × b)	Total Hourly Burden Cost (e = c × d)
CAH	513	30	$163.00	15,390	$2,508,508
Hospital	4,415	30	$163.00	132,450	$21,588,820
Total	4,928			147,840	$24,097,329

TABLE 221: 10 YEAR COST FOR ADDRESSING HEALTH EQUITY THROUGH QAPI PROGRAM

Year	Total Hourly Burden	Total Hourly Burden Cost
1	0	$0
2	147,840	$24,203,357
3	147,840	$24,309,852
4	147,840	$24,416,815
5	147,840	$24,524,249
6	147,840	$24,632,156
7	147,840	$24,740,537
8	147,840	$24,849,396
9	147,840	$24,958,733
10	147,840	$25,068,551
10 Year Total	1,330,560	$221,703,645

d. Maternal Health QAPI Activities for Hospitals (§ 482.21(e)) and CAHs (§ 485.641(d)(4))

As indicated in section XXI.C.4 of this final rule with comment period, we are finalizing the proposed revision to existing QAPI standards (§ 482.21; § 485.641) for hospitals and CAHs that offer obstetrical services without modifications. Below, we provide the comments we received on the proposed requirement that when the MMRC provides information to hospitals and CAHs, they incorporate this information into the facility's QAPI program.

Comment: Some commenters said that the proposed rule underestimated costs since it did not consider increases in wage and salaries for healthcare personnel.

Response: We appreciate and agree with the feedback regarding the need to include wage growth for healthcare staff in the cost estimates. As we noted in our comment response above regarding OB staff training costs, real wage costs for hospital staff are estimated to increase 0.44 percent annually so we are including a 0.44 annual increase in real wage rates starting in year 2 for this requirement.

Based on the comments received, we are making the following modification to the cost estimates: including a 0.44 percent annual increase in hourly rates for QAPI requirements starting in year 2 to take into account growing wages and salaries for healthcare workers.

Using loaded hourly wage rates from Table 186, we expect that when the MMRC provides information to hospitals and CAHs, incorporating this information into the facility's QAPI program will include the participation of a physician at $864.32 ($216.08 × 4 hours) and an RN at $372.40 ($93.10 × 4 hours). As indicated in Table 222, this would lead to a total cost of $1,236.72 per facility if the requirement went into effect in year 1. Since the requirement will not go into effect until year 2, we assume no burden in year 1. For years 2 to 10, we increase the estimated cost by 0.44 percent annually to account for growth in staff wage rates. As indicated in table 223, we estimate that the average annual cost will be $5,607,200 and the 10-year total cost will be $56,071,996.

TABLE 222: BASELINE ANNUAL COST FOR MMRC INFORMATION AND QAPI INCORPORATION

Provider Type	Number of Providers (a)	Annualized Hourly Burden (b)	Hourly Wage Cost (c)	Total Hourly Burden (d = a × b)	Total Hourly Burden Cost (e = c × d)
CAH	513	8	$154.59	4,104	$634,437
Hospital	4,415	8	$154.59	35,320	$5,460,119
Total	4,928			39,424	$6,094,556

TABLE 223: MMRC INFORMATION AND QAPI INCORPORATION 10 YEAR COST

Year	Total Hourly Burden	Total Hourly Burden Cost
1	0	$0
2	39,424	$6,121,372
3	39,424	$6,148,306
4	39,424	$6,175,359
5	39,424	$6,202,530
6	39,424	$6,229,822
7	39,424	$6,257,233
8	39,424	$6,284,765
9	39,424	$6,312,418
10	39,424	$6,340,192
10 Year Total	354,816	$56,071,996

e. Emergency Services Readiness for Hospitals (§ 482.55(c)) and CAHs (§ 485.618(e))

As indicated in section XXI.C.5 of this final rule with comment period, we are finalizing the proposed emergency services readiness standard for hospitals and CAHs without modifications. Below, we provide the comments we received on the proposed requirement's cost as well as our modifications to the final cost estimate based on these comments.

Comment: Some commenters said that the proposed rule underestimated costs since it did not consider increases in wage and salaries for healthcare personnel, as well as staff turnover.

Response: We appreciate and agree with the commenters. We are including a 0.44 annual increase in real wage rates starting in year 2 for the emergency services training requirements. While the emergency training cost estimate in the proposed rule included costs for turnover in years 2 through 10, it did not include them in year 1. To address concern regarding staff turnover and training for new staff members, we are including training costs for new staff members based on a 21 percent annual staff turnover rate, which is the same rate we used for the OB staff training requirement.

Comment: Some commenters said that the proposed rule underestimated the equipment costs since it did not consider the cost for maintaining and replacing required equipment.

Response: We agree that replacing equipment will add additional burden for facilities. Based on our experience, we estimate that the required equipment will need to be replaced once every 5 years. As a result, we include additional burden in year 6 for hospitals with emergency services to replace all call-in systems.

Based on the comments received, we are making the following modifications to the cost estimates: (1) including a 0.44 percent annual increase in hourly rates for training costs starting in year 2 to take into account growing wages and salaries for healthcare workers, (2) including additional costs in year 1 to account for training new staff members, and (3) including additional costs to replace call-in systems in year 6.

In section XXVI of this final rule with comment period, we have already discussed the cost for hospitals to ensure that they have adequate protocols in place for emergency services, as well as to document that applicable staff have successfully completed the training and demonstrate their knowledge on these topics. The training requirement for hospitals and CAHs provides flexibility regarding which staff will receive training. We expect, however, that they will likely focus their training on medical staff within emergency departments. This staff includes surgeons, physicians, physician assistants, nurse practitioners, nurse midwives, nurse anesthetists, registered nurses, and LPNs/LVNs.

To estimate the number of employees in CAHs and REHs that will likely receive training, we first obtained data from the Bureau of Labor Statistics (BLS) on the number of surgeons, physicians, physician assistants, nurse practitioners, nurse midwives, nurse anesthetists, registered nurses, and LPNs/LVNs working in hospitals (NAICS 622000). Since the BLS does not provide separate employment statistics for CAHs and hospitals, we assume that the number of employees needing training and, henceforth, the costs will be in proportion to the size of facilities, specifically the number of certified beds. We obtained information on the number of certified beds in hospitals and CAHs from CMS' Q1 2024 Provider of Services File—Hospital & Non-Hospital Facilities.[789] Using this database, we estimate that 98.88 percent of certified beds for hospitals are in hospitals with the remaining 1.12 percent in CAHs.

Based on our experience, we expect that initial staff training will take approximately 3 hours per employee. Using data from Table 186 on loaded wage rates for each employee type, we estimated the cost for training all medical staff in hospitals and CAHs in year 1 using the following formula: loaded wage rate for medical staff (surgeons, physicians, physician assistants, nurse practitioners, nurse midwives, nurse anesthetists, registered nurses, and LPNs/LVNs) × total number of each medical staff type working in hospitals and CAHs × 3 hours per employee. Using this formula, we estimate that training all medical staff would cost $724,555,386.

In hospitals, which have a larger number of beds, there is likely to be a greater division of staff among units, with medical staff specifically designated to work in emergency departments. In contrast, CAHs, which are smaller in size, are likely to have medical staff that work across units given their small size. We assume, therefore, that 20 percent of medical staff in hospitals and all medical staff in CAHs will receive the training. To calculate the baseline year 1 cost for hospitals and CAHs, therefore, we use the following formula: Total cost for training all hospital/CAH medical staff × % hospital (CAH) medical staff

[789] Centers for Medicare and Medicaid Services. Provider of Services File—Hospital & Non-Hospital Facilities, Q1 2024. *https://data.cms.gov/provider-characteristics/hospitals-and-other-facilities/provider-of-services-file-hospital-non-hospital-facilities/data* (Accessed April 30, 2024).

receiving training × Share of all Hospital and CAH Certified Beds. We then include the cost to train new employees who will need to receive 3 hours of training by multiplying our baseline cost estimates by 1.21 to account for an average hospital turnover rate of 21 percent annually.[790] As indicated in Table 224, we expect that the finalized requirement will cost approximately $9.8 million for CAHs and $173.4 million for hospitals in year 1.

For subsequent years, we expect that refresher training for medical staff, who received the full training in previous years, will take 1 hour to complete. In addition, new staff will need to receive the full 3-hour training. With an annual hospital turnover rate of approximately 21 percent,[791] we expect 21 percent of employees each year to be new employees who will need 3 hours of training and 79 percent of employees will need 1 hour of training. To calculate the burden for years 2 to 10, therefore, we use the following formula: (Total cost for training all hospital/CAH medical staff × % hospital(CAH) medical staff needing initial training × Share of all Hospital and CAH Certified Beds) + (Total cost for training all hospital/CAH medical staff × % hospital(CAH) medical staff receiving needing initial training × Share of all Hospital and CAH Certified Beds). To account for increases in real wage rates we increase the estimated cost by 0.44 percent annually. As indicated in Table 225, we estimate a total 10-year cost of $842,377,531.

TABLE 224: YEAR 1 EMERGENCY SERVICES PROTOCOL TRAINING COST

Provider Type	Number of Providers (a)	Number of Certified Beds (b)	Share of all Hospital and CAH Certified Beds (c)	Total Yearly Cost if All Hospital and CAH Medical Staff were Trained (d)	Total Hospital and CAH Medical Staff (e)	Share of Medical Staff Receiving Training (f)	Total Number of Staff Members (g = c × e)	Total Hourly Annual Cost Including Turnover (h = c × d × f × 1.21)	Total Hourly Burden Including Turnover (i = f × g × 3 × 1.21)	Average Cost per Staff Member (j = h /(f × g))	Average Cost per Facility (k = h / a)
CAH	513	12,582	0.011	$724,555,386	2,284,580	1	25,478	$9,777,137	92,484	$317	$19,059
Hospital	5,797	1,115,641	0.989	$724,555,386	2,284,580	0.2	2,259,102	$173,386,976	1,640,108	$317	$29,910

TABLE 225: 10 YEAR EMERGENCY SERVICES PROTOCOL TRAINING COST

Year	Hourly Burden Cost	Hourly Burden
1	$183,164,113	1,732,592
2	$71,966,240	677,763
3	$72,282,891	677,763
4	$72,600,936	677,763
5	$72,920,380	677,763
6	$73,241,230	677,763
7	$73,563,491	677,763
8	$73,887,170	677,763
9	$74,212,274	677,763
10	$74,538,808	677,763
10 Year Total	$842,377,531	7,832,463

To estimate the cost for hospitals to have certain basic equipment readily available, we consulted with medical experts on the requirements. Based on their experience, we expect that the most hospitals with emergency services already have drugs, blood and blood products, and biologicals commonly used in emergency procedures, as well as equipment and supplies commonly used in emergency procedures. As such, we do not estimate a burden for these requirements. There is likely, however, to be wide variation in hospitals that have call-in systems. Based on our experience, we estimate that 50 percent of hospitals already have call-in systems

[790] Nursing Solutions Incorporated, *2024 NSI National Health Care Retention & RN Staffing Report.* 2024.

[791] Nursing Solutions Incorporated, *2024 NSI National Health Care Retention & RN Staffing Report.* 2024.

while 50 percent will need to install them in their emergency departments.

As we noted above in estimating the cost for call-in systems for hospitals that offer obstetrical services, while we were not able to identify public estimates for the price of call-in systems, based on our experience we estimate that they will cost $2500 to $3500 per system, and we utilize the mid-point of the price estimate and assume each call-in system will cost $3000. We assume that 20 percent of hospital beds are allocated for emergency services and assume that there will need to be a call-in system for each bed. As indicated in Table 226, we estimate that this requirement will cost a total of $334,629,300 in year 1. We also expect that under normal use, call-in systems will need to be replaced in five years. As such, in Table 227 we estimate a total cost of $669,384,600 over 10 years.

TABLE 226: YEAR 1 EMERGENCY SERVICES' CALL-IN SYSTEM REQUIREMENT COST

Provider Type	Hospital Beds (b)	Number of Providers (a)	Share of Hospitals Needing Call-in Systems (c)	Share of Beds Needing Call-In System (d)	Call-In Systems Needed (e = b × c × d)	Price per Call-In System (f)	Total Annual Cost (g = e × f)	Average Cost per Facility (h = g / (a × c))
Hospital	1,115,641	5,797	0.5	0.2	111,564	$3,000	$334,692,300	$115,471

TABLE 227: 10 EMERGENCY SERVICES' CALL-IN SYSTEM REQUIREMENT COST

Year	Total Cost
1	$334,692,300
2	$0
3	$0
4	$0
5	$0
6	$334,692,300
7	$0
8	$0
9	$0
10	$0
10 Year Total Cost	$669,384,600

f. Transfer Protocols in Discharge Planning for Hospitals (§ 482.43(c))

As indicated in section XXI.C.6 of this final rule with comment period, we are finalizing the proposed emergency services readiness standard for hospitals with the modification that acute care hospitals are required to provide annual training to the relevant staff (as determined by the facility) regarding the hospital policies and procedures for transferring patients under its care. Below, we provide the comments we received on the proposed requirement's cost as well as our modifications to the final cost estimate based on these comments.

Comment: Some commenters said that the proposed rule underestimated costs since it did not consider increases in wage and salaries for healthcare personnel, as well as staff turnover.

Response: We appreciate and agree with the commenters. We are including a 0.44 annual increase in real wage rates starting in year 2 for the transfer protocol training requirements. To address concern regarding staff turnover and training for new staff members, we are including training costs for new staff members based on a 21 percent annual staff turnover rate.[792]

After consideration of the comments, we are revising the transfer protocol staff training costs to include a 0.44 percent annual increase in real wage rates to account for wage growth among healthcare staff starting in year 2. We are also including additional burden for staff training to account for staff turnover and new staff members who will need transfer protocol training.

Since hospital inpatients are included in those who may need to be transferred, we believe that medical staff across hospitals, and not just those in emergency departments, will need to receive training on transfer protocols. Specifically, we expect that all surgeons, physicians, physician assistants, nurse practitioners, nurse midwives, nurse anesthetists in hospitals will receive this training. We do not expect, however, that LPNs will receive this training and similarly expect that most RNs will not receive this training. Rather, we expect that among RNs, only experienced RNs who serve as transfer coordinators will receive it and estimate that this is only 5 percent of RNs nationwide. We estimate that each employee will require 1 hour of training annually and assume that that this training will occur on an annual basis. As indicated in Table 228, after increasing the estimated burden by 21 percent to account for the average annual turnover in hospitals [793] that will require training new employees, we

[792] Nursing Solutions Incorporated, *2024 NSI National Health Care Retention & RN Staffing Report.* 2024.

[793] Nursing Solutions Incorporated, *2024 NSI National Health Care Retention & RN Staffing Report.* 2024.

expect the requirement to cost $86,207,786 in year 1. For subsequent years, we increase the estimated annual cost by 0.44 percent to account for real wage growth for staff. As indicated in Table 229, we expect that this requirement to cost an average of $87,934,883 annually and $879,348,830 over 10 years.

TABLE 228: TRANSFER PROTOCOL TRAINING ANNUAL COST

Provider Type	Number of Providers (a)	Number of Certified Beds (b)	Share of all Hospital and CAH Certified Beds (c)	Total Hospital and CAH Medical Staff (d)	Total Number of Staff Members Receiving Training (e = c × d)	Total Hourly Burden Cost Including Turnover (f = g × h × 1.21)	Total Hourly Burden Including Turnover (g = e × 1 × 1.21)	Average Hourly Cost (h)	Average Cost per Staff Member Trained (I = (g / e))	Average Cost per Facility (k = f / a)
Hospital	5,797	1,115,641	0.989	422,240	417,531	$86,207,786	505,213	$171	$171	$14,871

TABLE 229: TRANSFER PROTOCOL TRAINING ANNUAL COST 10 YEAR COST

Year	Hourly Burden	Hourly Burden Cost
1	505,213	$86,207,786
2	505,213	$86,587,100
3	505,213	$86,968,084
4	505,213	$87,350,743
5	505,213	$87,735,086
6	505,213	$88,121,121
7	505,213	$88,508,854
8	505,213	$88,898,293
9	505,213	$89,289,445
10	505,213	$89,682,319
10 Year Total	5,052,127	$879,348,830

g. Summary of Regulatory Impact Analysis for Obstetrical and Emergency Services

In Tables 231 and 232 we provide an estimate of the total annual and 10-year financial and hourly burden for the requirements related to obstetrical and emergency services that include: (1) organization, staffing, and delivery of services for hospitals and CAHs as outlined in Table 215 and Table 217; (2) obstetrical services staff training for hospitals and CAHs as outlined in Table 219; (3) quality assessment and performance improvement program requirements for hospitals and CAHs as outlined in Table 221; (4) maternal health QAPI activity requirements for hospitals and CAHs as outlined in Table 223; (5) emergency services readiness requirements for hospitals and CAHs in Table 225 and Table 227; and (6) transfer protocols training for acute care hospitals as outlined in Table 229. These estimates exclude the cost for collection of information requirements that we have estimated above in Tables 199 and 200 to cost $129,748,120 million over 10 years and take 1,038,698 hours to complete. Overall, we estimate the total financial cost of the requirements will be approximately $4.10 billion and take $22.4 million hours to complete over 10 years.

We sought comments on several issues related to the regulatory impact analysis, including the following:

- Are there additional data sources that estimate the number of medical staff, who work with obstetrical patients?
- Are there additional data sources to estimate the number of hospital and CAH obstetrical rooms/suites?
- Are there any additional data sources to estimate the cost for the provisions of cardiac monitors, call-in systems, and fetal doppler or monitors?
- Are there additional data sources to estimate the number of medical staff who work with emergency care units?
- Are there data sources to estimate the number of hospital room/suites that are allocated for emergency services?
- Are there any additional staff members who are likely to receive training for emergency services and obstetrical services?

We did not receive responses to these comment solicitations.

TABLE 231: REGULATORY IMPACT ANALYSIS SUMMARY, ANNUAL AND 10-YEAR COST ESTIMATES

Year	Qualified OB Supervisor	Obstetrical Equipment	Obstetrical Services Staff Training	Addressing Health Equity Through QAPI Program	MMRC Engagement and QAPI Incorporation	Emergency Services Protocol Training	Emergency Services' Call-In System	Transfer Protocol Training	Total Cost for All Requirements
1	$269,842,496	$157,232,768	$0	$0	$0	$183,164,113	$334,692,300	$86,207,786	$1,031,139,463
2	$0	$0	$183,512,763	$24,203,357	$6,121,372	$71,966,240	$0	$86,587,100	$372,390,832
3	$0	$0	$31,989,460	$24,309,852	$6,148,306	$72,282,891	$0	$86,968,084	$221,698,592
4	$0	$0	$127,618,147	$24,416,815	$6,175,359	$72,600,936	$0	$87,350,743	$318,161,999
5	$0	$0	$52,412,283	$24,524,249	$6,202,530	$72,920,380	$0	$87,735,086	$243,794,529
6	$0	$157,232,768	$112,762,497	$24,632,156	$6,229,822	$73,241,230	$334,692,300	$88,121,121	$796,911,893
7	$0	$0	$65,555,192	$24,740,537	$6,257,233	$73,563,491	$0	$88,508,854	$258,625,307
8	$0	$0	$103,695,186	$24,849,396	$6,284,765	$73,887,170	$0	$88,898,293	$297,614,809
9	$0	$0	$74,117,148	$24,958,733	$6,312,418	$74,212,274	$0	$89,289,445	$268,890,017
10	$0	$0	$98,274,757	$25,068,551	$6,340,192	$74,538,808	$0	$89,682,319	$293,904,627
10 Year Total Cost	$269,842,496	$314,465,536	$849,937,432	$221,703,645	$56,071,996	$842,377,531	$669,384,600	$879,348,830	$4,103,132,067

TABLE 232: REGULATORY IMPACT ANALYSIS SUMMARY, ANNUAL AND 10-YEAR HOURLY ESTIMATES

Year	Obstetrical Services Staff Training	Addressing Health Equity Through QAPI Program	MMRC Engagement and QAPI Incorporation	Emergency Services Protocol Training	Transfer Protocol Training	Total Hourly Cost for All Requirements
1	0	0	0	1,732,592	505,213	2,237,805
2	1,728,286	147,840	39,424	677,763	505,213	3,098,526
3	299,950	147,840	39,424	677,763	505,213	1,670,191
4	1,191,375	147,840	39,424	677,763	505,213	2,561,615
5	487,150	147,840	39,424	677,763	505,213	1,857,390
6	1,043,487	147,840	39,424	677,763	505,213	2,413,728
7	603,980	147,840	39,424	677,763	505,213	1,974,221
8	951,191	147,840	39,424	677,763	505,213	2,321,431
9	676,895	147,840	39,424	677,763	505,213	2,047,135
10	893,589	147,840	39,424	677,763	505,213	2,263,829
10 Year Total Cost	7,875,903	1,330,560	354,816	7,832,463	5,052,127	22,445,869

h. Benefits

We invited comments on additional benefits related to the proposed requirements for obstetrical services in hospitals and CAHs but did not receive any information about additional benefits. Since we are not finalizing the requirement that hospitals and CAHs delineate and document obstetrical privileges for all practitioners, we are removing the benefits for this policy. Below, we detail the benefits from the finalized policies.

First, there are the financial benefits. As noted above in the statement of need, research suggests that maternal mortality and morbidity have widespread negative effects on pregnant and postpartum patients and their families and high financial costs for payors. One study found that pregnancy-related mortality in the United States costs more than $27.4 billion and resulted in the loss of 114,000 years of potential life between 2018 and 2020.[794] Another study showed that from birth to 5 years postpartum, nine maternal morbidities among the 2019 US birth cohort cost birthing parents and their children $32.3 billion, with $18.7 billion due to medical costs and $13.6 billion related to non-medical costs.[795] [796] A third study found that severe maternal morbidity during the prenatal to 30-day postpartum period was associated with a 75 percent increase in medical costs for patients utilizing Medicaid and a more than doubling in medical costs for commercially insured patients.[797] While these studies vary in their methodology, the pre-post birth time period analyzed, medical conditions analyzed, and cost estimates, they suggest that maternal morbidity and mortality impose high health and safety, as well as economic costs on birth parents, children, payors, and society.[798]

We believe that the policies we are finalizing will help reduce maternal morbidity and mortality and their associated costs for pregnant and postpartum patients and their families, as well as payors. Specifically, the finalized requirements that OB services are well-organized and in accordance with acceptable standards of practices, have adequate provisions and protocols for OB emergencies, complications, immediate post-delivery care and other patient health and safety events as identified as part of the facility's QAPI program, and that OB patient care units are supervised by an individual with the necessary education and training will provide the foundation for ensuring uniform high-quality OB services. The requirement that hospitals and CAHs that offer obstetrical services have equipment that includes a call-in-system, cardiac monitor, and fetal doppler or monitor kept at the hospital and CAH and readily available for treating obstetrical cases to meet the needs of patients in accordance with the scope, volume, and complexity of services offered will help ensure efficient and effective care that can help reduce patient morbidity and mortality. Similarly, OB staff training and appropriate transfer protocols can also help avert avoidable maternal complications and deaths.[799] Finally, engagement with recommendations from MMRCs and QAPI stratification of data can help facilities better identify unfavorable patient health and safety outcomes, which can allow them to

[794] White Robert, S., et al., *Economic burden of maternal mortality in the USA, 2018–2020.* Journal of Comparative Effectiveness Research, 2022. 11(13): 927–933.

[795] O'Neil, S.S., et al., *Societal cost of nine selected maternal morbidities in the United States.* PLOS ONE, 2022. 17(10): e0275656.

[796] These nine conditions included the following: amniotic fluid embolism, cardiac arrest, gestational diabetes mellitus, hemorrhage, hypertensive disorders, mental health conditions, renal disease, sepsis, and venous thromboembolism.

[797] Black, C.M., et al., *Costs of Severe Maternal Morbidity in U.S. Commercially Insured and Medicaid Populations: An Updated Analysis.* Women's Health Reports, 2021. 2(1): 443–451.

[798] Moran, P.S., et al., *Economic burden of maternal morbidity—A systematic review of cost-of-illness studies.* PLOS ONE, 2020. 15(1): e0227377.

[799] *https://saferbirth.org/aim-obstetric-emergency-readiness-resource-kit/.*

better tailor policies to address these issues.

Beyond reductions in maternal morbidity and mortality and their associated financial benefits, the finalized policies are likely also to reduce inequality among pregnant and postpartum women from different groups. For example, research shows that among women with any form of disability, there is a heightened risk for labor and delivery complications, as well as severe maternal morbidity and mortality. If hospitals and CAHs include training that helps health care practitioners better understand these risks and be more comfortable providing care to women with a disability, they may be able to better provide safe, high quality obstetric care, reducing obstetrical complications. Research also suggests that due to insufficient patient education by staff, women with limited English proficiency (LEP) experience disparities in obstetric care and are at risk for mental health conditions, including post-partum depression and substandard newborn care following neonatal ICU discharge.[800] If facilities engage in increasing language-concordant care and awareness among providers regarding the use of medical interpreters and materials in diverse languages, they may be able to improve patient satisfaction, decrease medical errors, and improve patient safety.[801] [802] Similarly, stratification of patient data can produce insights into health disparities that allow facilities to develop interventions to reduce them, with research showing that data collection and analysis by patient subgroup within health care facilities has an important impact on improving patient care consistently across patient populations.[803] [804] [805] [806] [807]

Beyond the benefits for obstetrical patients, our requirements are likely to have positive effects on the health and safety for patients generally. Our requirements for hospitals to have written policies and procedures for transferring patients under their care and to train medical staff regarding transfer protocols can support hospitals in expediting transfers when necessary. Efficient transfers to hospitals that can treat complex conditions and provide higher levels of care for all patients as needed. Similarly, our requirement that hospitals with emergency services must have adequate provisions and protocols for the care of patients with emergency conditions and train applicable staff on these protocols and provisions, is also likely to improve patient health and safety. Additional obstetric training for emergency department staff improves staff competencies (*i.e.,* skills, knowledge, comfort, confidence, and effectiveness) in managing obstetric emergencies, supporting improved maternal health and safety,[808] [809] [810] [811] [812] [813] while training in pediatric readiness,[814] [815] and geriatric readiness [816] [817] [818] [819] [820] improves staff capabilities in caring for these populations.

i. Alternatives Considered

We considered a variety of approaches when developing the finalized obstetrical services requirements for hospitals and CAHs. One approach was to leave the development of policies to improve obstetrical services to accrediting agencies or individual States. We decided against this approach, however, since there is likely to be wide variation across States and accrediting agencies in their requirements, leading to variation in obstetrical services for patients depending on the facility or State where they are located.

We also considered requiring specific topics for the proposed OB services training requirement as well as for the requirement to train staff on the protocols for the care of patients with emergency conditions. We ultimately decided, however, to provide facilities with flexibility in how they approach these trainings so that they could provide it in a way that leads to the best improvements in and highest quality of care for pregnant and postpartum women. Similarly, we considered defining specific subpopulations that facilities must analyze when using their QAPI program to identify inequalities in health outcomes. Ultimately, however, we decided to provide facilities with flexibility regarding which subpopulations they analyze since features of patient populations are likely to vary greatly across different facilities.

D. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on this year's proposed rule will be the number of reviewers of this final rule. We acknowledge that this assumption may understate or overstate

[800] Togioka, Brandon & Seligman, Katherine & Delgado Upegui, Carlos. (2022). Limited English proficiency in the labor and delivery unit. Current Opinion in Anesthesiology. 35. 285–291.

[801] Sentell, Tetine & Chang, Ann & Ahn, Hyeong Jun & Miyamura, Jill. (2015). Maternal Language and Adverse Birth Outcomes in a Statewide Analysis. Women & health. 56. 10.1080/03630242.2015.1088114.

[802] *https://www.ahrq.gov/sites/default/files/publications/files/lepguide.pdf*).

[803] Weinick, R.M. and R. Hasnain-Wynia, Quality Improvement Efforts Under Health Reform: How To Ensure That They Help Reduce Disparities—Not Increase Them. Health Affairs, 2011. 30(10): p. 1837–1843.

[804] Bardach, N.S. and M.D. Cabana, The unintended consequences of quality improvement. Curr Opin Pediatr, 2009. 21(6): p. 777–82.

[805] Perzynski, A.T., et al., Patient portals and broadband internet inequality. J Am Med Inform Assoc, 2017. 24(5): p. 927–932.

[806] Antonio, M.G., O. Petrovskaya, and F. Lau, Is research on patient portals attuned to health equity? A scoping review. J Am Med Inform Assoc, 2019. 26(8–9): p. 871–883.

[807] Sequist, T.D., et al., Effect of quality improvement on racial disparities in diabetes care. Arch Intern Med, 2006. 166(6): p. 675–81.

[808] Burke SM, Schmitt T, Kennedy P, et al. Emergency Medicine Obstetrics and Gynecology: A Case-Based Curriculum for Residents. *MedEdPORTAL.* 2023;19:11330.

[809] Espey E, Baty G, Rask J, Chungtuyco M, Pereda B, Leeman L. Emergency in the clinic: a simulation curriculum to improve outpatient safety. *Am J Obstet Gynecol.* Dec 2017;217(6):699.e1–699.e13.

[810] Cooper MI, Papanagnou D, Meguerdichian M, Bajaj K. Emergency Obstetrics for the Emergency Medicine Provider. *MedEdPORTAL.* Oct 13 2016;12:10481.

[811] Jacobs PJ. Using High-Fidelity Simulation and Video-Assisted Debriefing to Enhance Obstetrical Hemorrhage Mock Code Training. *J Nurses Prof Dev.* Sep/Oct 2017;33(5):234–239.

[812] Hopmann P, Varre JS, Duncan G, Devoe WB, Gable BD. Multidisciplinary Simulation of Trauma in Pregnancy with Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) Utilization. *Cureus.* Dec 2022;14(12):e32820.

[813] Harrington J, Duncan G, D. Angelo K G. Multidisciplinary Simulation Improves Resident Confidence for Pregnant Patients Requiring Surgical Intervention. *Cureus.* Mar 2022;14(3):e23454.

[814] Ames, S.G., et al., Emergency Department Pediatric Readiness and Mortality in Critically Ill Children. Pediatrics, 2019. 144(3).

[815] Newgard, C.D., et al., Emergency Department Pediatric Readiness and Short-term and Long-term Mortality Among Children Receiving Emergency Care. JAMA Network Open, 2023. 6(1): p. e2250941-e2250941.

[816] Keyes, DC, et al., Impact of a New Senior Emergency Department on Emergency Department Recidivism, Rate of Hospital Admission, and Hospital Length of Stay. Annals of Emergency Medicine, 2014. 63(5): p. 517–524.

[817] Dresden, S.M., et al., Geriatric Emergency Department Innovations: The Impact of Transitional Care Nurses on 30-day Readmissions for Older Adults. Acad Emerg Med, 2020. 27(1): p. 43–53.

[818] Foo, C.L., et al., Geriatric assessment and intervention in an emergency department observation unit reduced re-attendance and hospitalisation rates. Australas J Ageing, 2012. 31(1): p. 40–6.

[819] Chong, E., et al., Emergency Department Interventions for Frailty (EDIFY): Front-Door Geriatric Care Can Reduce Acute Admissions. Journal of the American Medical Directors Association, 2021. 22(4): p. 923–928.e5.

[820] Gettel, C.J., et al., An Outcome Comparison Between Geriatric and Nongeriatric Emergency Departments. Ann Emerg Med, 2023. 82(6): p. 681–689.

the costs of reviewing this rule. It is possible that not all commenters reviewed this year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule.

We welcomed any public comments on the approach in estimating the number of entities that would review the proposed rule. We did not receive any public comments specific to our solicitation.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $129.28 per hour, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm.* Assuming an average reading speed, we estimate that it would take approximately 8 hours for the staff to review half of this final rule. For each entity that reviews the rule, the estimated cost is $1,034.24 (8 hours × $129.28). Therefore, we estimate that the total cost of reviewing this regulation is $2,645,585.92 ($1,034.24 × 2,558).

E. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that many hospitals and CAHs are considered small businesses either by the Small Business Administration's size standards with total revenues of $41.5 million or less in any single year or by the hospital's not-for-profit status. Most ASCs and most CMHCs are considered small businesses with total revenues of $16.5 million or less in any single year. For details, we refer readers to the Small Business Administration's ''Table of Size Standards'' at *http://www.sba.gov/content/small-business-size-standards.*

Individuals and States are not included in the definition of a small entity. As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. We believe that this threshold will be reached by the requirements in this final rule with comment period. Therefore, the Secretary has certified that this final rule with comment period will have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has 100 or fewer beds. We estimate that this final rule with comment period will increase payments to small rural hospitals by approximately 3 percent; therefore, it should have a negligible impact on approximately 528 small rural hospitals. We note that the estimated payment impact for any category of small entity will depend on both the services that they provide as well as the payment policies and/or payment systems that may apply to them. Therefore, the most applicable estimated impact may be based on the specialty, provider type, or payment system.

For hospitals and CAHs, the finalized obstetrical services requirements will have an average annual cost of $423 million. According to the 2017 Economic Census,[821] revenues for general medical and surgical hospitals (NAIC 522110) exceeded $1 trillion in 2017, which is less than 0.50 percent of annual revenues.

The analysis above, together with the remainder of this preamble, provides a regulatory flexibility analysis and a regulatory impact analysis.

F. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2024, that threshold is approximately $183 million. This final rule with comment period does not mandate any requirements for State, local, or tribal governments. This final rule with comment period will not impose a mandate that will result in the expenditure by State, local, and Tribal Governments, in the aggregate. Based on the cost estimates discussed in this section, we have assessed the various costs and benefits of the final updates to the requirements for participation for hospitals and CAHs. For the private sector facilities, the regulatory impact analysis, together with the remainder of the preamble, constitutes the analysis required under UMRA.

G. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts state law, or otherwise has federalism implications. We have examined the OPPS and ASC provisions included in this final rule with comment period in accordance with Executive Order 13132, Federalism, and have determined that they would not have a substantial direct effect on State, local, or tribal governments, preempt State law, or otherwise have a federalism implication. As reflected in Table 201 of this final rule with comment period, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) would increase by 2.6 percent under this final rule with comment period. While we do not know the number of ASCs or CMHCs with government ownership, we anticipate that it is small. The analyses we have provided in this section of this final rule with comment period, in conjunction with the remainder of this document, demonstrate that this rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866, the RFA, and section 1102(b) of the Act.

This final rule with comment period will affect payments to a substantial number of small rural hospitals and a small number of rural ASCs, as well as other classes of hospitals, CMHCs, and ASCs, and some effects may be significant. However, as noted in section XXIII of this final rule with comment period, this rule should not have a significant effect on small rural hospitals.

The obstetrical services provisions in this final rule with comment period will not have a substantial direct effect on State, local, or tribal governments, preempt State law, or otherwise have a federalism implication.

H. Conclusion

The changes we are finalizing will affect all classes of hospitals paid under the OPPS as well as both CMHCs and ASCs. We estimate that most classes of hospitals paid under the OPPS would experience a modest increase or a minimal decrease in payment for services paid under the OPPS in CY

[821] United State Census Bureau.622110: General medical and surgical hospitals. *https://data.census.gov/profile/622110_-_General_medical_and_surgical_hospitals?n=622110&g=010XX00US.* Accessed October 16, 2024.

2025. Table 201 demonstrates the estimated distributional impact of the OPPS budget neutrality requirements that will result in a 3.0 percent increase in payments for all services paid under the OPPS in CY 2025, after considering all of the changes to APC reconfiguration and recalibration, as well as the OPD fee schedule increase factor, wage index changes, including the frontier State wage index adjustment, and estimated payment for outliers, changes to the pass-through payment estimate, and changes to outlier payments. However, some classes of providers that are paid under the OPPS would experience more significant gains or losses in OPPS payments in CY 2025.

The updates we are making to the ASC payment system for CY 2025 will affect each of the approximately 6,100 ASCs currently approved for participation in the Medicare program. The effect on an individual ASC would depend on its mix of patients, the proportion of the ASC's patients who are Medicare beneficiaries, the degree to which the payments for the procedures offered by the ASC are changed under the ASC payment system, and the extent to which the ASC provides a different set of procedures in the coming year than in previous years. Table 201 demonstrates the estimated distributional impact among ASC surgical specialties of the productivity-adjusted hospital market basket update factor of 2.9 percent for CY 2025.

The new conditions of participation and the modifications to current conditions of participation for hospitals and CAHs that offer obstetrical services and emergency services will have a total 10-year impact of approximately $4.23 billion as outlined in Tables 200 and 231. The average annual cost per hospital and CAH will be approximately $67,000.

Finally, the additional exceptions to the four walls requirement under the Medicaid clinic services benefit for IHS/Tribal clinics, and at State option, behavioral health clinics and clinics located in rural areas are estimated to have an $1.18 billion impact in transfers for fiscal years 2025–2029. Table 211 demonstrates the Federal and State share impacts on IHS/Tribal clinics, behavioral health clinics, clinics located in rural areas, and in aggregate. As explained earlier in this section of this final rule, there is uncertainty in the potential for changes in utilization and costs of clinic services because of uncertainty in provider availability and beneficiary demand.

I. Waiver Fiscal Responsibility Act Requirements

Please note that the Director of OMB has waived the requirements of section 263 of the Fiscal Responsibility Act of 2023 (Pub. L. 118–5) pursuant to section 265(a)(1) and (2) of that Act.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October 23, 2024.

List of Subjects

42 CFR Part 406

Diseases, Health facilities, Medicare.

42 CFR Part 407

Medicare.

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 411

Diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 435

Aid to families with dependent children, Grant programs—health, Medicaid, Reporting and recordkeeping requirements, Supplemental Security Income (SSI), Wages.

42 CFR Part 440

Grant programs—health, Medicaid.

42 CFR Part 457

Administrative practice and procedure, Grant programs—health, Health insurance, Reporting and recordkeeping requirements.

42 CFR Part 482

Grant programs—health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 485

Grant programs—health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare and Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 406—HOSPITAL INSURANCE ELIGIBILITY AND ENTITLEMENT

■ 1. The authority citation for part 406 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395i–2, 1395i–2a, 1395p, 1395q and 1395hh.

■ 2. Section 406.27 is amended by revising paragraph (d) to read as follows:

§ 406.27 Special enrollment periods for exceptional conditions.

* * * * *

(d) *SEP for formerly incarcerated individuals.* An SEP exists for Medicare eligible individuals who are no longer incarcerated on or after January 1, 2023.

(1) *SEP parameters and duration before January 1, 2025*—(i) *Eligibility.* An individual is eligible for this SEP if they are released from the custody of penal authorities between January 1, 2023, and December 31, 2024, as described in § 411.4(b) of this subchapter. The individual must demonstrate that they are eligible for Medicare and failed to enroll or reenroll in Medicare premium Part A due to being in custody of penal authorities and there is a record of release either through discharge documents or data available to SSA.

(ii) *SEP duration.* The SEP starts the day of the individual's release from the custody of penal authorities and ends the last day of the 12th month after the month in which the individual is released from the custody of penal authorities.

(2) *SEP parameters and duration beginning January 1, 2025*—(i) *Eligibility.* An individual is eligible for this SEP if they are released from confinement in a jail, prison, or other penal institution or correctional facility on or after January 1, 2025, and demonstrate that they are eligible for Medicare and failed to enroll or reenroll in Medicare premium Part A due to being so confined, and there is a record of release, either through documentation of discharge or data available to SSA. Individuals released to and residing in halfway houses after incarceration are not considered incarcerated or in confinement for the purposes of this SEP.

(ii) *SEP duration.* The SEP starts the day an individual is released from confinement as determined by SSA and ends the last day of the 12th month after the month in which the individual is released from confinement in a jail, prison, or other penal institution or correctional facility.

(3) *Entitlement*—(i) *General rule.* Entitlement begins the first day of the

month following the month of enrollment, so long as the date is on or after January 1, 2023.

(ii) *Special rule.* An individual has the option of requesting entitlement for a retroactive period of up to 6 months provided the date does not precede the month of their release from incarceration, the date is on or after January 1, 2023, and the individual pays the monthly premiums for the period of coverage (as required under § 406.32(f)). If retroactive enrollment is requested and the application is filed within the first 6 months of the SEP, the effective date is retroactive to the beginning of the month of their release from incarceration. If retroactive enrollment is requested and the application is filed in the last 6 months of the SEP, the coverage effective date is retroactive to the 6th month before the month of enrollment.

* * * * *

PART 407—SUPPLEMENTARY MEDICAL INSURANCE (SMI) ENROLLMENT AND ENTITLEMENT

■ 3. The authority citation for part 407 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395p, 1395q, and 1395hh.

■ 4. Section 407.23 is amended by revising paragraph (d) to read as follows:

§ 407.23 Special enrollment periods for exceptional conditions.

* * * * *

(d) *SEP for formerly incarcerated individuals.* An SEP exists for Medicare eligible individuals who are no longer incarcerated on or after January 1, 2023.

(1) *SEP parameters and duration before January 1, 2025*—(i) *Eligibility.* An individual is eligible for this SEP if they are released from the custody of penal authorities between January 1, 2023, and December 31, 2024, as described in § 411.4(b) of this subchapter. The individual must demonstrate that they are eligible for Medicare and failed to enroll or reenroll in SMI due to being in the custody of penal authorities and there is a record of release either through discharge documents or data available to SSA.

(ii) *SEP duration.* The SEP starts the day of the individual's release from the custody of penal authorities and ends the last day of the 12th month after the month in which the individual is released from the custody of penal authorities.

(2) *SEP parameters and duration beginning January 1, 2025*—(i) *Eligibility.* An individual is eligible for this SEP if they are released from confinement in a jail, prison, or other penal institution or correctional facility on or after January 1, 2025, and demonstrate that they are eligible for Medicare and failed to enroll or reenroll in SMI due to being so confined, and there is a record of release, either through documentation of discharge or data available to SSA. Individuals released to and residing in halfway houses after incarceration are not considered incarcerated or in confinement for the purposes of this SEP.

(ii) *SEP duration.* The SEP starts the day an individual is released from confinement as determined by SSA and ends the last day of the 12th month after the month in which the individual is released from confinement in a jail, prison, or other penal institution or correctional facility.

(3) *Entitlement*—(i) *General rule.* Entitlement begins the first day of the month following the month of enrollment, so long as the date is on after January 1, 2023.

(ii) *Special rule.* An individual has the option of requesting entitlement for a retroactive period of up to 6 months provided the date does not precede the month of their release from incarceration, the date is on or after January 1, 2023, and the individual pays the monthly premiums for the period of coverage (as required under § 408.4 of this subchapter). If retroactive enrollment is requested and the application is filed within the first 6 months of the SEP, the effective date is retroactive to the beginning of the month of their release from incarceration. If retroactive enrollment is requested and the application is filed in the last 6 months of the SEP, the coverage effective date is retroactive to the 6th month before the month of enrollment.

* * * * *

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 5. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

■ 6. Section 410.27 is amended by revising paragraph (a)(1)(iv)(B)(*1*) to read as follows:

§ 410.27 Therapeutic outpatient hospital or CAH services and supplies incident to a physician's or nonphysician practitioner's service: Conditions.

(a) * * *

(1) * * *

(iv) * * *

(B) * * *

(*1*) For purposes of this section, direct supervision means that the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed. For pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, direct supervision must be furnished as specified in §§ 410.47 and 410.49, respectively. Through December 31, 2025, the presence of the physician or nonphysician practitioner for the purpose of the supervision of pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services includes virtual presence through audio/video real-time communications technology (excluding audio-only); and

* * * * *

■ 7. Section 410.28 is amended by revising paragraph (e)(2)(iii) to read as follows:

§ 410.28 Hospital or CAH diagnostic services furnished to outpatients: Conditions.

* * * * *

(e) * * *

(2) * * *

(iii) Through December 31, 2025, the presence of the physician or nonphysician practitioner under paragraphs (e)(2)(i) and (ii) of this section includes virtual presence through audio/video real-time communications technology (excluding audio-only).

* * * * *

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 8. The authority citation for part 411 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395w-101 through 1395w-152, 1395hh, and 1395nn.

■ 9. Section 411.4 is revised to read as follows:

§ 411.4 Items and services for which neither the beneficiary nor any other person is legally obligated to pay.

(a) *General rule.* Except in the case of federally qualified health center services and as provided in § 411.8(b) (for services paid by a governmental entity), Medicare may not pay for an item or service under Part A or Part B if—

(1) The individual has no legal obligation to pay for the item or service; and

(2) No other person (by reason of such individual's membership in a prepayment plan or otherwise) has a legal obligation to provide or pay for the item or service.

(b) *Special conditions for payment for items or services furnished to an individual in the custody of a penal authority.* (1) An individual in the custody of a penal authority is considered to have a legal obligation to pay for items or services furnished to the individual only if the following conditions are met:

(i) State or local law requires the individual to pay the cost of items and services that the individual receives;

(ii) The penal authority enforces the requirement to pay for items or services by billing all individuals who receive such items or services, whether or not covered by Medicare or any other health insurance; and

(iii) The penal authority pursues collection of amounts owed for items or services received in the same way and with the same vigor that it pursues the collection of other debts.

(2) For purposes of this paragraph (b), a penal authority means a police department or other law enforcement agency, a government agency operating under a penal statute, or a State, local or Federal jail, prison, penitentiary, or similar institution.

(3) For purposes of this paragraph (b)—

(i) An individual is considered to be in the custody of a penal authority if the individual is:

(A) Incarcerated in a jail, prison, penitentiary, or similar institution;

(B) Temporarily outside of a jail, prison, penitentiary, or similar institution on medical furlough or similar arrangement;

(C) Escaped from confinement by a penal authority; or

(D) Required to reside in a mental health facility under a penal statute or rule.

(ii) Individuals who are not considered to be in the custody of a penal authority include, but are not limited to, individuals who are—

(A) Released to the community pending trial (including those in pretrial community supervision and those released pursuant to cash bail);

(B) On parole;

(C) On probation;

(D) On home detention or home confinement; or

(E) Required to live in a halfway house or other community-based transitional facility.

PART 416—AMBULATORY SURGICAL SERVICES

■ 10. The authority citation for part 416 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 11. Section 416.164 is amended by revising paragraphs (a)(4) and (b)(6) to read as follows:

§ 416.164 Scope of ASC services.

(a) * * *

(4) Drugs and biologicals for which separate payment is not allowed under the hospital outpatient prospective payment system (OPPS);

* * * * *

(b) * * *

(6) Non-opioid pain management drugs, biologicals, and medical devices as determined by CMS under § 416.174.

* * * * *

■ 12. Section 416.171 is amended by revising paragraph (b)(1) to read as follows:

§ 416.171 Determination of payment rates for ASC services.

* * * * *

(b) * * *

(1) Covered ancillary services specified in § 416.164(b), with the exception of radiology services and certain diagnostic tests as provided in § 416.164(b)(5) and non-opioid pain management drugs, biologicals, and medical devices as determined by CMS under § 416.174.

* * * * *

■ 13. Section 416.174 is revised to read as follows:

§ 416.174 Payment for non-opioid pain management drugs, biologicals, and medical devices.

(a) *Eligibility for separate payment for non-opioid pain management drugs and biologicals.* From January 1, 2025, through December 31, 2027, a non-opioid drug or biological is eligible for separate payment for an applicable calendar year if CMS determines it meets the following requirements through that year's rulemaking:

(1) The drug is approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FDCA), under an abbreviated new drug application under section 505(j) of the FDCA, or, in the case of a biological product, is licensed under section 351 of the Public Health Service Act. The product also has a label indication approved by the Food and Drug Administration to reduce postoperative pain, or produce postsurgical or regional analgesia, without acting upon the body's opioid receptors.

(2) The drug or biological does not have transitional pass-through payment status under § 419.64 of this subchapter. In the case where a drug or biological otherwise meets the requirements under this section and has transitional pass-through payment status that expires during the calendar year, the drug or biological will qualify for separate payment as specified in this paragraph (a) during such calendar year on the first day of the next quarter following the expiration of its pass-through status.

(3) The drug or biological has payment that is packaged into a payment for a covered outpatient department (OPD) service (or group of services) under a policy in this part.

(b) *Eligibility for separate payment for non-opioid medical devices.* From January 1, 2025, through December 31, 2027, a medical device is eligible for separate payment for an applicable calendar year if CMS determines it meets all of the following requirements through that year's rulemaking:

(1) The medical device is used to deliver a therapy to reduce postoperative pain, or produce postsurgical or regional analgesia, and has an application under section 515 of the FDCA that has been approved with respect to the device, has been cleared for market under section 510(k) of the FDCA, or is exempt from the requirements of section 510(k) of the FDCA pursuant to section 510(l) or (m) or 520(g) of the FDCA.

(2) The medical device has demonstrated the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed in a clinical trial or through data published in a peer-reviewed journal.

(3) The medical device does not have transitional pass-through payment status under § 419.66 of this subchapter. In the case where a medical device otherwise meets the requirements under this section and has transitional pass-through payment status that expires during the calendar year, the medical device will qualify for separate payment as specified in this paragraph (b) during such calendar year on the first day of the next calendar year quarter following the expiration of its pass-through status.

(4) The medical device has payment that is packaged into a payment for a covered OPD service (or group of services) under a policy in this part.

(c) *Payment amount.* From January 1, 2025, through December 31, 2027, the amount of payment for a qualifying non-opioid treatment for pain relief is as follows:

(1) For a qualifying drug or biological as defined in paragraph (a) of this

section, the amount of payment is the amount determined under section 1847A of the Act for the drug or biological that exceeds the portion of the otherwise applicable Medicare OPD fee schedule amount, which is determined to be zero dollars for calendar year 2025, subject to paragraph (c)(3) of this section.

(2) For a qualifying medical device as defined in paragraph (b) of this section, the amount of payment is the amount of the hospital's charges for the device, adjusted to cost, that exceeds the portion of the otherwise applicable Medicare OPD fee schedule amount, which is determined to be zero dollars for calendar year 2025, subject to paragraph (c)(3) of this section.

(3) The payment amounts in paragraphs (c)(1) and (2) of this section shall not exceed the estimated average of 18 percent of the OPD fee schedule amount of the volume weighted average of the most frequent five OPD primary procedures into which a non-opioid treatment for pain relief would be packaged.

■ 14. Section 416.320 is amended by revising paragraph (b) to read as follows:

§ 416.320 Retention and removal of quality measures under the ASCQR Program.

* * * * *

(b) *Immediate measure suspension.* If CMS determines that the collection and reporting activities related to a measure potentially raise patient safety concerns, CMS will immediately suspend the measure from the ASCQR Program and promptly notify ASCs and the public of the suspension. CMS will propose to retain, modify, or remove the suspended measure in the next feasible rulemaking cycle.

* * * * *

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

■ 15. The authority citation for part 419 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395l(t), and 1395hh.

■ 16. Section 419.2 is amended by revising paragraph (b)(15) to read as follows:

§ 419.2 Basis of payment.

* * * * *

(b) * * *

(15) Drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including but not limited to, diagnostic radiopharmaceuticals with per-day costs at or below the per-day diagnostic radiopharmaceutical packaging threshold for the applicable year, contrast agents, and pharmacologic stress agents);

* * * * *

■ 17. Section 419.41 is amended by adding paragraphs (h) through (j) to read as follows:

§ 419.41 Calculation of national beneficiary copayment amounts and national Medicare program payment amounts.

* * * * *

(h) For a therapeutic radiopharmaceutical for which payment is not packaged into a payment for a covered outpatient department (OPD) service (or group of services) and that does have on transitional pass-through payment status as described in § 419.64, to calculate the program payment and copayment amounts CMS does the following:

(1) Determines the average sales price (ASP) for the therapeutic radiopharmaceutical for the quarter established under the methodology described by section 1847A of the Act. If that amount is not available, then CMS calculates the mean unit cost (MUC) using the most recently available claims data for that therapeutic radiopharmaceutical.

(2) Subtracts from the amount determined under paragraph (h)(1) of this section the amount of the applicable Part B deductible provided under § 410.160 of this chapter.

(3) Multiplies the amount determined under paragraph (h)(1) of this section (less any applicable deductible under paragraph (h)(2) of this section) by 20 percent. This is the beneficiary's copayment amount for the drug or biological.

(4) Subtracts the amount determined under paragraph (h)(3) of this section from the amount determined under paragraph (h)(1) of this section (less any applicable deductible determined under paragraph (h)(2) of this section). This amount is the preliminary program amount.

(5) Adds to the preliminary program amount determined under paragraph (h)(4) of this section the amount by which the copayment amount would have exceeded the inpatient hospital deductible for that year. This amount is the final Medicare program payment amount.

(i) For a diagnostic radiopharmaceutical for which payment is not packaged into a payment for a covered OPD service (or group of services) and that does not have transitional pass-through payment status as described in § 419.64, to calculate the program payment and copayment amounts CMS does the following:

(1) Calculates the MUC using the most recently available claims data for that diagnostic radiopharmaceutical, if claims data are available. If claims data are not available, determines the ASP for the diagnostic radiopharmaceutical for the quarter established under the methodology described by section 1847A of the Act. If ASP data are not available, then based on the wholesale acquisition cost (WAC), under the methodology described by section 1847A of the Act. If WAC data are not available, then based on 95 percent of the average wholesale price.

(2) Subtracts from the amount determined under paragraph (i)(1) of this section the amount of the applicable Part B deductible provided under § 410.160 of this chapter.

(3) Multiplies the amount determined under paragraph (i)(1) of this section (less any applicable deductible under paragraph (i)(2) of this section) by 20 percent. This is the beneficiary's copayment amount for the drug or biological.

(4) Subtracts the amount determined under paragraph (i)(3) of this section from the amount determined under paragraph (i)(1) of this section (less any applicable deductible determined under paragraph (i)(2) of this section). This amount is the preliminary program amount.

(5) Adds to the preliminary program amount determined under paragraph (i)(4) of this section the amount by which the copayment amount would have exceeded the inpatient hospital deductible for that year. This amount is the final Medicare program payment amount.

(j) For a drug covered as an additional preventive service (DCAPS), as defined at § 410.64 of this chapter, the program payment amount is 100 percent of the payment amount determined as follows:

(1) If ASP data is available for the drug, consistent with part 414, subpart J, of this chapter, then the payment amount is determined using the methodology set forth in section 1847A of the Act and according to the provisions in part 414, subpart K, of this chapter.

(2) If ASP data is not available, then the payment amount is determined according to the most recently published National Average Drug Acquisition Cost (NADAC) prices for the drug and is the lesser of the median NADAC price of all generic forms of the drug or the lowest NADAC price brand name product.

(3) If ASP data and NADAC prices are not available, then the payment amount

is determined according to the most recently published pharmaceutical pricing data for the drug as included in the Federal Supply Schedule (FSS), as managed by the Department of Veterans Affairs per 48 CFR part 38, and is the lesser of the median FSS price of all generic forms of the drug or the lowest FSS price brand name product.

(4) If ASP data, NADAC prices, and FSS pharmaceutical prices are not available, then, for the period beginning January 1, 2025, through December 31, 2025, the payment amount is WAC plus 6 percent, or 3 percent if in an initial sales period consistent with 1847A(c)(4) of the Act, and beginning January 1, 2026, the payment amount is the invoice price determined by the Medicare Administrative Contractor (MAC).

■ 18. Section 419.43 is amended by adding paragraph (k) to read as follows:

§ 419.43 Adjustments to national program payment and beneficiary copayment amounts.

* * * * *

(k) *Payment for non-opioid pain management drugs and biologicals*—(1) *Eligibility for separate payment for non-opioid pain management drugs and biologicals.* From January 1, 2025, through December 31, 2027, a drug or biological is eligible for separate payment for an applicable calendar year if CMS determines it meets the following requirements through that year's rulemaking:

(i) The drug is approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FDCA), under an abbreviated new drug application under section 505(j) of the FDCA, or, in the case of a biological product, is licensed under section 351 of the Public Health Service Act. The product has a label indication approved by the Food and Drug Administration to reduce postoperative pain, or produce postsurgical or regional analgesia, without acting upon the body's opioid receptors.

(ii) The drug or biological does not have transitional pass-through payment status under § 419.64. In the case where a drug or biological otherwise meets the requirements under this section and has transitional pass-through payment status that expires during the calendar year, the drug or biological will qualify for separate payment as specified in this paragraph (k) during such calendar year on the first day of the next calendar year quarter following the expiration of its pass-through status.

(iii) The drug or biological has payment that is packaged into a payment for a covered OPD service (or group of services) under a policy in this section.

(2) *Eligibility for separate payment for non-opioid medical devices.* From January 1, 2025, through December 31, 2027, a medical device is eligible for separate payment for an applicable calendar year if CMS determines it meets the following requirements through that year's rulemaking:

(i) The medical device, is used to deliver a therapy to reduce postoperative pain, or produce postsurgical or regional analgesia, and has an application under section 515 of the FDCA that has been approved with respect to the device, been cleared for market under section 510(k) of the FDCA, or is exempt from the requirements of 510(k) of the FDCA pursuant to section 510(l) or (m) or 520(g) of the FDCA.

(ii) The medical device has demonstrated the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed in a clinical trial or through data published in a peer-reviewed journal.

(iii) The medical device does not have transitional pass-through payment status under § 419.66. In the case where a medical device otherwise meets the requirements under this section and has transitional pass-through payment status that expires during the calendar year, the medical device will qualify for separate payment as specified in this paragraph (k)(2) during such calendar year on the first day of the next calendar year quarter following the expiration of its pass-through status.

(iv) The medical device has payment that is packaged into a payment for a covered OPD service (or group of services) under a policy in this section.

(3) *Payment amount.* From January 1, 2025, through December 31, 2027, the amount of payment for a qualifying non-opioid treatment for pain relief is as follows:

(i) For a qualifying drug or biological as defined in paragraph (k)(1) of this section, the amount of payment is the amount determined under section 1847A for the drug or biological that exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the drug or biological, subject to paragraph (k)(3)(iii) of this section.

(ii) For a qualifying medical device as defined in paragraph (k)(2) of this section, the amount of payment is the amount of the hospital's charges for the device, adjusted to cost, that exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the device, subject to paragraph (k)(3)(iii) of this section.

(iii) The payment amounts in paragraph (k)(3)(i) and (ii) of this section shall not exceed the estimated average of 18 percent of the OPD fee schedule amount of the volume weighted average of the most frequent five OPD primary procedures into which a non-opioid treatment for pain relief would be packaged.

■ 19. Section 419.46 is amended by revising paragraph (i)(2) and adding paragraph (j) to read as follows:

§ 419.46 Requirements under the Hospital Outpatient Quality Reporting (OQR) Program.

* * * * *

(i) * * *

(2) *Immediate measure suspension.* If CMS determines that the collection and reporting activities related to a measure potentially raise patient safety concerns, CMS will immediately suspend the measure from the Hospital OQR Program and promptly notify hospitals and the public of the suspension. CMS will propose to retain, modify, or remove the suspended measure in the next feasible rulemaking cycle.

* * * * *

(j) *Requirements for submission of electronic clinical quality measures (eCQMs) under the Hospital OQR Program.* (1) Hospitals must utilize certified technology updated to be consistent with the Office of the National Coordinator for Health Information Technology's health information technology (IT) certification criteria, as adopted and updated in 45 CFR 170.315.

(2) Hospitals must use electronic health record technology certified to all eCQMs that are available to report under the Hospital OQR Program.

(3) Hospitals must use the most recent version of the eCQM electronic measure specifications for the applicable reporting period available on the Electronic Clinical Quality Improvement Resource Center website at *https://ecqi.healthit.gov/*, or another website as designated by CMS.

■ 20. Section 419.47 is amended by revising the section heading and paragraph (a) introductory text to read as follows:

§ 419.47 Coding and payment for Category B Investigational Device Exemption (IDE) studies and devices/drugs studies.

(a) *Creation of a new HCPCS code for Category B IDE studies that have a treatment arm and a placebo control arm.* CMS will create a new HCPCS code, or revise an existing HCPCS code,

to describe a Category B IDE study, which will include both the treatment and placebo control arms, related device(s) of the study, as well as routine care items and services, as specified under § 405.201 of this chapter, when CMS determines that:

* * * * *

■ 21. Section 419.82 is amended by revising paragraph (d)(1)(iii) to read as follows:

§ 419.82 Prior authorization for certain covered hospital outpatient department services.

* * * * *

(d) * * *

(1) * * *

(iii) The provisional affirmation or non-affirmation will be issued within 7-calendar days of receipt of the prior authorization request.

* * * * *

PART 435—ELIGIBILITY IN THE STATES, DISTRICT OF COLUMBIA, THE NORTHERN MARIANA ISLANDS, AND AMERICAN SAMOA

■ 22. The authority citation for part 435 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 23. Section 435.926 is amended by revising paragraphs (b) introductory text, (b)(1), (c)(1), and (d)(1) to read as follows:

§ 435.926 Continuous eligibility for children.

* * * * *

(b) *Eligibility.* The agency must provide continuous eligibility for the period specified in paragraph (c) of this section for an individual who is:

(1) Under age 19; and

* * * * *

(c) * * *

(1) The length of the continuous eligibility period is 12 months.

* * * * *

(d) * * *

(1) The child attains age 19;

* * * * *

PART 440—SERVICES: GENERAL PROVISIONS

■ 24. The authority citation for part 440 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 25. Section 440.90 is revised to read as follows:

§ 440.90 Clinic services.

Clinic services means preventive, diagnostic, therapeutic, rehabilitative, or palliative services that are furnished by a facility that is not part of a hospital but is organized and operated to provide medical care to outpatients. The term includes the following services furnished to outpatients (services in paragraphs (a) through (c) of this section are a mandatory part of clinic services, while services in paragraphs (d) and (e) of this section are optional):

(a) Services furnished at the clinic by or under the direction of a physician or dentist.

(b) Services furnished outside the clinic, by clinic personnel under the direction of a physician, to an individual who does not reside in a permanent dwelling or does not have a fixed home or mailing address.

(c) Services furnished outside a clinic that is a facility of the Indian Health Service, whether operated by the Indian Health Service or by a Tribe or Tribal organization (as authorized by the Indian Self-Determination and Education Assistance Act (ISDEAA), Pub. L. 93–638), by clinic personnel under the direction of a physician.

(d) Services furnished outside of a clinic that is primarily organized for the care and treatment of outpatients with behavioral health disorders, including mental health and substance use disorders, by clinic personnel under the direction of a physician.

(e) Services furnished outside of a clinic that is located in a rural area and is not a rural health clinic (as referenced in section 1905(a)(2)(B) of the Social Security Act and § 440.20(b)) by clinic personnel under the direction of a physician. States must include a definition of rural area in their State plans. This definition must be either a definition adopted and used by a Federal governmental agency for programmatic purposes, or a definition adopted by a State governmental agency with a role in setting State rural health policy.

PART 457—ALLOTMENTS AND GRANTS TO STATES

■ 26. The authority citation for part 457 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 27. Section 457.342 is revised to read as follows:

§ 457.342 Continuous eligibility for children.

A State must provide continuous eligibility for children under a separate CHIP in accordance with the terms of § 435.926 of this chapter, and subject to a child remaining ineligible for Medicaid, as required by section 2110(b)(1) of the Act and § 457.310 (related to the definition and standards for being a targeted low-income child) and the requirements of section 2102(b)(3) of the Act and § 457.350 (related to eligibility screening and enrollment).

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

■ 28. The authority citation for part 482 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr, unless otherwise noted.

■ 29. Section 482.21 is amended by—

■ a. Adding paragraph (b)(4);

■ b. Redesignating paragraphs (e) and (f) as paragraphs (f) and (g), respectively; and

■ c. Adding new paragraph (e).

The additions read as follows:

§ 482.21 Condition of participation: Quality assessment and performance improvement program.

* * * * *

(b) * * *

(4) Effective January 1, 2027, for hospitals that offer obstetrical services, the hospital must utilize its quality assessment and performance improvement (QAPI) program to assess and improve health outcomes and disparities among obstetrical patients on an ongoing basis. At a minimum, the hospital must:

(i) Analyze data and quality indicators collected for the QAPI program by diverse subpopulations as identified by the hospital among obstetrical patients.

(ii) Measure, analyze, and track data, measures, and quality indicators on patient outcomes and disparities in processes of care, services and operations among obstetrical patients.

(iii) Analyze and prioritize patient health outcomes and disparities, develop and implement actions to improve patient health outcomes and disparities, measure results, and track performance to ensure improvements are sustained among obstetrical patients.

(iv) Conduct at least one measurable performance improvement project focused on improving health outcomes and disparities among the hospital's population(s) of obstetrical patients annually.

* * * * *

(e) *Standard: Maternal health QAPI activities.* Effective January 1, 2027, for hospitals that offer obstetrical services, the following additional QAPI requirements apply:

(1) Obstetrical services leadership must engage in QAPI as specified in this section for obstetrical services, including but not limited to participating in data collection and monitoring as specified in paragraph (b) of this section.

(2) If a maternal mortality review committee (MMRC) is available at the State, Tribal, or local jurisdiction in which the hospital is located, the facility leadership, obstetrical services leadership, or their designate(s) must further have a process for incorporating publicly available MMRC(s) data and recommendations into the hospital QAPI program as specified in paragraph (b) of this section.

* * * * *

■ 30. Section 482.43 is amended by—

■ a. Redesignating paragraph (c) as paragraph (d); and

■ b. Adding new paragraph (c).

The addition reads as follows:

§ 482.43 Condition of participation: Discharge planning.

* * * * *

(c) *Standard: Transfer protocols.* Effective July 1, 2025, the hospital must have written policies and procedures for transferring patients under its care (inclusive of inpatient services) to the appropriate level of care (including to another hospital) as needed to meet the needs of the patient. The hospital must also provide annual training to relevant staff regarding the hospital policies and procedures for transferring patients under its care.

* * * * *

■ 31. Section 482.55 is amended by adding paragraph (c) to read as follows:

§ 482.55 Condition of participation: Emergency services.

* * * * *

(c) *Standard: Emergency services readiness.* Effective July 1, 2025, in accordance with the complexity and scope of services offered, there must be adequate provisions and protocols to meet the emergency needs of patients.

(1) *Protocols.* Protocols must be consistent with nationally recognized and evidence-based guidelines for the care of patients with emergency conditions, including but not limited to patients with obstetrical emergencies, complications, and immediate post-delivery care.

(2) *Provisions.* Provisions include equipment, supplies, and medication used in treating emergency cases. Such provisions must be kept at the hospital and be readily available for treating emergency cases to meet the needs of patients. The available provisions must include the following:

(i) Drugs, blood and blood products, and biologicals commonly used in life-saving procedures;

(ii) Equipment and supplies commonly used in life-saving procedures; and

(iii) Each emergency services treatment area must have a call-in-system for each patient.

(3) *Staff training.* Applicable staff, as identified by the hospital, must be trained annually on the protocols and provisions implemented pursuant to this section.

(i) The governing body must identify and document which staff must complete such training.

(ii) The hospital must document in the staff personnel records that the training was successfully completed.

(iii) The hospital must be able to demonstrate staff knowledge on the topics implemented pursuant to this section.

(iv) The hospital must use findings from its QAPI program, as required at § 482.21, to inform staff training needs and any additions, revisions, or updates to training topics on an ongoing basis.

■ 32. Section 482.59 is added to subpart D to read as follows:

§ 482.59 Condition of participation: Obstetrical services.

If the hospital offers obstetrical services, the services must be well organized and provided in accordance with nationally recognized acceptable standards of practice for the health care (including physical and behavioral health) of pregnant, birthing, and postpartum patients. If outpatient obstetrical services are offered, the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.

(a) *Standard: Organization and staffing.* Effective January 1, 2026, the organization of the obstetrical services must be appropriate to the scope of the services offered. As applicable, the services must be integrated with other departments of the hospital.

(1) Labor and delivery rooms/suites (including labor rooms, delivery rooms (including rooms for operative delivery), and post-partum/recovery rooms whether combined or separate) must be supervised by an experienced registered nurse, certified nurse midwife, nurse practitioner, physician assistant, or a doctor of medicine or osteopathy.

(2) Obstetrical privileges must be delineated for all practitioners providing obstetrical care in accordance with the competencies of each practitioner in accordance with § 482.22(c).

(b) *Standard: Delivery of service.* Effective January 1, 2026, Obstetrical services must be consistent with needs and resources of the facility. Policies governing obstetrical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care and safety.

(1) The following equipment must be kept at the hospital and be readily available for treating obstetrical cases to meet the needs of patients in accordance with the scope, volume, and complexity of services offered: call-in-system, cardiac monitor, and fetal doppler or monitor.

(2) There must be adequate provisions and protocols, consistent with nationally recognized and evidence-based guidelines, for obstetrical emergencies, complications, immediate post-delivery care, and other patient health and safety events as identified as part of the QAPI program (§ 482.21). Provisions include equipment (in addition to the equipment required under paragraph (b)(1) of this section), supplies, and medication used in treating emergency cases. Such provisions must be kept in the hospital and be readily available for treating emergency cases.

(c) *Standard: Staff training.* Effective January 1, 2027, the hospital must develop policies and procedures to ensure that relevant staff are trained on select topics for improving the delivery of maternal care.

(1) Training concepts must reflect the scope and complexity of services offered within the facility, including but not limited to:

(i) Facility-identified evidence-based best practices and protocols to improve the delivery of maternal care within the facility; and

(ii) The hospital must use findings from its QAPI program, as required at § 482.21, to inform staff training needs and any additions, revisions, or updates to training topics on an ongoing basis.

(2) The hospital must provide relevant new staff with initial training.

(3) The governing body must identify and document which staff must complete initial training and subsequent biannual training on the topics identified at paragraph (c)(1) of this section.

(4) The hospital must document in the staff personnel records that the training was successfully completed.

(5) The hospital must be able to demonstrate staff knowledge on the topics identified at paragraph (c)(1) of this section.

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

■ 33. The authority citation for part 485 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395(hh).

■ 34. Section 485.618 is amended by—

■ a. Redesignating paragraph (e) as paragraph (f); and
■ b. Adding new paragraph (e).
The addition reads as follows:

§ 485.618 Condition of participation: Emergency services.

* * * * *

(e) *Standard: Emergency services readiness.* Effective July 1, 2025, in accordance with the complexity and scope of services offered, there must be adequate provisions (as required under paragraphs (b) and (c) of this section) and protocols to meet the emergency needs of patients.

(1) *Protocols.* Protocols must be consistent with nationally recognized and evidence-based guidelines for the care of patients with emergency conditions, including but not limited to patients with obstetrical emergencies, complications, and immediate post-delivery care.

(2) *Staff training.* Applicable staff, as identified by the CAH, must be trained annually on the protocols and provisions implemented pursuant to this section.

(i) The governing body must identify and document which staff must complete such training.

(ii) The CAH must document in the staff personnel records that the training was successfully completed.

(iii) The CAH must be able to demonstrate staff knowledge on such training.

(iv) The CAH must use findings from its QAPI program, as required at § 485.641, to inform staff training needs and any additions, revisions, or updates to training topics on an ongoing basis.

■ 35. Section 485.641 is amended by adding paragraph (d)(4) and revising paragraph (e) to read as follows:

§ 485.641 Condition of participation: Quality assessment and performance improvement program.

* * * * *

(d) * * *

(4) Effective January 1, 2027, for CAHs that offer obstetrical services, the following additional QAPI requirements apply:

(i) Obstetrical services leadership must engage in QAPI as specified in this section for obstetrical services, including but not limited to participating in data collection and monitoring as specified in this paragraph (d) and paragraph (e) of this section.

(ii) If a maternal mortality review committee (MMRC) is available at the State, Tribal, or local jurisdiction in which the CAH is located, the facility leadership, obstetrical services leadership, or their designate(s) must further have a process for incorporating publicly available MMRC(s) data and recommendations into the CAH QAPI program as specified in this section.

(e) *Standard: Program data collection and analysis.* (1) The program must incorporate quality indicator data including patient care data, in order to achieve the goals of the QAPI program.

(2) Effective January 1, 2027, CAHs that offer obstetrical services, the CAH must utilize its QAPI program to assess and improve health outcomes and disparities among obstetrical patients on an ongoing basis. At a minimum, the CAH must:

(i) Analyze data and quality indicators collected for the QAPI program by diverse subpopulations as identified by the CAH among obstetrical patients.

(ii) Measure, analyze, and track health equity data, measures, and quality indicators on patient outcomes and disparities in processes of care, services and operations, and outcomes among obstetrical patients.

(iii) Analyze and prioritize identified patient health outcomes and disparities, develop and implement actions to improve patient health outcomes and disparities, measure results, and track performance to ensure improvements are sustained when disparities exist among obstetrical patients.

(iv) Conduct at least one measurable performance improvement project focused on improving health outcomes and disparities among the CAH's population(s) of obstetrical patients annually.

* * * * *

■ 36. Section 485.649 is added to read as follows:

§ 485.649 Condition of participation: Obstetrical services.

If the CAH offers obstetrical services, the services must be well organized and provided in accordance with nationally recognized acceptable standards of practice for the health care (including physical and behavioral health) of pregnant, birthing, postpartum patients. If outpatient obstetrical services are offered, the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.

(a) *Standard: Organization and staffing.* Effective January 1, 2026, the organization of the obstetrical services must be appropriate to the scope of the services offered. As applicable, the services must be integrated with other departments of the CAH.

(1) Labor and delivery rooms/suites (including labor rooms, delivery rooms (including rooms for operative delivery), and post-partum/recovery rooms whether combined or separate) must be supervised by an experienced registered nurse, certified nurse midwife, nurse practitioner, physician assistant, or a Doctor of Medicine or a Doctor of Osteopathy (MD/DO).

(2) Obstetrical privileges must be delineated for all practitioners providing obstetrical care in accordance with the competencies of each practitioner, and consistent with credentialing agreements established under § 485.616(b).

(b) *Standard: Delivery of service.* Effective January 1, 2026, obstetrical services must be consistent with needs and resources of the CAH. Policies governing obstetrical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care and safety.

(1) The following equipment must be kept at the CAH and be readily available for treating obstetrical cases to meet the needs of patients in accordance with the scope, volume, and complexity of services offered: call-in-system, cardiac monitor, and fetal doppler or monitor.

(2) There must be adequate provisions and protocols, consistent with nationally recognized and evidence-based guidelines, for obstetrical emergencies, complications, immediate post-delivery care, and other patient health and safety events as identified as part of the QAPI program (§ 485.641). Provisions include equipment (in addition to the equipment required under paragraph (b)(1) of this section), supplies, and medication used in treating emergency cases. Such provisions must be kept in the CAH and be readily available for treating emergency cases.

(c) *Standard: Staff training.* Effective January 1, 2027, the CAH must develop policies and procedures to ensure that relevant staff are trained on select topics for improving the delivery of maternal care.

(1) Training concepts must reflect the scope and complexity of services offered within the facility, including but not limited to:

(i) Facility-identified evidence-based best practices and protocols to improve the delivery of maternal care within the facility; and

(ii) The CAH must use findings from its quality assessment and performance improvement (QAPI) program, as required at § 485.641, to inform staff training needs and any additions, revisions, or updates to training topics on an ongoing basis.

(2) The CAH must provide relevant new staff with initial training.

(3) The governing body must identify and document which staff must complete initial training and subsequent biannual training on the topics identified at paragraph (c)(1) of this section.

(4) The CAH must document in the staff personnel records that the training was successfully completed.

(5) The CAH must be able to demonstrate staff knowledge on the topics identified at paragraph (c)(1) of this section.

Xavier Becerra,

Secretary, Department of Health and Human Services.

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